Maxor™

Ascension Personalized Care Prior Authorization Criteria Booklet

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Prior Authorization Criteria for ABILIFY MYCITE®

(aripiprazole tablet with sensor)

FDA APPROVED INDICATIONS

- Bipolar I Disorder
- Major Depressive Disorder (MDD)
- Schizophrenia

Bipolar I Disorder

1. Patient has a diagnosis of bipolar I disorder **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: 10-15 mg orally per day **AND**
4. Quantity requested does not exceed: 30 mg per day **AND**
5. Prescriber must provide justification or reason why oral tablet may not be used **AND** medical evidence demonstrates the need for an Ingestible Event Maker (IEM) sensor (documentation must be provided) **AND**
6. Prescribed by or in consultation with a psychiatrist

Major Depressive Disorder (MDD)

1. Patient has a diagnosis of major depressive disorder **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: 2-5 mg orally per day **AND**

Starting Dose	Recommended Dose	Maximum Dose
2 to 5 mg per day	5 to 10 mg per day	15 mg per day

4. Quantity requested does not exceed: 15 mg per day **AND**
5. Prescriber must provide justification or reason why oral tablet may not be used **AND** medical evidence demonstrates the need for an Ingestible Event Maker (IEM) sensor (documentation must be provided) **AND**
6. Prescribed by or in consultation with a psychiatrist

Schizophrenia

1. Patient has a diagnosis of Schizophrenia **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: **AND**

Starting Dose	Recommended Dose	Maximum Dose
10 to 15 mg per day	10 to 15 mg per day	30 mg per day

4. Quantity requested does not exceed: 30 mg per day **AND**
5. Prescriber must provide justification or reason why oral tablet may not be used **AND** medical evidence demonstrates the need for an Ingestible Event Maker (IEM) sensor (documentation must be provided) **AND**
6. Prescribed by or in consultation with a psychiatrist

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ May renew in up to 12 month intervals when patient does not show evidence of disease progression and criteria above continue to be met.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created separate criteria for Abilify medications and added Abilify Asimtufii based on CAB 5.18.2023.	5.2023
Update	Separated Abilify Mycite from injectable aripiprazole criteria; Updated formatting	8.2023
Annual Review	No Changes	5.2024
Update	Removed trial and failure of generic aripiprazole and an additional antipsychotic or antidepressant medication.	8.2024

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Prior Authorization Criteria for ABSORICA®, ACCUTANE® (isotretinoin)

1. Patient has diagnosis of severe recalcitrant nodular acne **AND**
2. Patient is 12 years of age or older **AND**
3. Dosage and direction: No more than 2 mg/kg/day given in two divided doses **AND**
4. Confirm patient had an adequate trial of **BOTH** of the following categories for acne treatments:
    a. Systemic (e.g. doxycycline, erythromycin, minocycline, oral contraceptives [Yasmin, Gianvi, Loryna, Nikki, Vestura, Yaz], spironolactone) **AND**
    b. Topical (e.g. clindamycin, erythromycin, benzoyl peroxide, tretinoin) **AND**
5. Confirm patient's weight is provided **AND**
6. Confirm dose does not exceed 2 mg/kg/day AND cumulative dosage does not exceed 220 mg/kg (approve for appropriate duration of therapy based on total cumulative dosage) **AND**
7. Member has intolerance or contraindications to the excipients in generic isotretinoin, Amnesteem, Claravis, Myorisan, and Zenatane **AND**
8. Prescribed by or in consultation with a dermatologist

INITIAL APPROVALS

✓ When above criteria are met, approve for appropriate duration of therapy such that total cumulative dosage will not exceed 220 mg/kg and initial duration does not exceed 20 weeks

RENEWALS

✓ Patient is eligible for renewal authorization consideration after a minimum 8-week isotretinoin- free period **AND**
✓ Documentation supports that the patient's acne remains as severe recalcitrant nodular **AND**
✓ When above criteria are met, approve for appropriate duration of therapy such that total cumulative dosage will not exceed 220 mg/kg and renewal duration does not exceed 20 weeks

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	9.2018; 9.2019
Update	Added Absorica LD Added Denial messages	1.2020
Update	Updated cumulative dosage range based on ADD guideline	7.2020
Annual Review	No Change	7.2021
Annual Review	No Change	7.2022
Annual Review	No Change	7.2023
Update	Removed drugs without PA; Separated criteria; updated format and wording	8.2023
Annual Review	Updated approval duration	6.2024

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Prior Authorization Criteria for ACCRUFER™ (ferric maltol)

1. Patient has a diagnosis of iron deficiency anemia **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: 30 mg (1 capsule) twice daily **AND**
4. Quantity requested does not exceed: 60 caps/30 days **AND**
5. Patient must have had an adequate trial of over-the-counter iron products (i.e., ferrous sulfate, ferrous gluconate)

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 7.3.2021	6.2021
Annual Review	No Changes	6.2022
Annual Review	No Changes	6.2023
Annual Review	No Changes	5.2024

REFERENCE:

1. Accrufer (ferric maltol) [prescribing information]. Austin, TX: Shield Therapeutics Inc; May 2022.
2. Accrufer (ferric maltol) [prescribing information]. Gateshead Quays, UK: Shield TX (UK) Ltd; October 2020.
3. American College of Obstetricians and Gynecologists. ACOG Practice Bulletin No. 95: anemia in pregnancy. *Obstet Gynecol.* 2008;112(1):201-207. doi:10.1097/AOG.0b013e3181809c0d[PubMed 18591330]
4. Centers for Disease Control and Prevention (CDC). Recommendations to prevent and control iron deficiency in the United States. *MMWR Recomm Rep*. 1998;47(RR-3):1-29.[PubMed 9563847]
5. El-Farrash RA, Ismail EA, Nada AS. Cord blood iron profile and breast milk micronutrients in maternal iron deficiency anemia. *Pediatr Blood Cancer.* 2012;58(2):233-238. doi:10.1002/pbc.23184[PubMed 21548016]
6. FIGO Working Group on Good Clinical Practice in Maternal-Fetal Medicine. Good clinical practice advice: Iron deficiency anemia in pregnancy. *Int J Gynaecol Obstet*. 2019;144(3):322-324. doi:10.1002/ijgo.12740[PubMed 30710364]
7. Gasche C, Ahmad T, Tulassay Z,et al; AEGIS Study Group. Ferric maltol is effective in correcting iron deficiency anemia in patients with inflammatory bowel disease: results from a phase-3 clinical trial program. *Inflamm Bowel Dis*. 2015;21(3):579-588. doi:10.1097/MIB.0000000000000314[PubMed 25545376]
8. Mueller M, et al. Patient Blood Management: Recommendations From the 2018 Frankfurt Consensus Conference. JAMA. 2019;321(10):983-997. doi:10.1001/jama.2019.0554

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Prior Authorization Criteria for ACTEMRA® SUBCUTANEOUS (tocilizumab)

FDA-APPROVED INDICATIONS

- Rheumatoid arthritis (RA): Treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs)
- Giant cell arteritis (GCA): Treatment of giant cell arteritis in adult patients
- Polyarticular juvenile idiopathic arthritis (pJIA): Treatment of active polyarticular juvenile idiopathic arthritis in patients ≥2 years of age
- Systemic juvenile idiopathic arthritis (SJIA): Treatment of active systemic juvenile idiopathic arthritis in patients ≥2 years of age
- Systemic Sclerosis-Associated Interstitial Lung Disease: Treatment of slowing the rate of decline in pulmonary function in adult patients

Diagnosis: for Rheumatoid Arthritis (RA)

1. Patient has diagnosis of moderate to severe Rheumatoid Arthritis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use:
    - <100 kg: 162 mg once every other week; increase to 162 mg once every week based on clinical response
    - ≥100 kg: 162 mg once every week **AND**
4. Quantity requested does not exceed: for subcutaneous use – 4 injections (162mg per pen or syringe)/month **AND**
5. Patient has had an inadequate response or has contraindications to at least one non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide) **AND**
6. Patient's weight is provided **AND**
7. Patient has failed to achieve symptom control after adequate therapy with, or has labeled contraindications to Adalimumab* (documentation required) **AND**
8. Patient is not receiving Actemra in combination with other biologic DMARDs **AND**
9. Prescribed by or in consultation with a rheumatologist

Diagnosis: for Polyarticular Juvenile Idiopathic Arthritis (pJIA)

1. Patient has diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis **AND**
2. Patient is 2 years of age or older **AND**
3. Dosage and direction of use:
    - <30 kg: 162 mg/dose once every 3 weeks
    - ≥30 kg: 162 mg/dose once every 2 weeks **AND**
4. Quantity requested does not exceed: for subcutaneous use – 2 injections (162mg per pen or syringe)/month (may vary depending on dosing schedule) **AND**
5. Patient's weight is provided **AND**
6. Patient has had an inadequate response or has labeled contraindications to non-biologic DMARDs (e.g., methotrexate, leflunomide)
7. Patient has failed to achieve symptom control after adequate treatment with, or has labeled contraindications to Adalimumab* (documentation required) **AND**
8. Patients is not receiving Actemra in combination with other biologic DMARDs **AND**
9. Prescribed by or in consultation with a rheumatologist

Diagnosis: for Systemic Juvenile Idiopathic Arthritis (sJIA)

1. Patient has diagnosis of systemic juvenile idiopathic arthritis **AND**
2. Patient is 2 years of age or older **AND**
3. Dosage and direction of use:
    - <30 kg: 162 mg/dose once every 2 weeks
    - ≥30 kg: 162 mg/dose once every week **AND**
4. Quantity requested does not exceed: for subcutaneous use – 2 injections (162mg per pen or syringe)/month (may vary depending on dosing schedule) **AND**
5. Patient's weight is provided **AND**
6. Patient has failed to achieve symptom control after adequate treatment with, or has labeled contraindications to Adalimumab* (documentation required) **AND**
7. Patients is not receiving Actemra in combination with other biologic DMARDs **AND**
8. Prescribed by or in consultation with a rheumatologist

Diagnosis: for Giant Cell Arteritis

1. Patient has diagnosis of Giant Cell Arteritis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 162 mg once every week as a subcutaneous injection **AND**
4. Quantity requested does not exceed: 4 injections (162mg per pen or syringe)/month **AND**
5. Patient has had an adequate trial and failure of or contraindication to a systemic glucocorticoid **AND**
6. Patients is not receiving Actemra in combination with other biologic DMARDs **AND**
7. Prescribed by or in consultation with a rheumatologist.

Diagnosis: for Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)

1. Patient has diagnosis of Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 162 mg subcutaneously once every week **AND**
4. Quantity requested does not exceed: 4 injections (162mg per pen or syringe)/month **AND**
5. Diagnosis is confirmed by high-resolution computed tomography or lung biopsy **AND**
6. Additional signs of systemic sclerosis are identified (one of the following):
    a. Skin thickening of the fingers (e.g., puffy fingers, sclerodactyly of the fingers)
    b. Fingertip lesions (e.g., digital tip ulcers, fingertip pitting scars)
    c. Telangiectasia
    d. Abnormal nailfold capillaries
    e. Pulmonary arterial hypertension
    f. Raynaud's phenomenon
    g. SSc-related autoantibodies (e.g., anticentromere, anti-topoisomerase I, anti-RNA polymerase III) **AND**
7. Patients is not receiving Actemra in combination with other biologic DMARDs **AND**
8. Prescribed by or in consultation with a rheumatologist or pulmonologist.

INITIAL APPROVALS

- ✓ *Please review formulary for current preferred adalimumab products. The trial of more than one preferred adalimumab product counts as **one** preferred product
- ✓ Prescriber attestation that labs/notes indicate patient has the disease or requires the medication **AND**
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided (e.g., improvement in symptoms, decrease in joint swelling and tenderness, etc.) **AND**
- ✓ Patient is not receiving medication in combination with other biologic DMARDs **AND**
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Revised	Revised	7.2018
Updated	Include criteria for Giant cell arteritis and cytokine release syndrome; formatted to new template	8.2019
Updated	Added default denial message	12.2019
Reviewed	Under Jan' 2020 CAB meeting, no change	1.2020
Update	Added trial and failure to HUMIRA	12.2020
Update	Annual Review: Added expanded indication for Systemic Sclerosis-Associated Interstitial Lung Disease; Updated dose for sJIA and Cytokine Release Syndrome; Updated denial message.	2.2022
Annual Review	Added expanded indication for COVID-19; Updated t/f verbiage for RA/pJIA; Removed TB requirement; Added initial approval requirement: MD attestation that labs/notes indicate patient has disease or requires the drug; Updated denial messages; updated concomitant med exclusion to other biologic DMARDs based on package insert	6.2023
Update	Updated criteria to include trial of adalimumab, updated initial approval verbiage, updated denial message, and removed "completed by" in history section.	8.2023
Annual Review	Removed IV dosage formulation from criteria; RA: Updated trial and failure wording; pJIA: Separated criteria pathway from sJIA; sJIA: Separated criteria pathway from pJIA; removed trial and failure requirement of DMARD based on guidelines; Giant cell arteritis: Updated trial and failure language; SSc-ILD: Updated diagnosis criteria; removed trial and failure requirements	6.2024

REFERENCE:

1. Actemra (tocilizumab) [prescribing information]. South San Francisco, CA: Genentech Inc; December 2022.
2. Alade SL, Brown RE, Paquet A Jr. Polysorbate 80 and E-Ferol toxicity. Pediatrics. 1986;77(4):593-597.[PubMed 3960626]
3. Barrett DM, Teachey DT, Grupp SA. Toxicity management for patients receiving novel T-cell engaging therapies. Curr Opin Pediatr. 2014;26(1):43-49.[PubMed 24362408]
4. Centers for Disease Control (CDC). Unusual syndrome with fatalities among premature infants: association with a new intravenous vitamin E product. MMWR Morb Mortal Wkly Rep. 1984;33(14):198-199. http://www.cdc.gov/mmwr/preview/mmwrhtml/00000319.htm.[PubMed 6423951]
5. Davies HD, Committee on Infectious Diseases. Infectious complications with the use of biologic response modifiers in infants and children. Pediatrics. 2016;138(2); e20161209.[PubMed 27432853]
6. Singh JA, Saag KG, Bridges SL, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Rheumatology 2016. 68(1):1-26.
7. Quartier P. Systemic Juvenile Idiopathic Arthritis/Pediatric Still's Disease, a Syndrome but Several Clinical Forms: Recent Therapeutic Approaches. J Clin Med. 2022 Mar 1;11(5):1357. doi: 10.3390/jcm11051357. PMID: 35268449; PMCID: PMC8911482.
8. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Recommendations for Nonpharmacologic Therapies, Medication Monitoring, Immunizations, and Imaging. Arthritis Care Res (Hoboken). 2022 Apr;74(4):505-520. doi: 10.1002/acr.24839. Epub 2022 Mar 1. PMID: 35233989; PMCID: PMC10231687.
9. Maz M, Chung SA, Abril A, Langford CA, Gorelik M, Guyatt G, Archer AM, Conn DL, Full KA, Grayson PC, Ibarra MF, Imundo LF, Kim S, Merkel PA, Rhee RL, Seo P, Stone JH, Sule S, Sundel RP, Vitobaldi OI, Warner A, Byram K, Dua AB, Husainat N, James KE, Kalot MA, Lin YC, Springer JM, Turgunbaev M, Villa-Forte A, Turner AS, Mustafa RA. 2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Giant Cell Arteritis and Takayasu Arteritis. Arthritis Rheumatol. 2021 Aug;73(8):1349-1365. doi: 10.1002/art.41774. Epub 2021 Jul 8. PMID: 34235884.

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Prior Authorization Criteria for ACTIMMUNE® (interferon gamma 1-b)

FDA-Approved Indications

- Reducing the frequency and severity of serious infections associated with Chronic Granulomatous Disease
- Delaying time to disease progression in patients with severe, malignant osteopetrosis

Diagnosis: Chronic Granulomatous Disease

1. Patient has a diagnosis of chronic granulomatous disease **AND**
2. Patient is 1 years of age or older **AND**
3. Dosage and direction of use:
    a. > 0.5 m^2 BSA: 50 mcg/m^2 subcutaneously three times weekly
    b. ≤0.5 m^2 BSA: 1.5 mcg/kg/dose subcutaneously three times weekly **AND**
4. Quantity requested does not exceed: 50 mcg/m^2 /dose **AND**
5. Prescribed by or in consultation with a hematologist, infectious disease specialist, or immunologist

Diagnosis: Severe Malignant Osteopetrosis

1. Patient has a diagnosis of severe malignant osteopetrosis **AND**
2. Patient is 1 month of age or older **AND**
3. Dosage and direction of use:
    a. > 0.5 m^2 BSA: 50 mcg/m^2 subcutaneously three times weekly
    b. ≤0.5 m^2 BSA: 1.5 mcg/kg/dose subcutaneously three times weekly **AND**
4. Quantity requested does not exceed: 50 mcg/m^2 /dose **AND**
5. Prescribed by or in consultation with an endocrinologist

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 12 months

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided
- ✓ Approval duration for renewal: 12 months.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated initial approval to 12 months	3.2024

REFERENCE:

1. Actimmune (interferon gamma-1b). [Prescribing information]. Deerfield, IL: Horizon Therapeutics USA, Inc. March 2021.

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Prior Authorization Criteria for ADASUVE® (loxapine)

1. Patient has a diagnosis of schizophrenia or bipolar I or II disorder AND
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: 10 mg by oral inhalation using an inhaler administered only by a healthcare professional **AND**
4. Quantity should not exceed: a single dose within any 24-hour period **AND**
5. Patient has agitation associated with schizophrenia or bipolar I or II disorder **AND**
6. Patient has had an adequate trial of at least two antipsychotics for acute agitation (e.g., olanzapine, ziprasidone) unless contraindicated **AND**
7. Prescriber attestation that patient does **not** have any of the following contraindications:
   a. Current diagnosis or history of asthma, chronic obstructive pulmonary disease (COPD), or other lung disease associated with bronchospasm **OR**
   b. Acute respiratory signs/symptoms (e.g., wheezing) **OR**
   c. Current use of medications to treat airways disease, such as asthma or COPD **OR**
   d. History of bronchospasm following ADASUVE treatment **OR**
   e. Known hypersensitivity to loxapine or amoxapine **AND**
8. Prescribed by or in consultation with a psychiatrist.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ May renew in up to 12 month intervals when patient does not show evidence of disease progression and criteria above continue to be met.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023

REFERENCE:

1. Adasuve (loxapine) [prescribing information]. Mountain View, CA: Alexza Pharmaceuticals Inc; January 2022.
2. Patel MX, et al. Joint BAP NAPICU evidence-based consensus guidelines for the clinical management of acute disturbance: de-escalation and rapid tranquillisation. *J Psychopharmacol.* 2018;32(6):601–640. doi:10.1177/0269881118776738
3. Pompili, M., Ducci, G., Galluzzo, A., Rosso, G., Palumbo, C., & de Berardis, D. (2021). The Management of Psychomotor Agitation Associated with Schizophrenia or Bipolar Disorder: A Brief Review. International Journal of Environmental Research and Public Health, 18.
4. Pacciardi, B., Calcedo, A. & Messer, T. Inhaled Loxapine for the Management of Acute Agitation in Bipolar Disorder and Schizophrenia: Expert Review and Commentary in an Era of Change. Drugs R D 19, 15–25 (2019). https://doi.org/10.1007/s40268-019-0262-3
5. Roppolo, LP, et al. Improving the management of acutely agitated patients in the emergency department through implementation of Project BETA (Best Practices in the Evaluation and Treatment of Agitation). *J Am Coll Emerg Physicians Open*. 2020;1(5):898-907. doi:10.1002/emp2.12138
6. Smith CM, Santalucia M, Bunn H, Muzyk A. Sublingual Dexmedetomidine for the Treatment of Agitation in Patients with Schizophrenia and Bipolar Disorder. Clin Psychopharmacol Neurosci. 2023 May 30;21(2):215-221. doi: 10.9758/cpn.2023.21.2.215. PMID: 37119214; PMCID: PMC10157019.
7. Zeller SL, Citrome L. Managing agitation associated with schizophrenia and bipolar disorder in the emergency setting. *West J Emerg Med*. 2016;17(2):165-172. doi:10.5811/westjem.2015.12.28763

Prior Authorization Criteria for ADBRY™ (tralokinumab-Idrm)

1. Patient has a diagnosis of moderate to severe atopic dermatitis **AND**
2. Patient is 12 years of age or older **AND**
3. Dosage and Direction for Use:
    a. 18 years and older: An initial dose of 600 mg (four 150 mg injections), followed by 300 mg (two 150 mg injections) administered every other week. A dosage of 300 mg every 4 weeks may be considered for patients below 100 kg who achieve clear or almost clear skin after 16 weeks of treatment
    b. 12-17 years of age: Initial dose of 300 mg (two 150 mg injections), followed by 150 mg every other week **AND**
4. Quantity requested does not exceed:
    a. 18 years and older- Initial: 600 mg (four 150 mg injections); Maintenance dose: 300 mg (two 150 mg injections) administered every other week **AND**
    b. 12-17 years of age- Initial: 300 mg (two 150 mg injections); Maintenance dose: 150 mg (one injection) every other week
5. Failure of all of the following, unless contraindicated or clinically significant adverse effects are experienced:
    a) Two formulary medium to very high potency topical corticosteroids, each used for at least 2 weeks **AND**
    b) One non-steroidal topical therapy: topical calcineurin inhibitor (i.e., tacrolimus 0.03% ointment and pimecrolimus 1% cream), Eucrisa, or Opzelura for at least 4 weeks **AND**
    c) One or more of the following systemic agents: corticosteroids, azathioprine, methotrexate, mycophenolate mofetil, or cyclosporine **AND**
6. Patient is not receiving Adbry in combination with another biologic medication indicated for AD or an oral JAK inhibitor indicated for AD or other inflammatory conditions **AND**
7. Prescribed by or in consultation with a specialist such as a dermatologist

INITIAL APPROVALS

✓ Initial approval will be granted for 1 year

RENEWALS

✓ Confirm clinical improvement in signs and symptoms of AD and documentation of current disease severity. If clear or almost clear skin is achieved in the initial authorization period and the dose is not reduced to every-4-week injections, clinical rationale supporting continuation of every-2-week injections.
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 1.27.2022	1.2022
Annual Review	No Changes	1.2023
Update	Updated initial approval duration from 6 months to 1 year	10.2023
Annual Review	Updated age to 12 years and older; updated dosing	1.2024

REFERENCE:

1. Adbry (tralokinumab) [prescribing information]. Madison, NJ: LEO Pharm Inc; December 2023.
2. Alade SL, Brown RE, Paquet A Jr. Polysorbate 80 and E-Ferol toxicity. Pediatrics. 1986;77(4):593-597.[PubMed 3960626]
3. Centers for Disease Control (CDC). Unusual syndrome with fatalities among premature infants: association with a new intravenous vitamin E product. MMWR Morb Mortal Wkly Rep. 1984;33(14):198-199.[PubMed 6423951]
4. Clements T, Rice TF, Vamvakas G, et al. Update on transplacental transfer of IgG subclasses: impact of maternal and fetal factors. FrontImmunol. 2020;11:1920. doi:10.3389/fimmu.2020.01920[PubMed 33013843]
5. Lucente P, Iorizzo M, Pazzaglia M. Contact sensitivity to Tween 80 in a child. Contact Dermatitis. 2000;43(3):172.[PubMed 10985636]
6. Palmeira P, Quinello C, Silveira-Lessa AL, Zago CA, Carneiro-Sampaio M. IgG placental transfer in healthy and pathological pregnancies. Clin DevImmunol. 2012;2012:985646. doi:10.1155/2012/985646[PubMed 22235228]
7. Pentsuk N, van der Laan JW. An interspecies comparison of placental antibody transfer: new insights into developmental toxicity testing of monoclonal antibodies. Birth Defects Res B Dev Reprod Toxicol. 2009;86(4):328-344. doi:10.1002/bdrb.20201[PubMed 19626656]
8. Shelley WB, Talanin N, Shelley ED. Polysorbate 80 hypersensitivity. Lancet. 1995;345(8960):1312-1313. doi:10.1016/s0140-6736(95)90963-x[PubMed 7746084]
9. Silverberg JI, Toth D, Bieber T, et al; ECZTRA 3 study investigators. Tralokinumab plus topical corticosteroids for the treatment of moderate-to-severe atopic dermatitis: results from the double-blind, randomized, multicentre, placebo-controlled phase III ECZTRA 3 trial. Br J Dermatol. 2021;184(3):450-463. doi:10.1111/bjd.19573[PubMed 33000503]

Prior Authorization Criteria for ADLARITY®
(donepezil transdermal system)

1. Patient has diagnosis of mild, moderate, or severe dementia associated with Alzheimer's Disease **AND**
2. Patient is 50 years of age or older **AND**
3. Dosage and direction of use:
    - The recommended starting dosage is 5 mg/day; the dosage may be increased to the maximum recommended dosage of 10 mg/day after 4 to 6 weeks. One transdermal patch should be applied to the skin once weekly.
    - If a patient has been on 5 mg/day oral donepezil for at least 4-6 weeks or on 10 mg/day of oral donepezil, the recommended starting dosage is 10 mg/day **AND**
4. Quantity requested does not exceed: 4 patches/28 days **AND**
5. Patient has tried at least one generic cholinesterase inhibitor (i.e., rivastigmine tablets, transdermal patches, or galantamine).

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 1 year

RENEWALS

✓ Documentation of positive clinical response to therapy **AND**
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 6.16.2022	6.2022
Annual Review	No Changes	6.2023
Annual Review	No Changes	5.2024

REFERENCE:

1. Adlarity (donepezil) [prescribing information]. Grand Rapids, MI: Corium, Inc: March 2022
2. Aricept (donepezil) [prescribing information]. New York, NY: Pfizer; December 2018.
3. Aricept tablets and orally disintegrating tablets (donepezil) [prescribing information]. Woodcliff Lake, NJ: Eisai Inc; December 2021.
4. National Institute for Health and Care Excellence (NICE). Dementia: assessment, management and support for people living with dementia and their careers. NICE guideline 97. https://www.nice.org.uk/guidance/ng97/evidence/full-guideline-pdf-4852695709. Published June 2018. Accessed June 8, 2022.
5. Birks JS, Harvey RJ. Donepezil for dementia due to Alzheimer's disease. Cochrane Database Syst Rev. 2018;6(6):CD001190. doi:10.1002/14651858.CD001190.pub3[PubMed 29923184]

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Prior Authorization Criteria for AFINITOR, AFINITOR DISPERZ (everolimus tablets and tablets for oral suspension)

FDA Indications

Afinitor is indicated for:

- Treatment of postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer in combination with exemestane, after failure of treatment with letrozole or anastrozole
- Treatment of adult patients with progressive neuroendocrine tumors of pancreatic origin (PNET) with unresectable, locally advanced or metastatic disease
- Treatment of adult patients with progressive, well-differentiated, non-functional NET of gastrointestinal (GI) or lung origin with unresectable, locally advanced or metastatic disease
- Treatment of adult patients with advanced RCC after failure of treatment with sunitinib or sorafenib
- Treatment of adult patients with renal angiomyolipoma and TSC, not requiring immediate surgery
- Treatment of tuberous Sclerosis Complex (TSC)-Associated Subependymal Giant Cell Astrocytoma (SEGA) in adult and pediatric patients aged 1 year and older that requires therapeutic intervention but cannot be curatively resected

Afinitor Disperz is indicated for:

- Treatment of tuberous Sclerosis Complex (TSC)-Associated Subependymal Giant Cell Astrocytoma (SEGA) in adult and pediatric patients aged 1 year and older that requires therapeutic intervention but cannot be curatively resected
- Adjunctive treatment of adult and pediatric patients aged 2 years and older with TSC-associated partial-onset seizures

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year.
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Annual Review	Updated criteria to oncology template; updated approval duration to 1 year	7.2024

REFERENCE:

1. Afinitor [Prescribing Information] East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2022.
2. Afinitor Disperz. [Prescribing Information] East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2022.

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Prior Authorization Criteria for AKLIEF® (trifarotene)

1. Patient has diagnosis of acne vulgaris **AND**
2. Patient is 9 years of age or older **AND**
3. Dosage and direction of use: Apply a thin layer to the affected areas of the face and/or trunk once a day, in the evening, on clean and dry skin **AND**
4. Quantity requested does not exceed: 45 gram pump/30 days **AND**
5. Patient has adequate trial of at least one generic retinoid product (e.g. tretinoin, adapalene, tazarotene)

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 1 year

RENEWALS

✓ Approval duration for renewal: 2 years

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	11.2019
Update	Add Dosage and Quantity Denial Message	2.2020
Annual Review	Update format	2.2021
Annual review	Remove page number	3.2022
Annual review	No change	3.2023
Annual review	No change	3.2024

REFERENCE:

1. Aklief (trifarotene) [prescribing information]. Fort Worth, TX: Galderma Laboratories LP; January 2022.
2. Tan J, Thiboutot D, Popp G, et al. Randomized phase 3 evaluation of trifarotene 50 µg/g cream treatment of moderate facial and truncal acne. J Am Acad Dermatol. 2019;80(6):1691-1699. doi:10.1016/j.jaad.2019.02.044[PubMed 30802558]
3. Zaenglein AL, Pathy AL, Schlosser BJ, et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol. 2016;74(5):945-973.e33. doi:10.1016/j.jaad.2015.12.037[PubMed 26897386].

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Prior Authorization Criteria for ALECENSA® (alectinib)

FDA-APPPROVED INDICATIONS

- Adjuvant treatment in adult patients following tumor resection of anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) (tumors ≥ 4 cm or node positive) as detected by an FDA approved test
- Treatment of adult patients with ALK-positive metastatic NSCLC as detected by an FDA-approved test.

1. Patient has an FDA approved diagnosis **AND**
2. Patient is 18 years of age or older **AND**
3. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
- ✓ Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Approval duration for renewal: 1 year
- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA Created	7.2022
Annual Review	No change	7.2023
Annual Review	Updated duration to 1 year; updated renewal language	2.2024
Update	Updated criteria to include expanded indication of for adjuvant treatment and general oncology verbiage based on FDA package insert and NCCN guidelines	5.2024

REFERENCE:

1. Alecensa Prescribing Information. South San Francisco, CA: Genentech USA, Inc. September 2021. Available at https://www.gene.com/download/pdf/alecensa_prescribing.pdf. Accessed July 12, 2022.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed April 26, 2024.
3. National Comprehensive Cancer Network Guidelines. Non-Small Cell Lung Cancer. Version 4.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/nscl_blocks.pdf. Accessed April 26, 2024.

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Prior Authorization Criteria for ALKERAN (melphalan tablet)

FDA Indications

- Palliative treatment of multiple myeloma
- Palliation of non-resectable epithelial carcinoma of the ovary

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated duration to 1 year; updated wording	5.2024

REFERENCE:

1. Melphalan. [Prescribing information]. Morristown, NJ: Alvogen, Inc. November 2021.

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Prior Authorization Criteria for ALUNBRIG (brigatinib)

FDA-Approved Indications

- Treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated duration to 1 year; updated verbiage; added FDA indication section	5.2024

REFERENCE:

1. ALUNBRIG. [Prescribing Information]. Lexington, MA. Takeda Pharmaceuticals America, Inc: October 2022.

Prior Authorization Criteria for AMPYRA (dalfampridine ER)

1. Patient has diagnosis of multiple sclerosis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction for use: 10 mg twice daily **AND**
4. Quantity requested does not exceed: 60 tablets/30 days **AND**
5. Patient has impaired walking ability as demonstrated by an objective measure such as a Timed 25-foot Walk test **AND**
6. Prescribed by or in consultation with a neurologist

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 12 months
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided
- ✓ Approval duration for renewal: 12 months.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Update	Updated initial approval duration from 6 months to 12 months	10.2023

REFERENCE:

1. Ampyra [package insert]. Acorda Therapeutics, Inc. Ardsley, NY. November 2021.

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Prior Authorization Criteria for Injectable Medications for Anemia (Erythropoietic) Treatment – Retacrit

FDA- APROVED INDICATIONS

- Anemia due to chronic kidney disease
- Anemia due to chemotherapy in patients with cancer
- Anemia due to zidovudine use in patients with HIV infection
- Reduction of allogeneic red blood cell transfusions in patients undergoing elective, noncardiac, nonvascular surgery

Diagnosis: Anemia due to chronic kidney disease

1. Diagnosis is treatment of anemia related to chronic kidney disease **AND**
2. Dosage and directions for use: the dosage is within FDA recommended dosing or dose is supported by compendia or medical literature. Check package insert during review (dosage recommendation based on age, indications, converting from another erythropoiesis-stimulating agent, etc) **AND**
3. Quantity does not exceed: based on FDA-approved recommendation per package insert **AND**
4. Patient's serum ferritin is > 100 ng/mL OR serum transferrin saturation (TSAT) > 20 % OR patient is receiving supplemental iron therapy **AND**
5. Patient's Hemoglobin is < 10 g/dL for initial therapy and < 11 g/dl for continuation therapy **AND**
6. For patients not receiving dialysis, both of the following:
   a. The rate of hemoglobin decline indicates the likelihood of requiring an RBC transfusion **AND**
   b. Goal of therapy is to reduce the risk of alloimmunization or other RBC transfusion-related risks

Diagnosis: Anemia due to chemotherapy in patients with cancer

1. Diagnosis is treatment of anemia due to myelosuppressive chemotherapy in patients with cancer **AND**
2. Dosage and directions for use: the dosage is within FDA recommended dosing or dose is supported by compendia or medical literature. Check package insert during review (dosage recommendation based on age, indications, converting from another erythropoiesis-stimulating agent, etc) **AND**
3. Quantity does not exceed: based on FDA-approved recommendation per package insert **AND**
4. Patient's Serum ferritin is > 100 ng/mL OR serum transferrin saturation (TSAT) > 20 % OR patient is receiving supplemental iron therapy **AND**
5. Patient's Hemoglobin is < 10 g/dL **AND**
6. Patient has a minimum of two additional months of planned chemotherapy **AND**
7. Goal of chemotherapy is not curative **AND**
8. Anemia cannot be managed by transfusion

Diagnosis: Anemia due to zidovudine in patients with HIV infections

1. Diagnosis is treatment of anemia due to zidovudine **AND**
2. Dosage and directions for use: the dosage is within FDA recommended dosing or dose is supported by compendia or medical literature. Check package insert during review (dosage recommendation based on age, indications, converting from another erythropoiesis-stimulating agent, etc) **AND**
3. Quantity does not exceed: based on FDA-approved recommendation per package insert **AND**
4. Patient's Serum ferritin is > 100 ng/mL OR serum transferrin saturation (TSAT) > 20 % OR patient is receiving supplemental iron therapy **AND**
5. Patient's Hemoglobin is < 10 g/dL for initial therapy and <12 g/dl for continuation therapy **AND**
6. Zidovudine dose is $\leq$ 4200mg/week **AND**
7. Endogenous serum erythropoietin levels of $\leq$500mUnits/mL

Diagnosis: Reduction of need for allogeneic RBC transfusions in surgery patients

1. Patient is undergoing surgery and has high risk for perioperative blood loss **AND**
2. Dosage and directions for use: the dosage is within FDA recommended dosing or dose is supported by compendia or medical literature. Check package insert during review (dosage recommendation based on age, indications, converting from another erythropoiesis-stimulating agent, etc) **AND**
3. Quantity does not exceed: based on FDA-approved recommendation per package insert **AND**
4. Surgery is elective, noncardiac, and nonvascular **AND**
5. Perioperative hemoglobin >10 to ≤13 **AND**
6. Patient is unwilling to donate autologous blood pre-operatively

INITIAL APPROVALS

- ✓ Initial approval duration will be 12 months.
- ✓ For reduction of need for allogeneic RBC transfusions in surgery patients, approval will be 2 months

RENEWALS

- ✓ Review initial approval criteria
- ✓ May renew in up to 12 month intervals

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Revised	Created	5.2018
Update	Added reference level for hemoglobin and iron. Update Format/Add Denial Message	4.2020
Update	Formatting/punctuation changes	2.2021
Annual Review	No Changes	4.2022
Update	Separated indications; Added new indication for reduction of perioperative RBC transfusion; Notated which indications were drug specific; Added package label requirements to all indications	4.2023
Update	Created separate criteria for Retacrit	9.2023
Annual Review	Updated dosage verbiage to include “the dosage is within FDA recommended dosing or dose is supported by compendia or medical literature”	4.2024

REFERENCE:

1. Retacrit (epoetin alfa-epbx) [prescribing information]. Lake Forest, IL: Hospira, Inc; January 2020.

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Prior Authorization Criteria for ARAZLO™ (tazarotene lotion 0.045%)

1. Patient diagnosis of acne vulgaris **AND**
2. Patient is 9 years of age or older **AND**
3. Dosage and Direction for Use: Apply a thin layer to the affected areas once daily **AND**
4. Quantity requested does not exceed: based on affected area **AND**
5. Patient has had an adequate trial and failure of both of the following:
    a. Generic tazarotene product **AND**
    b. Topical adapalene or tretinoin product

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 4.9.2020	4.2020
Annual Review	No Change	4.2021
Annual Review	No Change	4.2022
Annual Review	No Change	4.2023
Update	Clarified trial and failure to a tazarotene product and adapalene or tretinoin product	11.2023

REFERENCE:

1. Arazlo (tazarotene) [prescribing information]. Bridgewater, NJ: Bausch Health US. LLC; December 2019.
2. Butler DC, Heller MM, Murase JE. Safety of dermatologic medications in pregnancy and lactation: Part II. Lactation. J Am Acad Dermatol. 2014;70(3):417.e1-e10; quiz 427. doi: 10.1016/j.jaad.2013.09.009.[PubMed 24528912]
3. Centers for Disease Control (CDC). Neonatal deaths associated with use of benzyl alcohol—United States. MMWR Morb Mortal Wkly Rep. 1982;31(22):290-291. http://www.cdc.gov/mmwr/preview/mmwrhtml/00001109.htm[PubMed 6810084]
4. Chien AL, Qi J, Rainer B, Sachs DL, Helfrich YR. Treatment of acne in pregnancy. J Am Board Fam Med. 2016;29(2):254-262. doi: 10.3122/jabfm.2016.02.150165.[PubMed 26957383]
5. Fabior (tazarotene) [prescribing information]. Greenville, NC: Mayne Pharma; June 2018.
6. "Inactive" ingredients in pharmaceutical products: update (subject review). American Academy of Pediatrics (AAP) Committee on Drugs. Pediatrics. 1997;99(2):268-278.[PubMed 9024461]
7. Kong YL, Tey HL. Treatment of acne vulgaris during pregnancy and lactation. Drugs. 2013;73(8):779-787. doi: 10.1007/s40265-013-0060-0.[PubMed 23657872]

Prior Authorization Criteria for ARCALYST™ (rilonacept)

FDA-APPROVED INDICATIONS

- Cryopyrin-Associated Periodic Syndromes (CAP) including Familial Cold Auto-Inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS): in adults and pediatric patients 12 years and older.
- Deficiency of IL-1 Receptor Antagonist (DIRA): maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in adults and pediatric patients weighing at least 10 kg.
- Recurrent Pericarditis (RP): for treatment of recurrent pericarditis (RP) and reduction in risk of recurrence in adults and children 12 years and older

Diagnosis: for Cryopyrin-Associated Periodic Syndromes (CAPS)

1. Patient has diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) including Familial Cold Autoinflammatory Syndrome (FCAS), or Muckle Wells Syndrome (MWS) **AND**
2. Patient is 12 years of age and older **AND**
3. Dosage and directions:
    a. Adult patient:
        i. Initial loading dose: 320 mg given as two separate injections (160 mg /2 mL per injection) on the same day at two different sites.
        ii. Maintenance: 160 mg/2 mL once weekly.
    b. Pediatric patients (12 to 17 years):
        i. Initial loading dose: 4.4 mg/kg/dose once weekly administered as 1 or 2 separate injections on the same day at different sites.
        ii. Maintenance: 160 mg/ 2 mL once weekly.
4. Quantity limit must not exceed: two-220 mg vials (one vial delivers 160 mg/2 ml) for initial loading dose; four-220 mg vials/28 days for maintenance dose **AND**
5. Patient has a documented genetic mutation in the NLRP3 gene (also called CIAS1) **AND**
6. Arcalyst is not being used in conjunction with an anti-TNF drug or anakinra **AND**
7. Prescribed by or in consultation with a specialist such as a rheumatologist, geneticist, allergist/immunologist, or dermatologist.

Diagnosis: for Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

1. Patient has diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) **AND**
2. Patient weighs 10 kg or more **AND**
3. Dosage and directions: initial:
    - Adult patient: 320 mg once weekly administered as 1 or 2 separate injections (160 mg /2 mL per injection) on the same day at different sites **AND**
    - Pediatric patients weighting 10 kg or more: 4.4 mg/kg/dose (up to a max of 320 mg) once weekly administered as 1 or 2 separate injections on the same day at different sites **AND**
4. Quantity limit must not exceed: eight-220 mg vials (one vial delivers 160 mg/2 ml)/28 days **AND**
5. Patient has a documented genetic mutation of the IL1RN gene **AND**
6. Arcalyst is not being used in conjunction with an anti-TNF drug or anakinra **AND**
7. Prescribed by or in consultation with a specialist such as a rheumatologist, geneticist, allergist/immunologist, or dermatologist.

Diagnosis: for Recurrent pericarditis (RP)

1. Patient has diagnosis of recurrent pericarditis (RP)
2. Patient is at least 12 years of age **AND**
3. Dosage and directions:
    - Adult patient:
        - Initial loading dose: 320 mg given as two separate injections (160 mg /2 mL per injection) on the same day at two different sites.

- Maintenance: 160 mg/2 ml once weekly.
- Pediatric patients (12 to 17 years):
  - Initial loading dose: 4.4 mg/kg/dose once weekly administered as 1 or 2 separate injections on the same day at different sites.
  - Maintenance: 160 mg/2 mL once weekly.

4. Quantity limit must not exceed: two-220 mg vials for loading dose; four-220 mg vials/28 days for maintenance dose **AND**
5. Patient had an inadequate response or adverse reaction to a nonsteroidal anti-inflammatory drug (NSAID) plus colchicine OR systemic corticosteroids (i.e., prednisone) **AND**
6. Arcalyst is not being used in conjunction with an anti-TNF drug or anakinra **AND**
7. Prescribed by or in consultation with a specialist such as a cardiologist.

INITIAL APPROVALS

- ✓ Note: ARCALYST is supplied in single-dose vials containing a sterile, white to off-white, lyophilized powder. Each vial contains 220 mg of rilonacept. Reconstitution with 2.3 mL of preservative-free Sterile Water for Injection is required prior to subcutaneous administration of the drug. The reconstituted ARCALYST is 80-mg/mL solution.
- ✓ A volume of 2 ml can be withdrawn which is designed to deliver 160 mg for SQ administration only.
- ✓ Initial approval is granted for 1 year

RENEWALS

- ✓ Documentation of positive clinical response to therapy
- ✓ Initial approval is granted for 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	3.2017
Update	Add Denial Message/Reformat	6.2020
Annual Review	No Changes	6.2021
Updated	Added expanded indication: Deficiency of Interleukin-1 Receptor Antagonist (DIRA) and Recurrent pericarditis (RP)	5.2022
Annual Review	No Changes	5.2023
Annual Review	No Changes	5.2024

REFERENCE:

1. Arcalyst (rilonacept) [prescribing information]. London, UK: Kiniksa Pharmaceuticals (UK) Ltd; May 2021.
2. Goldback-Mansky R, Shroff SD, Wilson M, et al, "A Pilot Study to Evaluate the Safety and Efficacy of the Long-Acting Interleukin-1 Inhibitor Rilonacept (Interleukin-1 Trap) in Patients With Familial Cold Autoinflammatory Syndrome," Arthritis Rheum, 2008, 58(8):2432-42.[PubMed 18668591]
3. Hoffman HM, Throne ML, Amar NJ, et al, "Efficacy and Safety of Rilonacept (Interleukin-1 Trap) in Patients With Cryopyrin-Associated Periodic Syndromes: Results From Two Sequential Placebo-Controlled Studies," Arthritis Rheum, 2008, 58(8):2443-52.[PubMed 18668535]
4. Hoffman HM, Throne ML, Amar NJ, et al, "Long-Term Efficacy and Safety Profile of Rilonacept in the Treatment of Cryopyin-Associated Periodic Syndromes: Results of a 72-Week Open-Label Extension Study," Clin Ther, 2012, 34(10):2091-103.[PubMed 23031624]
5. Miyamae T, "Cryopyrin-Associated Periodic Syndromes: Diagnosis and Management," Pediatr Drugs, 2012, 14(2):109-17.[PubMed 22335455]
6. Radin A, Marbury T, Osgood G, et al, "Safety and Pharmacokinetics of Subcutaneously Administered Rilonacept in Patients With Well-Controlled End-Stage Renal Disease (ESRD)," J Clin Pharmacol, 2010, 50(7):835-41.[PubMed 20035038]
7. Klein AL, Imazio M, Cremer P, et al. Phase 3 trial of interleukin-1 trap rilonacept in recurrent pericarditis. N Engl J Med. 2021;384(1):31-41. doi:10.1056/NEJMoa2027892[PubMed 33200890]
8. Welzel T, Kuemmerle-Deschner JB. Diagnosis and Management of the Cryopyrin-Associated Periodic Syndromes (CAPS): What Do We Know Today? J Clin Med. 2021 Jan 1;10(1):128. doi: 10.3390/jcm10010128. PMID: 33401496; PMCID: PMC7794776.

Prior Authorization Criteria for ARIKAYCE (amikacin inhalation)

1. Patient has diagnosis of pulmonary mycobacterium avium complex (MAC) lung disease **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 590 mg (one 8.4 mL vial) via nebulized inhalation once daily **AND**
4. Quantity requested does not exceed: 28 vials/28 days **AND**
5. Patient has received a minimum of 6 consecutive months of multidrug background regimen therapy and has not achieved a negative sputum culture **AND**
6. Mycobacterium avium complex is susceptible to amikacin **AND**
7. Requested medication is being used as part of a combination antibacterial drug regimen **AND**
8. Prescribed by or in consultation with a pulmonologist or infectious disease specialist

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 12 months.

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided
- ✓ Requested medication will be used as part of a combination antibacterial drug regimen
- ✓ Approval duration for renewal: 12 months.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Added requirement for culture to be susceptible to amikacin	3.2024

REFERENCE:

1. Arikayce (amikacin). [Prescribing Information]. Bridgewater, NJ: Insmed Inc. February 2023.

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Prior Authorization Criteria for AUGTYRO™ (repotrectinib)

1. Patient has locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for use: 160 mg orally once daily for 14 days, then increase to 160 mg twice daily **AND**
4. Quantity requested does not exceed: 240 capsules/30 days **AND**
5. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
6. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created from CAB 12.14.2023	12.2023

REFERENCE:

1. <800> Hazardous Drugs—Handling in Healthcare Settings. *United States Pharmacopeia and National Formulary* (USP 43-NF 38). Rockville, MD: United States Pharmacopeia Convention; 2020:74-92.
2. Augtyro (repotrectinib) [prescribing information]. Princeton, NJ: Bristol-Meyers Squibb Company; November 2023.
3. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer (Version 2.2023). https://www.nccn.org/professionals/physician_gls/pdf/nscl_blocks.pdf. Accessed March 8, 2023.

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Prior Authorization Criteria for AUSTEDO® & AUSTEDO® XR TAB (deutetrabenazine)

FDA Approved Indications

- Chorea associated with Huntington's disease
- Tardive dyskinesia

Chorea associated with Huntington's disease

1. Patient has a diagnosis of chorea associated with Huntington disease confirmed by genetic testing **AND**
2. Patient is 18 years and older **AND**
3. Dosage and Direction for Use:
    a. Austedo: Initial dose is 6 mg twice daily. May titrate in weekly increments of 6 mg up to a maximum daily dosage of 48 mg
    b. Austedo XR: Initial dose is 12 mg daily. May titrate in weekly increments of 6 mg up to a maximum daily dosage of 48 mg **AND**
4. Quantity requested does not exceed 48 mg/day **AND**
5. Patient is not on concomitant therapy with other vesicular monoamine transporter 2 (VMAT2) inhibitors such as Xenazine (tetrabenazine) or Ingrezza (valbenazine) **AND**
6. Prescribed by or in consultation with a neurologist

Tardive dyskinesia

1. Patient has a diagnosis of moderate to severe tardive dyskinesia **OR**
2. Patient is 18 years and older **AND**
3. Dosage and Direction for Use:
    a. Austedo: Initial dose is 6 mg twice daily. May titrate in weekly increments of 6 mg up to a maximum daily dosage of 48 mg
    b. Austedo XR: Initial dose is 12 mg daily. May titrate in weekly increments of 6 mg up to a maximum daily dosage of 48 mg **AND**
4. Quantity requested does not exceed 48 mg/day **AND**
5. One of the following:
    a. Patient has symptoms despite a trial dose reduction or discontinuation of medication known to cause tardive dyskinesia **OR**
    b. Patient is not a candidate for a trial dose reduction or discontinuation of medications known to cause tardive dyskinesia **AND**
6. Patient is not on concomitant therapy with other vesicular monoamine transporter 2 (VMAT2) inhibitors such as Xenazine (tetrabenazine) or Ingrezza (valbenazine) **AND**
7. Prescribed by or in consultation with a neurologist or psychiatrist

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 5.4.2023	5.2023
Annual Review	Split indications into separate criteria pathways; added exclusion of concomitant therapy	5.2024

REFERENCE:

1. Austedo (deutetrabenazine) tablets [prescribing information]. Parsippany, NJ: Teva Pharmaceuticals USA Inc; February 2023.
2. Wietholter JP, Sizemore J, Piechowski K. Crushing deutetrabenazine for treatment of tardive dyskinesia in a patient with severe orofacial symptoms: a case report. Am J Health Syst Pharm. 2020;77(18):1477-1481. doi:10.1093/ajhp/zxaa205[PubMed 32761113]
3. Bhidayasiri R, Fahn S, Weiner WJ, et al. Evidence-based guideline: treatment of tardive syndromes: report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology 2013; 81:463.
4. Ricciardi L, Pringsheim T, Barnes TRE, et al. Treatment Recommendations for Tardive Dyskinesia. Can J Psychiatry 2019; 64:388.

Prior Authorization Criteria for AUVELITY™ (dextromethorphan hydrobromide and bupropion hydrochloride)

1. Patient has a diagnosis of major depressive disorder (MDD) **AND**
2. Patient is 18 years and older **AND**
3. Dosage and direction for use: the recommended starting dosage is one tablet once daily with a maximum dosage of one tablet twice daily **AND**
4. Quantity requested does not exceed: 60 tablets/30 days **AND**
5. Patient has had a trial and failure, for a minimum 4 weeks of therapy, to at least two generic antidepressants with different mechanism of actions, such as selective serotonin reuptake inhibitor (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), bupropion, mirtazapine, trazodone, vilazodone, or Trintellix, etc. **AND**
6. Prescribed by or in consultation with a mental health provider

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 11.3.2022	11.2022
Annual review	Updated formatting; added prescriber requirement; added trial duration	10.2023

REFERENCE:

1. Auvelity (dextromethorphan and bupropion) [prescribing information]. New York City, New York: Axsome Therapeutics Inc; August 2022.
2. Hasin DS, et al. Epidemiology of adult DSM-5 major depressive disorder and its specifiers in the United States. JAMA Psychiatry. 2018;75(4):336–346
3. National Institute of Mental Health. Depression. Updated July 2022. Accessed October 22, 2022. https://www.nimh.nih.gov/health/topics/depression
4. Papakostas GI, et al. A meta-analysis of early sustained response rates between antidepressants and placebo for the treatment of major depressive disorder. J Clin Psychopharmacol. 2006;26(1):56–60. doi:10.1097/01.jcp.0000195042.62724.76

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Prior Authorization Criteria for AUVI-Q® (epinephrine injection)

1. Patient has diagnosis of allergic reactions (type I) including anaphylaxis **AND**
2. Patient is of any age, as long as dosage is appropriate to body weight **AND**
3. Dosage and direction of use:
    - Patients 7.5 to 15 kg: 0.1 mg
    - Patients 15 to 30 kg: 0.15 mg
    - Patients ≥ 30 kg: 0.3 mg **AND**
4. Quantity requested does not exceed: 2 pens/fill **AND**
5. Patient has tried and failed, or the provider indicates inappropriateness to, generic epinephrine auto-injectors

INITIAL APPROVALS

✓ Initial authorization may be granted for a period of 1 year

RENEWALS

✓ Documentation of positive clinical response to therapy has been proven
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	1.2021
Updated	Updated quantity limit and epinephrine requirement	4.2021
Annual Review	No Changes	4.2022
Annual Review	No Changes	4.2023
Annual Review	Updated reference	4.2024

REFERENCE:

1. Auvi-Q (epinephrine) [prescribing information]. Richmond, VA: Kaleo Inc; February 2024.
2. Epinephrine Injection [prescribing information]. So El Monte, CA: International Medication systems Limited; August 2022.
3. Barach EM, Nowak RM, Lee TG, Tomlanovich MC. Epinephrine for treatment of anaphylactic shock. JAMA. 1984;251(16):2118-2122.[PubMed 6708262]
4. Simons FE, Ardusso LR, Bilò MB, et al. World Allergy Organization anaphylaxis guidelines: summary. J Allergy Clin Immunol. 2011;127(3):587-593. doi:10.1016/j.jaci.2011.01.038[PubMed 21377030]

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Prior Authorization Criteria for AYVAKIT™ (avapritinib)

FDA-APPROVED INDICATIONS

- Gastrointestinal Stromal Tumor (GIST): Adult with unresectable or metastatic GIST harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations.
- Advanced Systemic Mastocytosis (AdvSM): Adult patients with AdvSM. AdvSM includes patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL).
- Indolent Systemic Mastocytosis: Adult patients with indolent systemic mastocytosis (ISM)

Diagnosis: for Gastrointestinal Stromal Tumor (GIST)

1. Patient diagnosis of unresectable or metastatic gastrointestinal stromal tumor (GIST) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: 300 mg orally once daily **AND**
4. Quantity requested does not exceed: 1 tab/day; 300 mg orally once daily **AND**
5. Confirm presence of a PDGFRA exon 18 mutations including *PDGFRA D842V mutations* **AND**
6. Patient has documentation of adequate trial of imatinib **AND**
7. Prescribed by or in consultation with an oncologist.

Diagnosis: for Advanced Systemic Mastocytosis (AdvSM)

1. Patient diagnosis of advanced systemic mastocytosis (AdvSM) including patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SMAHN), and mast cell leukemia (MCL) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: 200 mg orally once daily **AND**
4. Quantity requested does not exceed: 1 tab/day; 200 mg orally once daily **AND**
5. Confirm patient has one of the following subtypes of advanced systemic mastocytosis**:**
   a. Aggressive systemic mastocytosis; OR
   b. Systemic mastocytosis with an associated hematological neoplasm; OR
   c. Mast cell leukemia **AND**
6. Confirm patient has platelet count ≥ 50 x 10^9/L (≥ 50,000/mcL) **AND**
7. Prescribed by or in consultation with an oncologist.

Diagnosis: for Indolent Systemic Mastocytosis (ISM)

1. Patient diagnosis of indolent systemic mastocytosis **AND**
2. Dosage and Direction for Use: 25 mg orally once daily **AND**
3. Quantity requested does not exceed: 1 tab/day; 25 mg orally once daily **AND**
4. Confirm patient has platelet count ≥ 50 x 10^9/L (≥ 50,000/mcL) **AND**
5. Prescribed by or in consultation with an oncologist.

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to “Off-Label Use Policy”).
- ✓ Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA Criteria created based on CAB 2.13.2020	2.2020
Annual Review	No changes	2.2021
Updated	Added denial message and formatting	2.2022
Updated	Added expanded indication for Advanced Systemic Mastocytosis (AdvSM)	10.2022
Annual Review	No changes	2.2023
Annual Review	Added expanded indication for indolent systemic mastocytosis; updated approval duration to 1 year	11.2023

REFERENCE:

1. <800> Hazardous Drugs—Handling in Healthcare Settings. *United States Pharmacopeia and National Formulary* (USP 43-NF 38). Rockville, MD: United States Pharmacopeia Convention; 2020:74-92.
2. Ayvakit (avapritinib) [prescribing information]. Cambridge, MA: Blueprint Medicines Corporation; May 2023.
3. US Department of Health and Human Services; Centers for Disease Control and Prevention; National Institute for Occupational Safety and Health. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings 2016. https://www.cdc.gov/niosh/docs/2016-161/. Updated September 2016. Accessed Jan 18, 2023.
4. National Comprehensive Cancer Network. Systemic Mastocytosis (Version 2.2022). https://www.nccn.org/professionals/physician_gls/pdf/gist_blocks.pdf. Accessed Jan 18, 2023.
5. National Comprehensive Cancer Network. Gastrointestinal Stromal Tumors (Version 2.2022). https://www.nccn.org/professionals/physician_gls/pdf/mastocytosis_blocks.pdf. Accessed Jan 18, 2023.

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Prior Authorization Criteria for BALVERSA® (erdafitinib)

1. Patient has a diagnosis of locally advanced or metastatic urothelial carcinoma **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: maximum dose 9 mg orally once a day **AND**
4. Quantity requested does not exceed: 84 tabs/28 days **AND**
5. Confirm susceptible FGFR3 genetic alterations by an FDA-approved companion diagnostic tests (i.e. therascreen FGFR RGQ RT-PCR Kit) **AND**
6. Disease has progressed on or after at least one line of prior systemic therapy **AND**
7. Prescribed by or in consultation with an oncologist.

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
- ✓ Initial authorization will be granted for 1 year

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided with current chart notes, and other pertinent information to demonstrate patient has experienced a positive response with therapy.
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	5.2019
Update	Update Format / Add Denial Message	5.2020
Annual review	No change	5.2021
Annual review	No change	5.2022
Annual review	No change	5.2023
Annual review	Updated initial and renewal approval duration and updated criteria verbiage	5.2024

REFERENCE:

1. Balversa (erdafitinib) [prescribing information]. Horsham, PA: Janssen Products LP; March 2023.
2. Loriot Y, Necchi A, Park SH, et al; BLC2001 Study Group. Erdafitinib in locally advanced or metastatic urothelial carcinoma. N Engl J Med. 2019;381(4):338-348. doi:10.1056/NEJMoa1817323[PubMed 31340094]
3. Siefker-Radtke AO, Necchi A, Park SH, et al; BLC2001 Study Group. Efficacy and safety of erdafitinib in patients with locally advanced or metastatic urothelial carcinoma: long-term follow-up of a phase 2 study. Lancet Oncol. Published online January 11, 2022. S1470-2045(21)00660-4. doi:10.1016/S1470-2045(21)00660-4[PubMed 35030333]
4. National Comprehensive Cancer Network. Bladder Cancer (Version 2.2024). Available at: https://www.nccn.org/professionals/physician_gls/pdf/bladder_blocks.pdf. Accessed May 2, 2024.

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Prior Authorization Criteria for BARACLUDE® (entecavir)

1. Patient has diagnosis of chronic hepatitis B virus infection **AND**
2. Patient must be 2 years of age or older **AND**
3. Dosage and Directions for use:
    a) Nucleoside-treatment-naïve with compensated liver disease (≥16 years old): 0.5 mg once daily
    b) Lamivudine-refractory or known lamivudine or telbivudine resistance mutations (≥16 years old): 1 mg once daily
    c) Decompensated liver disease (adults): 1 mg once daily
    d) Pediatrics: dosed by weight, please optimize quantity based on prescribed dosing scheduling **AND**
4. Quantity requested does not exceed:
    a) 30 tablets/30 days **OR**
    b) Patients up to 30 kg: 420 mL/21 days **AND**
5. Patient has evidence of viral replication **AND**
6. Patient has one of the following:
    a) Persistent elevations in aminotransaminases (ALT or AST) **OR**
    b) Evidence of histologically active disease **AND**
7. Prescribed by or in consultation with a specialist such as a gastroenterologist, hepatologist, or infectious disease specialist

INITIAL APPROVALS

- ✓ Initial approval will be for a period of 12 months (1 year).
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided
- ✓ Approval duration for renewal: 12 months.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on existing criteria	7.2019
Updated	Add Denial Message	1.2020
Annual Review	No changes	1.2021
Annual Review	No changes	1.2022
Annual Review	No changes	1.2023
Annual Review	Updated renewal criteria; updated format; clarified requirements; added resistance to lamivudine exclusion	9.2023
Annual Review	Added brand name may be subject to formulary exclusions language; removed resistance to lamivudine	7.2024

REFERENCE:

1. Baraclude (entecavir) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; November 20189
3. Lok, Anna SF. Hepatitis B virus: Overview of management. UpToDate. July 2021. Accessed July 19, 2024.

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Prior Authorization Criteria for BAXDELA (delafloxacin meglumine tablet)

FDA-Approved Indications

- Treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults caused by the following susceptible microorganisms: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae*, *Streptococcus anginosus* Group (including *Streptococcus anginosus*, *Streptococcus intermedius*, and *Streptococcus constellatus*), *Streptococcus pyogenes*, *Enterococcus faecalis*, *Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae,* and *Pseudomonas aeruginosa*
- Treatment of community-acquired bacterial pneumonia (CABP) in adults caused by the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible [MSSA] isolates only), *Klebsiella pneumoniae*, *Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae*, *Chlamydia pneumoniae*, *Legionella pneumophila,* and *Mycoplasma pneumoniae*

Diagnosis: Acute Bacterial Skin and Skin Structure infection

1. Patient has a diagnosis of acute bacterial skin and skin structure infection (ABSSSI) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 450 mg orally every 12 hours for 5-14 days **AND**
4. Quantity requested does not exceed: 28 tablets/14 days **AND**
5. Antimicrobial susceptibility testing shows susceptibility to delafloxacin unless testing is not available **AND**
6. One of the following:
    a. Patient has had trial and failure of or contraindication to a first line therapy, such as a trimethoprim-sulfamethoxazole, tetracyclines, or clindamycin **OR**
    b. Patient was started on Baxdela (IV or oral) in an in-patient setting and request is for continuation of treatment course **AND**
7. Prescribed by or in consultation with an infectious disease specialist

Diagnosis: Community-Acquired Bacterial Pneumonia

1. Patient has a diagnosis of community-acquired bacterial pneumonia (CABP) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 450 mg orally every 12 hours for 5-10 days **AND**
4. Quantity requested does not exceed: 20 tablets/10 days **AND**
5. Antimicrobial susceptibility testing shows susceptibility to delafloxacin, unless unavailable **AND**
6. One of the following:
    a. Patient has had trial and failure of or contraindication to a first line therapy, such as a macrolide, respiratory fluoroquinolone, doxycycline, or beta-lactam **OR**
    b. Patient was started on Baxdela in an in-patient setting and request is for continuation of treatment course **AND**
7. Prescribed by or in consultation with an infectious disease specialist

INITIAL APPROVALS

✓ Initial authorization will be granted for 1 fill

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	12.2023

REFERENCE:

1. Baxdela (delafloxacin meglumine). [Prescribing Information]. Lincolnshire, IL: Melinta Therapeutics, LLC. June 2021.

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Prior Authorization Criteria for BENLYSTA (belimumab)

FDA-APPROVED INDICATIONS

- Active, antibody-positive, systemic lupus erythematosus (SLE): Patients who are 5 years of age and older with active, systemic lupus erythematosus who are receiving standard therapy
- Active lupus nephritis: Patients aged 5 years and older with active lupus nephritis who are receiving standard therapy

Diagnosis: for Systemic Lupus Erythematosus (SLE)

1. Patient has diagnosis of autoantibody-positive, systemic lupus erythematosus **AND**
2. Patient is 5 years of age or older **AND**
3. Dosage and direction of use:
    - Patients under 18 years of age: 10 mg/kg at 2-week intervals for the first 3 doses and at 4-week intervals thereafter given as an IV infusion
    - Adult patients: 200 mg once weekly given as a subcutaneous injection **AND**
4. Quantity requested does not exceed: 4 doses/28 days **AND**
5. Clinical documentation provided which confirms positive autoantibody test (e.g. anti-nuclear antibody [ANA] greater than laboratory reference range and/or anti-double-stranded DNA [anti-dsDNA] greater than 2 fold the laboratory reference if tested by ELISA) **AND**
6. Patient does not have severe active central nervous system lupus **AND**
7. Patient is currently receiving standard therapy for SLE (e.g. anti-malarials, corticosteroids, immunosuppressives) **AND**
8. Patient is not receiving Benlysta in combination with other biologics (e.g., Enbrel, Humira, Cimzia, Kineret), Lupkynis, or Saphnelo **AND**
9. Prescribed by or in consultation with a specialist such as a rheumatologist or nephrologist

Diagnosis: for Active Lupus Nephritis

1. Patient has diagnosis of active lupus nephritis **AND**
2. Patient is 5 years of age or older **AND**
3. Dosage and direction of use: 400 mg once weekly for 4 doses then 200 mg weekly thereafter **AND**
4. Quantity requested does not exceed: initial dosing: 8/28 days; maintenance dose: 4 doses/28 days **AND**
5. Patient has Class III (focal), IV (diffuse), or V (membranous) lupus nephritis (documentation provided) **AND**
6. Patient does not have severe active central nervous system lupus **AND**
7. Patient is currently receiving standard therapies such as cyclosporine, mycophenolate, azathioprine **AND**
8. Patient is not receiving Benlysta in combination with other biologics (e.g., Enbrel, Humira, Cimzia, Kineret), Lupkynis, or Saphnelo **AND**
9. Prescribed by or in consultation with a specialist such as a nephrologist or rheumatologist.

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 1 year

RENEWALS

✓ Documentation of positive clinical response to therapy has been proven
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on client request	1.2021
Updated	Updated SLE diagnosis	3.2021
Annual review	Updated clinical criteria; Updated denial message.	3.2022
Updated	Added expanded indication to include patient age 5 year old and older for active lupus nephritis; updated default message.	10.2022
Updated	Format update	3.2023
Updated	Updated FDA indication section; added CNS lupus exclusion; removed t/f for SLE indication; added Lupyknis, Saphnelo exclusion; removed dialysis exclusion for LN	10.2023

REFERENCE:

1. Benlysta (belimumab) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; December 2020. Ilaris powder for injection (canakinumab) [prescribing information]. Dorval, Quebec, Canada: Novartis Pharmaceuticals Canada Inc; January 2017.
2. Emmi G, Silvestri E, Squatrito D, et al. Favorable pregnancy outcome in a patient with systemic lupus erythematosus treated with belimumab: A confirmation report. Semin Arthritis Rheum. 2016;45(6):e26-e27. doi:10.1016/j.semarthrit.2016.03.005[PubMed 27079761]
3. Navarra SV, Guzmán RM, Gallacher AE, et al, "Efficacy and Safety of Belimumab in Patients With Active Systemic Lupus Erythematosus: A Randomised, Placebo-Controlled, Phase 3 Trial," Lancet, 2011, 26(377):721-31.[PubMed 21296403]
4. Wallace DJ, Stohl W, Furie RA, et al, "A Phase II, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study of Belimumab in Patients With Active Systemic Lupus Erythematosus," Arthritis Rheum, 2009, 61(9):1168-78.[PubMed 19714604]

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Prior Authorization Criteria for BOSULIF (bosutinib)

FDA-APPROVED INDICATIONS

- Adult and pediatric patients 1 year of age and older with chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML), newly-diagnosed or resistant or intolerant to prior therapy
- Adult patients with accelerated phase (AP), or blast phase (BP) Ph+ CML with resistance or intolerance to prior therapy

1. Patient has an FDA approved diagnosis **AND**
2. Patient is
    a. For chronic phase: 1 year and older
    b. For accelerated phase or blast phase: 18 years of age and older **AND**
3. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Annual Review	Updated duration of approval to 1 year; updated age for chronic phase to 1 year and older; added FDA-approved indication section	1.2024

REFERENCE:

1. BOSULIF [Prescribing Information]. New York, NY. Pfizer Labs: September 2023.

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Prior Authorization Criteria for BREXAFEMME® (ibrexafungerp)

FDA Approved Indications

- Treatment of vulvovaginal candidiasis (VVC)
- Reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC)

Indication: Treatment of vulvovaginal candidiasis (VVC)

1. Patient has diagnosis of vulvovaginal candidiasis (VVC) **AND**
2. Patient is 12 years of age and older or patient is a post-menarchal pediatric female **AND**
3. Dosage and direction of use: 300 mg (two tablets of 150 mg) twice a day for one day, for a total treatment dosage of 600 mg **AND**
4. Quantity requested does not exceed: 4 tablets/fill up to 2 times for acute VVC **AND**
5. Patient has no more than 2 previous episodes of acute VVC within the past 12 months **AND**
6. Patient has had an adequate trial, intolerance or contraindication to a course of oral fluconazole

Indication: Reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC)

1. Patient has diagnosis of vulvovaginal candidiasis (VVC) **AND**
2. Patient is 12 years of age and older or patient is a post-menarchal pediatric female **AND**
3. Dosage and direction of use: 300 mg (two tablets of 150 mg) twice a day for one day (e.g., in the morning and in the evening), for a total daily dosage of 600 mg (four 150 mg tablets) monthly for six months **AND**
4. Quantity requested does not exceed: 4 tablets/fill up to 6 months **AND**
5. Patient has history of RVVC with 3 or more acute VVC episodes within the past 12 months **AND**
6. Patient has had an adequate trial, intolerance or contraindication to a course of oral fluconazole.

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a one-time approval

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided and other pertinent information demonstrate patient has experienced a positive response.
- ✓ Approval duration for renewal: one-time approval as needed for acute VVC, 6 month approval for RVVC

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 7.15.2021	7.2021
Annual Review	No Changes	7.2022
Annual Review	Added expanded indication for RVVC; Removed t/f requirement of topical azoles based on treatment recommendations.	7.2023
Annual Review	No Change	1.2024

REFERENCE:

1. Cadet R, et al. A Phase 2b, dose-finding study evaluating oral ibrexafungerp vs fluconazole in vulvovaginal candidiasis (DOVE). Obstet Gynecol. 2019;133 (suppl):113S–114S. doi: 10.1097/01.AOG.0000558840.33387.ee
2. Centers for Disease Control and Prevention (CDC). Vaginal candidiasis. November 10, 2020. Accessed July 8, 2021. https://www.cdc.gov/fungal/diseases/candidiasis/genital/index.htm
3. Gonçalves B, et al. Vulvovaginal candidiasis: Epidemiology, microbiology and risk factors. Crit Rev Microbiol. 2016;42(6):905-927. doi:10.3109/1040841X.2015.1091805
4. Brexafemme (ibrexafungerp) [prescribing information]. Jersey City, NJ: Scynexis Inc; November 2022.

5. Donders G, Sziller IO, Paavonen J, Hay P, de Seta F, Bohbot JM, Kotarski J, Vives JA, Szabo B, Cepulienė R, Mendling W. Management of recurrent vulvovaginal candidosis: Narrative review of the literature and European expert panel opinion. Front Cell Infect Microbiol. 2022 Sep 9;12:934353. doi: 10.3389/fcimb.2022.934353. PMID: 36159646; PMCID: PMC9504472.
6. Phillips NA, Bachmann G, Haefner H, Martens M, Stockdale C. Topical Treatment of Recurrent Vulvovaginal Candidiasis: An Expert Consensus. Womens Health Rep (New Rochelle). 2022 Jan 31;3(1):38-42. doi: 10.1089/whr.2021.0065. PMID: 35136875; PMCID: PMC8812501.

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Prior Authorization Criteria for BRINEURA® (cerliponase alfa kit)

1. Patient has a diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2 disease) or tripeptidyl peptidase 1 (TPP1) deficiency confirmed by a genetic test **AND**
2. Patient is greater than 37 weeks post-menstrual age (gestational age at birth plus post-natal age) or older **AND**
3. Dosage and direction of use:
    a. Birth to < 6 months of age: 100 mg every other week
    b. 6 months to < 1 year of age: 150 mg every other week
    c. 1 year to < 2 years of age: 200 mg every other week for 4 doses, followed by 300 mg every other week
    d. 2 years of age and older: 300 mg every other week by intraventricular infusion **AND**
4. Quantity requested does not exceed: 1 kit/14 days **AND**
5. Patient weighs ≥ 2.5 kg (5.5 lbs) **AND**
6. Prescribed by or in consultation with a neurologist, geneticist or metabolic specialist

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 1 year.

RENEWALS

✓ Documentation of positive clinical response to therapy has been provided.
✓ Approval duration for renewal: 12 months.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated indication, dosing, added patient weight requirement, duration of approval and reference.	7.2024

REFERENCE:

1. Brineura (cerliponase alfa kit). [Prescribing information]. Novato, CA: BioMarin Pharmaceutical Inc. July 2024.

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Prior Authorization Criteria for BRONCHITOL® (mannitol)

Treatment of Cystic Fibrosis

1. Patient has diagnosis of Cystic Fibrosis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 400 mg (10 capsules) twice a day by oral inhalation, in the morning and evening, with the later dose taken 2-3 hours before bedtime **AND**
4. Quantity requested does not exceed: 560 capsules/28 days **AND**
5. Confirmed that patient has passed the Bronchitol Tolerance test **AND**
6. Patient has had an adequate trial of hypertonic saline and Pulmozyme **AND**
7. Prescribed by or in consultation with a pulmonologist or specialist affiliated with a cystic fibrosis care center.

Bronchitol Tolerance Test (BTT)

1. Patient has diagnosis of Cystic Fibrosis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: Instructions are provided by the healthcare provider in a step-wise approach **AND**
4. Quantity requested does not exceed: 1 tolerance test carton/kit **AND**
5. Medication is administered and supervised by a healthcare provider who is able to manage acute bronchospasm. The test is used to identify patients who are suitable candidates for BRONCHITOL maintenance therapy for Cystic Fibrosis **AND**
6. Prescribed by or in consultation with a specialist such as a pulmonologist or specialist affiliated with a cystic fibrosis care center.

INITIAL APPROVAL

- ✓ Initial approval duration will be 1 year

RENEWAL

- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 2.25.2021	3.2021
Annual Review	No Changes	3.2022
Annual Review	No Changes	3.2023
Updated	Added Bronchitol Tolerance Test; Updated denial message	8.2023
Annual Review	Updated prescriber verbiage, updated initial and renewal approval duration, and updated format	2.2024

REFERENCE:

1. Aridol (mannitol) [prescribing information]. Coral Springs, FL: Methapharm Inc; received September 2019.
2. Bronchitol (mannitol) [prescribing information]. Cary, NC: Chiesi USA Inc; October 2020.
3. Bronchitol (mannitol) [product information]. Frenchs Forest, NSW, Australia: Pharmaxis Ltd; October 2015.

4. De Boeck K, Haarman E, Hull J, et al. Inhaled dry powder mannitol in children with cystic fibrosis: A randomised efficacy and safety trial. J Cyst Fibros. 2017;16(3):380-387.[PubMed 28258928]
5. Expert Panel Report 3, "Guidelines for the Diagnosis and Management of Asthma," Clinical Practice Guidelines, National Institutes of Health, National Heart, Lung, and Blood Institute, NIH Publication No. 08-4051, prepublication 2007. Available at http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.htm
6. Leuppi JD, Brannan JD, and Anderson SD, "Bronchial Provocation Tests: The Rationale for Using Inhaled Mannitol as a Test for Airway Hyperresponsiveness," Swiss Med Wkly, 2002, 132(13-14):151-8.[PubMed 12070787]
7. Leuppi JD, Tandjung R, Anderson SD, et al, "Prediction of Treatment-Response to Inhaled Corticosteroids by Mannitol-Challenge Test in COPD: A Proof of Concept," Pulm Pharmacol Ther, 2005, 18(2):83-8.[PubMed 15649849]

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Prior Authorization Criteria for BRUKINSA™ (zanubrutinib)

FDA-APPROVED INDICATIONS

- Mantle cell lymphoma (MCL): treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy
- Waldenström's macroglobulinemia (WM): treatment of adult patients with Waldenström's macroglobulinemia
- Relapsed or refractory marginal zone lymphoma (MZL): treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti–CD20-based regimen
- Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL): treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)

1. Patient has an FDA approved diagnosis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: 160 mg (two 80mg capsules) orally twice daily or 320 mg (four 80mg capsules) orally once daily; swallow whole with water and with or without food **AND**
4. Quantity requested does not exceed: 120 capsules per 30 days **AND**
5. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
6. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
- ✓ Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA Criteria created based on CAB 12.5.2019	12.2019
Update	Update Quantity Per Month / Update formulation to capsules	01.2021
Update	Annual Review: updated criteria to include expanded indication for Waldenström's macroglobulinemia (WM), marginal zone lymphoma (MZL).	01.2022
Annual Review	Annual Review: Removed criteria requirement that patient has received at least one prior induction therapy for Waldenström's macroglobulinemia (WM).	01.2023
Update	Update criteria to included expanded indication of Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).	03.2023
Annual Review	Updated duration of approval to 1 year; removed requirement for induction therapy for MZL; updated format to oncology drug format	12.2023

REFERENCE:

1. Brukinsa (zanubrutinib) [prescribing information]. San Mateo, CA: BeiGene USA Inc; April 2023.
2. Song Y, Zhou K, Zou D, et al. Safety and activity of the investigational Bruton tyrosine kinase inhibitor zanubrutinib (BGB-3111) in patients with mantle cell lymphoma from a phase 2 trial. Blood. 2018;132(suppl 1):S132. [Abstract 132 from ASH 20187 Annual meeting].

3. Tam CS, Trotman J, Opat S, et al. Phase 1 study of the selective BTK inhibitor zanubrutinib in B-cell malignancies and safety and efficacy evaluation in CLL. Blood. 2019;134(11):851-859.[PubMed 31340982]
4. National Comprehensive Cancer Network. B-Cell Lymphomas (Version 5.2022). https://www.nccn.org/professionals/physician_gls/pdf/b-cell_blocks.pdf Accessed December 29, 2022.
5. National Comprehensive Cancer Network. Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma (Version 1.2023). https://www.nccn.org/professionals/physician_gls/pdf/b-cell_blocks.pdf Accessed December 29, 2022.
6. National Comprehensive Cancer Network. Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) (Version 2.2023). https://www.nccn.org/professionals/physician_gls/pdf/cll_blocks.pdf. Accessed March 9, 2023.

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Prior Authorization Criteria for BYLVAY™ (odevixibat) tablets and pellets

FDA Approved Indications

- Treatment of pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC).
- Treatment of cholestatic pruritus in patients 12 months of age and older with Alagille syndrome (ALGS)

Diagnosis: Progressive Familial Intrahepatic Cholestasis (PFIC)

1. Patient has diagnosis of progressive familial intrahepatic cholestasis (PFIC) with molecular genetic testing **AND**
2. Patient is 3 months of age and older **AND**
3. Dosage and Direction for Use: Recommended dosage is 40 mcg/kg once daily, if there is no improvement in pruritus after 3 months, the dosage may be increased in 40 mcg/kg increments up to 120 mcg/kg once daily not to exceed a total daily dose of 6 mg.

Body Weight	Once Daily Dosage (mcg)
7.4 and below	200
7.5 to 12.4	400
12.5 to 17.4	600
17.5 to 25.4	800
25.5 to 35.4	1,200
35.5 to 45.4	1,600
45.5 to 55.4	2,000
55.5 and above	2,400

**Note: oral pellets are intended for use by patients weighing less than 19.5 kilograms and capsules are intended for use by patients weighing 19.5 kilograms or above

4. Quantity requested does not exceed: 6 mg/day **AND**
5. Patient does not have PFIC type 2 with ABCB11 variants resulting in nonfunctional or complete absence of bile salt export pump (BSEP) protein **AND**
6. Patient has moderate to severe pruritus **AND**
7. Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory **AND**
8. Patient does not have prior or active hepatic decompensation events **AND**
9. Patient has had an adequate trial of at least **two** of the following medications used to treat pruritus: ursodiol, bile acid sequestrants (i.e., cholestyramine, colesevelam), rifampin, naltrexone, or sertraline **AND**
10. Prescribed by or in consultation with a gastroenterologist or hepatologist.

Diagnosis: Alagille syndrome (ALGS)

1. Patient has diagnosis of Alagille syndrome (ALGS) confirmed by genetic testing demonstrating a JAG1 or NOTCH2 deletion or mutation **AND**
2. Patient is 12 months of age and older **AND**
3. Dosage and Direction for Use: Recommended dosage is: 120 mcg/kg taken orally once daily **AND**

Body Weight	Once Daily Dosage (mcg)
7.4 and below	600
7.5 to 12.4	1,200
12.5 to 17.4	1,800
17.5 to 25.4	2,400
25.5 to 35.4	3,600

35.5 to 45.4	4,800
45.5 to 55.4	6,000
55.5 and above	7,200

**Note: oral pellets are intended for use by patients weighing less than 19.5 kilograms and capsules are intended for use by patients weighing 19.5 kilograms or above

4. Quantity requested does not exceed: 120 mcg/kg/day **AND**
   Patient does not have PFIC type 2 with ABCB11 variants **AND**
5. Patient has cholestasis **AND**
6. Patient has moderate to severe pruritus associated with Alagille syndrome **AND**
7. Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory **AND**
8. Patient does not have prior or active hepatic decompensation events **AND**
9. Patient has had an adequate trial of at least **two** of the following medications used to treat pruritus: ursodiol, bile acid sequestrants (i.e., cholestyramine, colesevelam), rifampin, naltrexone, or sertraline **AND**
10. Prescribed by or in consultation with a specialist such as a gastroenterologist or hepatologist.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 6 months

RENEWALS

✓ Confirm patient is tolerating therapy and patient has a positive response to therapy (e.g., decrease in serum bile acids and pruritus). Documentation must be provided.
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 8.12.2021	8.2021
Annual Review	No Change	8.2022
Annual Review	Updated t/f requirement to two agents for PFIC; Added expanded indication of cholestatic pruritus in patients with Alagille syndrome (ALGS); Added dosing chart for pediatric patients for both diagnoses; Updated initial approval duration; Updated denial message	8.2023
Annual Review	Updated contraindication to no history of hepatic decompensation events; removed PFIC requirement from AS criteria; added genetic testing requirement for AS dx	3.2024

REFERENCE:

1. Bylvay (odevixibat) [prescribing information]. Boston, MA: Albireo Pharma Inc; July 2023.
2. Jacquemin E. Progressive familial intrahepatic cholestasis. Clin Res Hepatol Gastroenterol. 2012;36 Suppl 1:S26-S35. doi:10.1016/S2210-7401(12)70018-9.
3. Jacquemin E, et al. Ursodeoxycholic acid therapy in pediatric patients with progressive familial intrahepatic cholestasis. Hepatology. 1997;25(3):519-523. doi:10.1002/hep.510250303.
4. Progressive Familial Intrahepatic Cholestasis Advocacy and Resource Network. Diagnosis and treatment. Accessed August 10, 2021. https://www.pfic.org/diagnosisand-treatment-of-pfic/
5. Poupon R, Chopra S. Pruritus associated with cholestasis. Lindor KD, Grover S, eds. UpToDate. Waltham, MA: UpToDate Inc. Updated February 16, 2021. Accessed August 10, 2021. https://www.uptodate.com/contents/pruritus-associated-withcholestasis
6. National Organization for Rare Diseases (NORD). Primary Biliary Cholangitis. July 31, 2023. Available from: https://rarediseases.org/rare-diseases/primary-biliary-cholangitis/
7. National Organization for Rare Diseases (NORD). Primary Sclerosing Cholangitis July 31, 2023. Available from: https://rarediseases.org/rare-diseases/primary-sclerosing-cholangitis/

8. Kamath BM, et al. Outcomes of childhood cholestasis in Alagille syndrome: Results of a multicenter observational study. Hepatol Comm. 2020; 4:387-398. https://doi.org/10.1002/hep4.1468
9. National Organization of Rare Disorders (NORD). Alagille syndrome. Accessed July 31, 2023. https://rarediseases.org/rare-diseases/alagille-syndrome/
10. National Organization for Rare Diseases (NORD). Biliary Atresia. Accessed July 31, 2023. Available from: https://rarediseases.org/rare-diseases/extrahepatic-biliary-atresia/
11. Siddiqi I, Tadi P. Progressive Familial Intrahepatic Cholestasis. [Updated 2022 Jul 4]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK559317/
12. Thompson R. J., Arnell H., Artan R., Baumann U., Calvo P. L., Czubkowski P., Dalgic B., D'Antiga L., Durmaz Ö., Fischler B., Gonzalès E., Grammatikopoulos T., Gupte G., Hardikar W., Houwen , (2022). Odevixibat treatment in progressive familial intrahepatic cholestasis: a randomised, placebo-controlled, phase 3 trial. Lancet Gastroenterol Hepatol, 7(9), 830–42. doi: 10.1016/S2468-1253(22)00093-0
13. Ganschow R, Maucksch C. Odevixibat Treatment of Alagille Syndrome: A Case Report. JPGN Rep. 2023 Mar 24;4(2):e301. doi: 10.1097/PG9.0000000000000301. PMID: 37200711; PMCID: PMC10187842.

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Prior Authorization Criteria for CABOMETYX® (cabozantinib)

FDA-Approved Indications

- Treatment of patients with advanced renal cell carcinoma (RCC)
- Treatment of patients with advanced renal cell carcinoma, as a first-line treatment in combination with nivolumab
- Treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib
- Treatment of treatment of adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA Criteria created based on utilization	7.2021
Updated	Updated denial message and format	1.2022
Annual Review	Updated expanded indication of Locally advanced or metastatic differentiated thyroid cancer (DTC); updated nivolumab to Opdivo Added denial message.	10.2022
Annual Review	Added requested medication follows appropriate sequence of therapy language; added oncology renewal criteria	10.2023
Update	Updated duration to 1 year; updated to oncology template; updated indication	5.2024

REFERENCE:

1. Cabometyx (cabozantinib) tablet [prescribing information]. Alameda, CA: Exelixis, Inc; September 2023.
2. National Comprehensive Cancer Network. Kidney Cancer (Version 3.2023). https://www.nccn.org/professionals/physician_gls/pdf/kidney_blocks.pdf. Accessed Oct 18, 2022.
3. National Comprehensive Cancer Network. Hepatocellular Cancer (Version 2.2022). https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary_blocks.pdf. Accessed Oct 18, 2022.

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Prior Authorization Criteria for CALQUENCE® (acalabrutinib)

FDA-APPROVED INDICATIONS

- Adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy
- Adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist.

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA Created 7-15-22; Updated criteria to include new tablet formulation	8.2022
Updated	Updated criteria to include use of Calquence as a single-agent therapy for CLL/SLL	2.2023
Annual Review	Update format and references	7.2023
Annual Review	Updated to oncology template; updated duration to 1 year	5.2024

REFERENCE:

1. Calquence (acalabrutinib tablets) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; August 2022.
2. National Comprehensive Cancer Network (NCCN). NCCN clinical practice guidelines in oncology – B-Cell Lymphomas, version 5.2023. NCCN Web site. https://www.nccn.org/professionals/physician_gls/pdf/b-cell_blocks.pdf. Accessed July 21, 2023.
3. National Comprehensive Cancer Network. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (version 3.2023). https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed July 21, 2023.

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Prior Authorization Criteria for CAMZYOS ™ (mavacamten)

1. Patient has a diagnosis of symptomatic obstructive hypertrophic cardiomyopathy (HCM) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: recommended starting dose is 5 mg once daily; allowable subsequent doses with titration are 2.5, 5, 10, or 15 mg once daily. Dosage must be individualized based on clinical status and echocardiographic assessment of patient response **AND**
4. Quantity requested does not exceed: 1 tab/day (30/30 days) **AND**
5. Patient has NYHA Class II or III with documented left ventricular ejection fraction (LVEF) ≥55% **AND**
6. Patient has hypertrophic obstructive cardiomyopathy confirmed with left ventricular outflow tract [LVOT] gradient ≥50 mm Hg **AND**
7. Patient is not currently diagnosed with a disorder that causes cardiac hypertrophy that mimics oHCM (i.e., Fabry disease, amyloidosis, or Noonan syndrome with LV hypertrophy) **AND**
8. Patient had an adequate trial of a beta-blocker (i.e., metoprolol, propranolol, atenolol), calcium channel blocker (i.e., verapamil, diltiazem), or disopyramide **AND**
9. Prescribed by or in consultation with a specialist such as a cardiologist.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 6 months.

RENEWALS

✓ Interrupt treatment if LVEF <50% or if worsening clinical status.
✓ Confirm clinical improvement in signs and symptoms (i.e., Improvement of mixed pVO2 by ≥1.5 mL/kg/min plus at least one NYHA class reduction or a ≥3.0 mL/kg/min pVO2 increase without NYHA class worsening).
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 5.19.2022	5.2022
Annual Review	Added disopyramide as a trial requirement option; removed criteria: at least 45 kg, resting oxygen saturation of ≥90% requirement, and patient is not currently being treated with disopyramide, or ranolazine; Updated denial message	5.2023
Annual Review	No changes	5.2024

REFERENCE:

1. 2020 AHA/ACC Guideline for the Diagnosis and Treatment of Patients With Hypertrophic Cardiomyopathy: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol 2020;Nov 20.
2. American Heart Association. Hypertrophic cardiomyopathy (HCM). November 17, 2020. Accessed May 30, 2023. https://www.heart.org/en/health-topics/cardiomyopathy/what is-cardiomyopathy-in-adults/hypertrophic-cardiomyopathy.
3. Burstein Waldman C, et al. A plain language summary of the EXPLORER-HCM study: mavacamten for obstructive hypertrophic cardiomyopathy. Future Cardiol. 2021;17(7):1269–1275. doi:10.2217/fca-2021-0044.
4. Camzyos (mavacamten) [prescribing information]. Brisbane, CA: MyoKardia Inc; June 2023.
5. Hegde SM, et al. Effect of mavacamten on echocardiographic features in symptomatic patients with obstructive hypertrophic cardiomyopathy. J Am Coll Cardiol. 2021;78(25):2518–2532. doi:10.1016/j.jacc.2021.09.1381
6. Maron MS, et al. Occurrence of clinically diagnosed hypertrophic cardiomyopathy in the United States. Am J Cardiol. 2016;117:1651–1654. doi:10.1016/j.amjcard.2016.02.044.

7. Olivotto I, Oreziak A, Barriales-Villa R, et al; EXPLORER-HCM study investigators. Mavacamten for treatment of symptomatic obstructive hypertrophic cardiomyopathy (EXPLORER-HCM): a randomised, double-blind, placebo-controlled, phase 3 trial. Lancet. 2020;396(10253):759-769. doi:10.1016/S0140-6736(20)31792-X[PubMed 32871100].
8. Zampieri M, et al. Mavacamten, a novel therapeutic strategy for obstructive hypertrophic cardiomyopathy. Curr Cardiol Rep. 2021;23(7):79. doi:10.1007/s11886-021-01508-0

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Prior Authorization Criteria for CAPRELSA (vandetanib)

FDA-Approved Indications

- Treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated to oncology template; updated duration to 1 year	5.2024

REFERENCE:

1. Caprelsa (vandetanib). [Prescribing Information]. Cambridge, MA: Genzyme Corporation. April 2024.

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Prior Authorization Criteria for CARBAGLU (carglumic acid)

FDA-Approved Indications

- Adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency.
- Maintenance therapy for the treatment of chronic hyperammonemia due to NAGS deficiency.
- Adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA).

Diagnosis: Acute or Chronic Hyperammonemia due to NAGS deficiency

1. Patient has diagnosis of hyperammonemia due to N-acetylglutamate synthase deficiency **AND**
2. Dosage and directions:
    a. Acute: 100 mg/kg to 250 mg/kg daily
    b. Chronic 10 mg/kg to 100 mg/kg
3. If disease is acute, requested medication is being used as adjunctive therapy along with other ammonia-lowering therapies (e.g., intravenous fluid rehydration, protein restriction, or dialysis) **AND**
4. Prescribed by or in consultation with a metabolic disease specialist

Diagnosis: Acute Hyperammonemia due to Propionic Acidemia (PA) or Methylmalonic Acidemia (MMA)

1. Patient has diagnosis of hyperammonemia due to propionic acidemia or methylmalonic acidemia **AND**
2. Dosage and directions:
    a. ≤15 kg: 150/mg/kg/day divided into two doses for maximum of 7 days
    b. >15 kg: 3.3 g/m^2/day divided into two doses for maximum of 7 days
3. Requested medication is being used as adjunctive therapy **AND**
4. Prescribed by or in consultation with a metabolic disease specialist

INITIAL APPROVALS

- ✓ For chronic disease caused by NAGS deficiency: Initial authorization will be granted for a period of 12 months
- ✓ For acute disease caused by NAGS deficiency: Initial authorization will be granted for 3 months
- ✓ For acute disease caused by MMA or PA: Authorization will be granted for 7 days
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ For chronic disease caused by NAGS deficiency only
    - Documentation of positive clinical response to therapy has been provided
    - Approval duration for renewal: 12 months.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Renewal	Updated indication, dosing, provided ammonia-lowering therapies examples, and references.	8.2024

REFERENCE:

1. Carbaglu (carglumic acid). [Prescribing Information]. Bridgewater, NJ: Recordati Rare Diseases. January 2024.

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Prior Authorization Criteria for CERDELGA® (eliglustat)

1. Patient has a diagnosis of type 1 Gaucher Disease **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use:
   a. *Extensive metabolizers (Ems) and Intermediate metabolizers (IMs):* 84 mg capsules orally twice daily
   b. *Poor metabolizers (PMs):* 84 mg orally once daily **AND**
4. Quantity requested does not exceed: 56/28 days **AND**
5. Disease is confirmed by an enzyme assay demonstrating a deficiency of beta- glucocerebrosidase (glucosidase) enzyme activity OR by genetic testing **AND**
6. Patient is symptomatic (e.g., anemia, thrombocytopenia, bone disease, hepatomegaly, splenomegaly) **AND**
7. Patient is a CYP2D6 extensive metabolizer (EM), intermediate metabolizers (IM), or poor metabolizers (PM) as detected by an FDA-cleared test **AND**
8. Physician attestation that patient is not a CYP2D6 ultra-rapid metabolizer and does **not** have any of the following contraindications:
   a. EMs:
      i. Taking a strong or moderate CYP2D6 inhibitor with a strong or moderate CYP3A inhibitor **OR**
      ii. Moderate or severe hepatic impairment **OR**
      iii. Mild hepatic impairment taking a strong or moderate CYP2D6 inhibitor
   b. IMs
      i. Taking a strong or moderate CYP2D6 inhibitor with a strong or moderate CYP3A inhibitor **OR**
      ii. Taking a strong CYP3A inhibitor **OR**
      iii. Any degree of hepatic impairment
   c. PMs
      i. Taking a strong CYP3A inhibitor **OR**
      ii. Any degree of hepatic impairment **AND**
9. Prescribed by or in consultation with a specialist such as an endocrinologist or a physician that specializes in the treatment of Gaucher disease.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Documentation of clinical response to therapy
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated format; updated references	3.2024

REFERENCE:

1. Cerdelga (eliglustat) [prescribing information]. Waterford, Ireland: Genzyme Ireland Ltd; January 2024.
2. Charrow J, Andersson HC, Kaplan P. Enzyme replacement therapy and monitoring for children with type 1 Gaucher disease: consensus recommendations. J Pediatr. 2004; 144: 112-20.

3. Gary SE, Ryan E, Steward AM, Sidransky E. Recent advances in the diagnosis and management of Gaucher disease. Expert Rev Endocrinol Metab. 2018 Mar;13(2):107-118. doi: 10.1080/17446651.2018.1445524. Epub 2018 Mar 12. PMID: 30058864; PMCID: PMC6129380.
4. Hollak, CEM, Weinreb NJ. The attenuated/late onset lysosomal storage disorders: therapeutic goals and indications for enzyme replacement treatment in Gaucher and Fabry disease. Best Pract Res Clin Endocrinol Metab. 2015; 29: 205-218.
5. Pastores GM, Weinreb NJ, Aerts H, et al. Therapeutic goals in the treatment of Gaucher disease. Semin Hematol. 2004; 41(suppl 5): 4-14.
6. Andersson HC, Charrow J, Kaplan P, et al. Individualization of long-term enzyme replacement therapy for Gaucher disease. Genet Med. 2005; 7(2): 105-110.
7. M.Á. Torralba-Cabeza, M. Morado-Arias, A. Pijierro-Amador, M.C. Fernández-Canal, J. Villarrubia-Espinosa, Recommendations for oral treatment for adult patients with type 1 Gaucher disease, Revista Clínica Española (English Edition), Volume 222, Issue 9, 2022, Pages 529-542.

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Prior Authorization Criteria for CHENODAL® (chenodiol tablet)

1. Patient has a diagnosis of radiolucent gallstones **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 13-16 mg/kg/day in two divided doses **AND**
4. Quantity requested does not exceed: dosed by weight, please optimize quantity based on prescribed dosing scheduling **AND**
5. Patient is not a candidate for surgery due to increased risk (such as systemic disease or age) **AND**
6. Prescribed by or in consultation with a hepatologist or gastroenterologist

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 12 months.

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided
- ✓ Approval duration for renewal: 12 months
- ✓ Maximum lifetime limit of 2 years

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	No changes	3.2024

REFERENCE:

1. Chenodal (chenodiol). [Prescribing information]. San Diego, CA: Travere Therapeutics. May 2021.

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Prior Authorization Criteria for CHOLBAM (cholic acid) capsules

FDA-Approved Indications

- Treatment of bile acid synthesis disorders due to single enzyme defects (SEDs).
- Adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea or complications from decreased fat soluble vitamin absorption.

Diagnosis: Bile Acid Synthesis Disorders

1. Patient has a diagnosis of a bile acid synthesis disorder **AND**
2. Dosage and Direction for Use:
    a. *Bile acid synthesis disorder:* 10 to 15 mg/kg administered orally once daily, or in two divided doses
    b. **AND**
    c. *Bile acid synthesis disorder with familial hypertriglyceridemia*: 11 to 17 mg/kg orally once daily, or in two divided doses
3. Quantity requested does not exceed: 17 mg/kg. Dose is based on weight. Please check package insert for dosing recommendation table **AND**
4. Confirm that bile acid synthesis disorder is due to single enzyme defects (SEDs) confirmed by mass spectrometry (FAB-MS) or other biochemical testing or genetic testing **AND**
5. Prescribed by or in consultation with a specialist such as a hepatologist or a gastroenterologist.

Diagnosis: Peroxisomal Disorders (PDs)

1. Patient has a diagnosis of peroxisomal disorders (PDs) including Zellweger spectrum disorders **AND**
2. Dosage and Direction for Use:
    a. *PD*: 10 to 15 mg/kg administered orally once daily, or in two divided doses **AND**
    b. *PD with familial hypertriglyceridemia*: 11 to 17 mg/kg orally once daily, or in two divided doses
3. Quantity requested does not exceed: 17 mg/kg. Dose is based on weight. Please check package insert for dosing recommendation table **AND**
4. Peroxisomal disorder is confirmed by mass spectrometry (FAB-MS) or other biochemical testing or genetic testing **AND**
5. Patient exhibits manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption **AND**
6. Requested medication is being used as adjunctive treatment **AND**
7. Prescribed by or in consultation with a specialist such as a hepatologist or a gastroenterologist.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 3 months

RENEWALS

✓ Documentation of clinical response to therapy (e.g., improvements in liver function tests, liver enzymes or improvement in steatorrhea).
✓ Patient does not develop complete biliary obstruction
✓ Discontinue treatment if liver function does not improve within 3 months of starting treatment, if complete biliary obstruction develops, or if there are persistent clinical or laboratory indicators of worsening liver function or cholestasis
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Added adjunctive treatment requirement for PDS	2.2024

REFERENCE:

1. Cholbam® capsules [prescribing information]. San Diego, CA: Retrophin; March 2023
2. Anderson, J.N., Ammous, Z., Eroglu, Y. et al. Cholbam® and Zellweger spectrum disorders: treatment implementation and management. Orphanet J Rare Dis 16, 388 (2021). https://doi.org/10.1186/s13023-021-01940-z
3. Bile acid synthesis disorders. National Organization for Rare Diseases. Updated 2020. Available at: https://rarediseases.org/rare-diseases/bile-acid-synthesis-disorders/. Accessed on August 6, 2023.
4. Gonzales, E., Matarazzo, L., Franchi-Abella, S. et al. Cholic acid for primary bile acid synthesis defects: a life-saving therapy allowing a favorable outcome in adulthood. Orphanet J Rare Dis 13, 190 (2018). https://doi.org/10.1186/s13023-018-0920-5
5. Zellweger spectrum disorders. National Organization for Rare Diseases. Updated 2020. Available at: https://rarediseases.org/rare-diseases/zellweger-spectrum-disorders/. August 6, 2023.
6. Steinberg SJ, Raymond GV, Braverman NE, et al. Zellweger Spectrum Disorder. 2003 Dec 12 [Updated 2020 Oct 29]. In: Adam MP, Ardinger HH, Pagon RA, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2021. Updated October 29, 2020. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1448/. August 6, 2023.
7. Fawaz R, Baumann U, Ekong U, et al. Guideline for the evaluation of cholestatic jaundice in infants: joint recommendations of the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition. J Pediatr Gastroenterol Nutrition. 2017;64(1):154-168.

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Prior Authorization Criteria for CIBINQO™ (abrocitinib)

1. Patient has diagnosis of moderate to severe atopic dermatitis **AND**
2. Patient is 12 years of age or older **AND**
3. Dosage and direction of use: 100 mg orally once daily. May increase to 200mg once daily if an adequate response is not achieved after 12 weeks of the 100 mg dose. The 50 mg once daily dose can be used for patients with moderate renal impairment or for those who are CYP2C19 poor metabolizers **AND**
4. Quantity requested does not exceed: 30 tablets/30 days **AND**
5. Patient has failure of all the following, unless contraindicated or clinically significant adverse effects are experienced:
    a) Two formulary medium to very high potency topical corticosteroids, each used for at least 2 weeks **AND**
    b) One non-steroidal topical therapy*: topical calcineurin inhibitor (e.g., tacrolimus 0.03% ointment and pimecrolimus 1% cream) or Eucrisa, each used for at least 4 weeks; * These agents may require prior authorization **AND**
    c) One or more of the following systemic agents: corticosteroids, azathioprine, methotrexate, mycophenolate mofetil, or cyclosporine **AND**
6. Patient is not receiving Cibinqo in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants (e.g., other TNF-inhibitors, Kineret, azathioprine, cyclosporine, etc.) **AND**
7. Prescribed by or in consultation with a dermatologist.

INITIAL APPROVALS

- ✓ Initial authorization will be granted for the 100 mg dose for a period of 1 year
- ✓ Note: the 100 mg dose can be increase to 200 mg once daily if the patient did not receive an adequate response after 12 weeks of therapy.

RENEWALS

- ✓ Documentation of positive response to the therapy **AND**
- ✓ Patient is not receiving Cibinqo in combination with other biologic DMARDs or potent immunosuppressants (e.g., other TNF-inhibitors, Kineret, azathioprine, cyclosporine, etc.)
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB	2.2022
Updated	Updated criteria: removed criteria: patient has had an adequate trial of a biologic (i.e., Dupixent or Adbry). Updated denial message.	12.2022
Annual Review	Updated criteria to include expanded indication of patients 12 years of age and older.	2.2023
Annual Review	Removed TB Requirement, updated denial message, updated format, and updated reference.	2.2024

REFERENCE:

1. Bieber T, Simpson EL, Silverberg JI, et al; JADE COMPARE Investigators. Abrocitinib versus placebo or dupilumab for atopic dermatitis. N Engl J Med. 2021;384(12):1101-1112. doi:10.1056/NEJMoa2019380[PubMed 33761207]
2. Cibinqo (abrocitinib) [prescribing information]. New York, NY: Pfizer Labs; December 2023.
3. Cibinqo (abrocitinib) [product monograph]. Kirkland, Quebec, Canada: Pfizer Canada ULC; June 2023.

4. Schwartz DM, Kanno Y, Villarino A, Ward M, Gadina M, O'Shea JJ. JAK inhibition as a therapeutic strategy for immune and inflammatory diseases. Nat Rev Drug Discov. 2017;17(1):78. doi:10.1038/nrd.2017.267[PubMed 29282366]
5. Silverberg JI, Simpson EL, Thyssen JP, et al. Efficacy and safety of abrocitinib in patients with moderate-to-severe atopic dermatitis: a randomized clinical trial. JAMA Dermatol. 2020;156(8):863-873. doi:10.1001/jamadermatol.2020.1406[PubMed 32492087]
6. Vestergaard C, Wollenberg A, Barbarot S, et al. European task force on atopic dermatitis position paper: treatment of parental atopic dermatitis during preconception, pregnancy and lactation period. J Eur Acad Dermatol Venereol. 2019;33(9):1644-1659. doi:10.1111/jdv.15709[PubMed 31231864]

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Prior Authorization Criteria for COMETRIQ (cabozantinib)

FDA-Approved Indications

- Treatment of patients with progressive, metastatic medullary thyroid cancer (MTC)

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated duration to 1 year; updated oncology template	5.2024

REFERENCE:

1. Cometriq (cabozantinib). [Prescribing Information]. Alameda, CA: Exelixis, Inc. August 2023.

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Prior Authorization Criteria for Continuous Glucose Monitoring devices/CGM devices (Freestyle Libre®, Dexcom®, Medtronic Guardian Connect®, etc.)

Summary of commonly-used devices (table 1):

Brand	Model	FDA approved age	Sensor Replacement frequency (QLL for Sensor)	Transmitter Replacement frequency (QLL)	Receiver/Reader Device (QLL)
Freestyle	Libre	> 18	10 days (3/30 days)	No transmitter	Until device broken (1/year)
	Libre 2	> 4	14 days (2/28 days)	No transmitter	Until device broken (1/year)
	Libre 3	> 4	14 days (2/28 days)	No transmitter	Until device broken (1/year)
Dexcom	G7	≥ 2	10 days (3/30 days)	10 days (3/30 days) *Sensor has built-in transmitter	Until device broken (1/year) *optional, patients may use only the app on a compatible smart device, only the receiver, or both at the same time.
	G6			Every 3 months (1/90 days)	Until device broken (1/year)
	G4, G5		7 days (4/28 days)	Every 3 months (1/90 days)	Until device broken (1/year)
Medtronic	Guardian Connect	14 to 75 years	7 days (5/30 days)	Until device broken (1/year)	No receiver/reader device
Eversense (implantable CGM; under medical benefit)	Eversense	≥ 18	1/90 days (1/90 days)	Up to 1 year (1/year)	No receiver/reader device

Please note:

- The listed CGMs products are not all-inclusive. Due to advanced technology, a new generation of the same brand CGM product(s) may have different approved age limit, sensor replacement frequency, removal or addition of new parts (sensor/transmitter/receiver/etc.). Some products may be covered under medical benefits (e.g., Eversense implantable CGMs). Reviewers are encouraged to check product label for updates.
- For continuation of CGM use, Maxor adjudication system has "COT (continuation of therapy) Grandfather" in place to allow claims to be processed without PA rejection upon initial PA approval.

PA criteria:

1. Confirm plan covers CGM **AND**
2. Patient has diagnosis of type 1 or type 2 diabetes mellitus **AND**
3. Confirm patient is on an insulin regimen or continuous subcutaneous insulin infusion. Includes patients on a basal insulin regimen, basal and prandial insulin regimen, or continuous subcutaneous insulin infusion (insulin pump)) **OR**
4. Patient has documented history of problematic severe hypoglycemia:
    a. Recurrent (more than one) level 2 hypoglycemic events (glucose < 54 mg/dL) despite 2 or more attempts to adjust medication or modify treatment plan **OR**
    b. A history of one level 3 hypoglycemic event (glucose <54 mg/dL) characterized by altered mental and/or physical state requiring another person's assistance for treatment of hypoglycemia **AND**
5. Confirm patient meets FDA-approved age requirement based on product label or Table 1 above **AND**
6. Quantity requested does not exceed based on product label or Table 1 above (please check all required parts of CGM, e.g. sensor, transmitter, receiver/reader) **AND**
7. If requested product is non-preferred, confirm patient has an adequate trial of both Freestyle Libre AND Dexcom

INITIAL APPROVALS

- ✓ Initial approval will be granted for a period of 1 year
- ✓ Please ensure existing MPAs for test strips or other SMBG products, as well as previous CGMS products are updated accordingly.

RENEWALS

- ✓ Confirm continuation of utilization of CGM products
- ✓ Approval duration for renewal: 1 year
- ✓ Please ensure existing MPAs for test strips or other SMBG products, as well as previous CGMS products are updated accordingly.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 7.30.2020	7.2020
Updated	Changed criteria to allow for inability to use SMBG alone as qualifier for coverage	5.2021
Annual Review	No changes	6.2022
Annual Review	Updated criteria to include: patient is using an insulin regimen or continuous subcutaneous insulin infusion or patient has hypoglycemia episodes; Removed requirement: patient perform frequent testing four or more times per day, patient is insulin dependent (three or more daily injections) or on an insulin pump device, or patient's insulin regimen requires frequent adjustment due to unstable A1c or frequent hypoglycemic episodes; updated denial message.	5.2023
Updated	Updated denial language; removed documentation requirement for testing frequency; updated trial and failure requirements	8.2023
Annual Review	No changes	5.2024

REFERENCE:

1. Freestyle Libre Products: https://provider.myfreestyle.com/freestyle-libre-resources.html;
2. Dexcom Products: https://www.dexcom.com/guides
3. Medtronic Guardian Connect: User manual https://www.medtronicdiabetes.com/download-library
4. Eversence: https://resources.eversensediabetes.com/sites/resources/files/2020-05/LBL-1632-01-001%20Rev%20E_Eversense%20User%20Guide_mgdL_R1.pdf
5. American Diabetes Association. Standards of medical care in diabetes – 2023. Diabetes Care. 2024;47(Suppl 1): S126-S144. 2. Grunberger G, Sherr J, Allende M, et al. American Association of Clinical
6. Endocrinology clinical practice guideline: the use of advanced technology in the management of persons with diabetes mellitus. Endocr Pract. 2021 Jun;27(6):505-537.
7. Choudhary P, Rickels MR, Senior PA, Vantyghem MC, Maffi P, Kay TW, Keymeulen B, Inagaki N, Saudek F, Lehmann R, Hering BJ. Evidence-informed clinical practice recommendations for treatment of type 1 diabetes complicated by problematic hypoglycemia. Diabetes Care. 2015 Jun;38(6):1016-29. doi: 10.2337/dc15-0090. PMID: 25998294; PMCID: PMC4439532.
8. Sharifi Y, Ebrahimpur M, Tamehrizadeh SS. Hypoglycemic unawareness: challenges, triggers, and recommendations in patients with hypoglycemic unawareness: a case report. J Med Case Rep. 2022 Jul 21;16(1):283. doi: 10.1186/s13256-022-03498-1. PMID: 35858952; PMCID: PMC9301883.

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Prior Authorization Criteria for COPIKTRA (duvelisib)

FDA-Approved Indications

- Treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL) after at least two prior therapies.

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated duration of approval; added FDA approved dx and age	5.2024

REFERENCE:

1. Copiktra. [Prescribing Information]. Las Vegas, NV. Secura Bio, Inc: December 2021.

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Prior Authorization Criteria for COTELLIC (cobimetinib)

FDA Indications

- Treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib
- Treatment of adult patients with histiocytic neoplasms, as a single agent

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated duration of approval; added FDA approved age	5.2024

REFERENCE:

1. Cotellic (cobimetinib). [Prescribing Information]. San Francisco: Genentech, Inc. May 2023.

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Prior Authorization Criteria for CRESEMBA® (isavuconazonium sulfate capsule)

1. Patient has diagnosis of invasive aspergillosis or invasive mucormycosis
2. Patient is 6 years of age or older **AND**
3. Dosage and direction of use:
    a. 18 years of age and older:
        i. Loading dose: 372 mg every 8 hours for 6 doses
        ii. Maintenance dose: 372 mg once daily
    b. 6-18 years of age:
        i. 16-17 kg: Loading dose 149 mg every 8 hours for 6 doses; Maintenance dose: 149 mg once daily
        ii. 18-24 kg: Loading dose 223.5 mg every 8 hours for 6 doses; Maintenance dose: 223.5 mg once daily
        iii. 25-31 kg: Loading dose 298 mg every 8 hours for 6 doses; Maintenance dose: 298 mg once daily
        iv. 32 kg or greater: Loading dose 372 mg every 8 hours for 6 doses; Maintenance dose: 372 mg once daily **AND**
4. Quantity requested does not exceed:
    a. 18 years of age and older (186 mg capsules):
        i. Loading dose: 12 capsules/2 days
        ii. Maintenance dose: 2 capsules/1 day
    b. 6- 18 years of age (74.5 mgcapsules):
        i. 16-17 kg: Loading dose: 12 capsules/2 days; Maintenance dose: 2 capsules/1 day
        ii. 18-24 kg: Loading dose: 18 capsules/2 days; Maintenance dose: 3 capsules/1 day
        iii. 25-31 kg: Loading dose: 24 capsules/2 days; Maintenance dose: 4 capsules/1 day
        iv. 32 kg: Loading dose: 30 capsules/2 days; Maintenance dose: 5 capsules/1 day **AND**
5. Patient weighs 16 kg and greater **AND**
6. Prescribed by or in consultation with an infectious disease specialist

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 3 months.

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided and prescriber attests to need for continued therapy
- ✓ Approval duration for renewal: 3 months.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Annual Review	Updated age range to 6 years and older; update dosing; updated minimum weight to 16 kg	1.2024

REFERENCE:

1. CRESEMBA [Prescribing Information] Northbrook, IL: Astellas Pharma US, Inc; December 2023.

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Prior Authorization Criteria for CUPRIMINE® capsules, DEPEN® tablets (penicillamine)

FDA Approved Indications

- Wilson's disease
- Cystinuria

Diagnosis: Wilson's disease

1. Patient has diagnosis of Wilson's disease **AND**
2. Dosage and direction of use:
    a. **Adults**:
        i. Initial: 250 to 500 mg/day; increase dose in 250 mg increments every 4 to 7 days to 15 to 20 mg/kg/day (~1 to 1.5 g/day) in 2 to 4 divided doses; maximum dose: 2 g/day
        ii. Maintenance: 10 to 15 mg/kg/day (~750 to 1,000 mg/day) in 2 or 3 divided doses.
    b. **Pediatric patients:** 20 mg/kg/day in 2 to 3 divided doses, round off to the nearest 250 mg dose **AND**
3. Quantity requested does not exceed: 2 g/day or 240 tablets/capsules/30 days
4. If request is for brand name, patient must have tried and failed generic penicillamine or have medical justification to support inability to use generic penicillamine **AND**
5. Prescribed by or in consultation with a specialist.

Diagnosis: Cystinuria

1. Patient has diagnosis of Cystinuria **AND**
2. Dosage and direction of use:
    i. **Adults**: 2 g/day with a range of 1 to 4 g/day (16 tablets/capsules) in 4 divided doses. Dosage should be individualized to an amount that limits cysteine excretion to 100 to 200mg/day
    ii. **Pediatric patients:** 20 to 40 mg/kg/day in 4 divided doses; maximum daily dose: 40 mg/kg/day **AND**
3. Quantity requested does not exceed: 4 g/day or 480 tablets/capsules/30 days
4. If request is for brand name, patient must have tried and failed generic penicillamine or have medical justification to support inability to use generic penicillamine **AND**
5. Patient has failure of a urinary alkalinizing agent (e.g., potassium citrate) unless contraindicated or clinically significant adverse effects are experienced **AND**
6. Prescribed by or in consultation with a specialist.

INITIAL APPROVALS

- ✓ Initial approval will be granted for a period of 1 year
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created from CAB 10.22.2020	10.2020
Updated	Combined default denial comment	5.2021
Annual review	No changes	11.2021
Annual review	No changes	11.2022
Annual Review	Remove age requirement and updated dosage for Wilson's disease based on guidelines; updated dosage for Cystinuria; Removed RA diagnosis per RA guidelines – not recommended; Updated denial message; Format update	8.2023
Annual review	Added brand name may be subject to formulary exclusion language	7.2024

REFERENCE:

1. Cuprimine (penicillamine) [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; November 2019.
2. Depen (penicillamine) [prescribing information]. Somerset, NJ: Meda Pharmaceuticals Inc; January 2019.
3. DeBerardinis RJ, Coughlin CR 2nd, Kaplan P. Penicillamine therapy for pediatric cystinuria: experience from a cohort of American children. J Urol. 2008;180(6):2620-2623.[PubMed 18951580].
4. European Association for Study of Liver. EASL Clinical Practice Guidelines: Wilson's disease. J Hepatol. 2012;56(3):671-685.[PubMed 22340672]
5. Roberts EA and Schilsky ML. Diagnosis and treatment of Wilson disease: an update. American Association for Study of Liver Diseases (AASLD). Hepatology. 2008;47(6):2089-2111. doi: 10.1002/hep.22261.[PubMed 18506894].
6. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. Arthritis Care Res (Hoboken). 2016;68(1):1-25.[PubMed 26545825].
7. "Treatment Guidelines for Lead Exposure in Children. American Academy of Pediatrics Committee on Drugs," Pediatrics, 1995, 96(1 Pt 1):155-60.[PubMed 7596706].
8. Saroli Palumbo C, Schilsky ML. Clinical practice guidelines in Wilson disease. Ann Transl Med. 2019 Apr;7(Suppl 2):S65. doi: 10.21037/atm.2018.12.53. PMID: 31179302; PMCID: PMC6531645.
9. Schilsky ML, Roberts EA, Bronstein JM, Dhawan A, Hamilton JP, Rivard AM, Washington MK, Weiss KH, Zimbrean PC. A multidisciplinary approach to the diagnosis and management of Wilson disease: Executive summary of the 2022 Practice Guidance on Wilson disease from the American Association for the Study of Liver Diseases. Hepatology. 2023 Apr 1;77(4):1428-1455. doi: 10.1002/hep.32805. Epub 2022 Dec 7. PMID: 36152019.

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Prior Authorization Criteria for CUVRIOR™ (trientine tetrahydrochloride)

1. Patient has diagnosis of Wilson's disease **AND**
2. Patient is 18 years and older **AND**
3. Dosage and direction of use: 300 mg up to 3,000 mg taken orally in divided doses (two times daily) **AND**
4. Quantity requested does not exceed: 300 tablets/30 days (3,000 mg/day or 10 tablets/day) **AND**
5. Patient has had a failure/intolerance/contraindication to generic penicillamine (Cuprimine or Depen) up to maximally indicated doses **AND**
6. Patient will discontinue penicillamine before starting Cuvrior **AND**
7. Prescribed by or in consultation with a specialist

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 1 year.

RENEWALS

✓ Documentation of positive clinical response to therapy has been provided **AND**
✓ Patient has not developed significant adverse effects or condition has not worsen while on therapy **AND**
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2019
Update	Add Denial Message	2.2020
Annual review	Added Additional Clinical Rules section; Updated denial message	7.2021
Annual review	No changes	7.2022
Update	Added Cuvrior from CAB 4.20.2023	4.2023
Annual review	Updated format	7.2023
Update	Separated criteria from Syprine	8.2023
Annual Review	Updated format	7.2024

REFERENCE:

1. Condamine L, Hermine O, Alvin P, Levine M, Rey C, Courtecuisse V. Acquired sideroblastic anaemia during treatment of Wilson's disease with triethylene tetramine dihydrochloride. Br J Haematol. 1993;83(1):166-168.[PubMed 8435326]
2. Cuvrior Prescribing Information. Chicago, IL: Orphalan; April 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215760s000lbl.pdf.
3. Roberts EA and Schilsky ML, "Diagnosis and Treatment of Wilson Disease: An Update. American Association for Study of Liver Diseases (AASLD)," Hepatology, 2008, 47(6):2089-2111.[PubMed 18506894]
4. Syprine Prescribing Information. Bridewater, NJ: Valeant Pharmaceuticals: December 2016. Available at: www.syprine.com. Accessed August 30, 2019.
5. Trientine hydrochloride capsules [prescribing information]. Princeton, NJ: Dr. Reddy's Laboratories; July 2019.
6. Saroli Palumbo C, Schilsky ML. Clinical practice guidelines in Wilson disease. Ann Transl Med. 2019 Apr;7(Suppl 2):S65. doi: 10.21037/atm.2018.12.53. PMID: 31179302; PMCID: PMC6531645.
7. Schilsky ML, Roberts EA, Bronstein JM, Dhawan A, Hamilton JP, Rivard AM, Washington MK, Weiss KH, Zimbrean PC. A multidisciplinary approach to the diagnosis and management of Wilson disease: Executive summary of the 2022 Practice Guidance on Wilson disease from the American Association for the Study of Liver Diseases. Hepatology. 2023 Apr 1;77(4):1428-1455. doi: 10.1002/hep.32805. Epub 2022 Dec 7. PMID: 36152019.

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Prior Authorization Criteria for CYLTEZO® (adalimumab-adbm)

FDA-APPROVED INDICATIONS

- Rheumatoid arthritis (RA): Adult patients with moderately to severely active rheumatoid arthritis
- Juvenile idiopathic arthritis (JIA): Polyarticular Juvenile Idiopathic Arthritis: Pediatric patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis
- Psoriatic arthritis (PsA): Adult patients with active psoriatic arthritis
- Ankylosing spondylitis (AS): Adult patients with active ankylosing spondylitis
- Plaque Psoriasis (PP): Adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate
- Crohn's disease (CD): Pediatric patients 6 years of age and older with moderately to severely active Crohn's disease who have had an inadequate response to corticosteroids or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate
- Ulcerative colitis (UC): Adult patients 18 years of age and older with moderately to severely active ulcerative colitis who have had an inadequate response to immunosuppressants such as corticosteroids, azathioprine or 6-mercaptopurine (6-MP)
- Hidradenitis suppurativa (HS): Moderate to severe hidradenitis suppurativa in patients 18 years of age and older
- Uveitis (UV): Adults patients 18 years of age and older with non-infectious intermediate, posterior, and panuveitis

Diagnosis: for Rheumatoid Arthritis (RA)

1. Patient has diagnosis of moderate to severe rheumatoid arthritis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 40 mg every other week, 40 mg every week or 80 mg every other week for patients that are not receiving methotrexate **AND**
4. Quantity requested does not exceed: 4 pens (40mg per pen)/28 days or 2 pens (80mg per pen)/28 days **AND**
5. Patient has had an inadequate response or has contraindications to at least one non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide) **AND**
6. Patient is not receiving medication in combination with other biologic DMARDS **AND**
7. For non-preferred Adalimumab formulations, patient has had an adequate trial of ALL preferred Adalimumab formulations **AND**
8. Prescribed by or in consultation with a rheumatologist.

Diagnosis: for Polyarticular Juvenile Idiopathic Arthritis (JIA)

1. Patient has diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis **AND**
2. Patient is 2 years of age or older **AND**
3. Dosage and direction of use:

Pediatric Weight 2 Years of Age and Older	Recommended Dosage
10 kg (22 lbs) to less than 15 kg (33 lbs)	10 mg every other week
15 kg (33 lbs) to less than 30 kg (66 lbs)	20 mg every other week
30 kg (66 lbs) and greater	40 mg every other week

AND

4. Quantity requested does not exceed: 2 pens (10, 20, or 40mg per pen)/28 days **AND**
5. Patient has had an inadequate response or has contraindications to at least one non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide) **AND**
9. Patient is not receiving medication in combination with other biologic DMARDS **AND**

10. For non-preferred Adalimumab formulations, patient has had an adequate trial of ALL preferred Adalimumab formulations **AND**
11. Prescribed by or in consultation with a rheumatologist.

Diagnosis: for Psoriatic Arthritis (PsA) and Ankylosing Spondylitis (AS)

1. Patient has diagnosis of psoriatic arthritis OR ankylosing spondylitis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 40 mg every other week, 40 mg every week or 80 mg every other week for patients that are not receiving methotrexate **AND**
4. Quantity requested does not exceed: 4 pens (40mg per pen)/28 days or 2 pens (80mg per pen)/28 days
5. Patient has had an inadequate response or has contraindications to:
    a. PsA: at least ONE non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide;
    b. AS: at least TWO scheduled/maintenance NSAIDs, each used for a duration of at least four weeks; **AND**
6. Patient is not receiving medication in combination with other biologic DMARDS **AND**
7. For non-preferred Adalimumab formulations, patient has had an adequate trial of ALL preferred Adalimumab formulations **AND**
8. Prescribed by or in consultation with a rheumatologist.

Diagnosis: for Plaque Psoriasis (PP)

1. Patient has diagnosis of moderate to severe chronic plaque psoriasis
2. PP is affecting more than 3% of body surface area (BSA) or affecting crucial body areas (e.g., hands, feet, face, or genitals) **AND**
3. Patient is 18 years of age or older **AND**
4. Dosage and direction of use: Initial 80 mg as a single dose; maintenance: 40 mg every other week beginning 1 week after initial dose **AND**
5. Quantity requested does not exceed: initial dose: 3 pens/21 days (may vary depending on product package) maintenance: 2 pens (40mg per pen)/28 days **AND**
6. Patient has had an adequate trial and failure of both UV or systemic therapy (methotrexate, acitretin, cyclosporine) AND topical therapy (corticosteroids, calcipotriene, calcitriol, tazarotene, tacrolimus) **AND**
7. Patient is not receiving medication in combination with other biologic DMARDS **AND**
8. For non-preferred Adalimumab formulations, patient has had an adequate trial of ALL preferred Adalimumab formulations **AND**
9. Prescribed by or in consultation with a rheumatologist or dermatologist.

Diagnosis: for Ulcerative Colitis (UC)

1. Patient has diagnosis of moderately to severely active ulcerative colitis (UC) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: Initial 160 mg (given on day 1 or split and given over 2 consecutive days), then 80 mg 2 weeks later (day 15); Maintenance: 40 mg every other week beginning day 29 **AND**
4. Quantity requested does not exceed: Initial: 3 pens (80mg/pen)/28 days (may vary depending on product package); Maintenance: 4 pens (20mg or 40mg per pen)/28 days or 2 pens (80mg per pen)/28 days **AND**
5. Patient has the patient had an adequate trial and failure of at least one of the following: topical or oral 5-ASA agents, glucocorticoids, azathioprine, or 6-mercaptopurine **AND**
6. Patient is not receiving medication in combination with other biologic DMARDs **AND**
7. For non-preferred Adalimumab formulations, patient has had an adequate trial of ALL preferred Adalimumab formulations **AND**
8. Prescribed by or in consultation with a gastroenterologist.

Diagnosis: for Crohn's Disease (CD)

1. Patient has diagnosis of moderate to severe Crohn's disease **AND**
2. Patient is 6 years of age or older **AND**
3. Dosage and direction of use:
    a. Adults: Initial 160 mg (given on day 1 or split and given over 2 consecutive days), then 80 mg 2 weeks later (day 15); Maintenance: 40 mg every other week beginning day 29;
    b. Pediatric Patients 6 years and older:

Pediatric Weight	Recommended Dosage	
	Days 1 and 15	Starting on Day 29
17 kg (37 lbs) to less than 40 kg (88 lbs)	Day 1: 80 mg Day 15: 40 mg	20 mg every other week
40 kg (88 lbs) and greater	Day 1: 160 mg (single dose or split over two consecutive days) Day 15: 80 mg	40 mg every other week

AND

4. Quantity requested does not exceed: Initial: 3 pens (80mg/pen)/28 days (may vary depending on product package); Maintenance: 2 pens (40mg per pen)/28 days **AND**
5. Patient has the patient had an adequate trial and failure of at least one of the following: azathioprine, 6-mercaptopurine, methotrexate, glucocorticoids **AND**
6. Patient is not receiving medication in combination with other biologic DMARDs **AND**
7. For non-preferred Adalimumab formulations, patient has had an adequate trial of ALL preferred Adalimumab formulations **AND**
8. Prescribed by or in consultation with a gastroenterologist.

Diagnosis: for Hidradenitis Suppurativa (HS)

1. Patient has diagnosis of Hidradenitis Suppurativa (sometimes referred to as: "acne inversa, acne conglobata, apocrine acne, apocrinitis, Fox-den disease, hidradenitis axillaris, HS, pyodermia sinifica fistulans, Velpeau's disease, and Verneuil's disease.") **AND**
2. Patient is 18 years of age and older
3. Dosage and direction of use: Initial 160 mg (given on day 1 or split and given over 2 consecutive days), then 80 mg 2 weeks later (day 15); Maintenance: 40 mg every week or 80 mg every other week beginning day 29 **AND**
4. Quantity requested does not exceed: Initial: 3 pens (80mg/pen)/28 days (may vary depending on product package); Maintenance: 4 pens (40mg per pen)/28 days or 2 pens (80mg per pen)/28 days **AND**
5. Patient has had an adequate trial and failure of at least TWO of the following:
    a. topical clindamycin;
    b. Intra-lesional corticosteroids;
    c. Topical resorcinol;
    d. At least two extended courses of oral antibiotics for at least 12 weeks including tetracycline (e.g. doxycycline) and antibiotic combinations such as clindamycin plus rifampin;
    e. Oral retinoids;
    f. Anti-androgenic therapy (cyproterone acetate, oral contraceptive pills, spironolactone) **AND**
6. For patients with severe disease (i.e., PUCAI score >65, abdominal distension or tenderness, profuse bloody diarrhea, signs of systemic illness, may require surgery), patient has had an adequate trial of ONE of the formulary alternatives listed above **AND**
7. Patient is not receiving medication in combination with other biologic DMARDs **AND**
8. For non-preferred Adalimumab formulations, patient has had an adequate trial of ALL preferred Adalimumab formulations **AND**
9. Prescribed by or in consultation with a dermatologist, rheumatologist, or gastroenterologist.

Diagnosis: for Uveitis

1. Patient has diagnosis of non-infectious intermediate, posterior, or panuveitis **AND**
2. Patient is 18 years of age and older **AND**

Dosage and direction of use: Initial 80 mg as a single dose; maintenance: 40 mg every other week beginning 1 week

after initial dose **AND**

3. Quantity requested does not exceed: 2 pens (10, 20, or 40mg per pen)/28 days **AND**
4. Patient had an adequate trial of topical or oral corticosteroids (e.g., prednisolone acetate, prednisone) **AND** an adequate trial of a non-biologic immunosuppressant therapy (e.g., azathioprine, methotrexate, cyclosporine, tacrolimus) **AND**
5. Patient is not receiving medication in combination with other biologic DMARDs **AND**
6. For non-preferred Adalimumab formulations, patient has had an adequate trial of **ALL** preferred Adalimumab formulations **AND**
7. Prescribed by or in consultation with an ophthalmologist

INITIAL APPROVALS

- ✓ Please review formulary for current preferred adalimumab formulations. All non-formulary adalimumab products must first try and fail **ALL** preferred formulary adalimumab formulations.
- ✓ Prescriber attestation that labs/notes indicate patient has the disease or requires the medication **AND**
- ✓ Confirm patient's weight is provided **AND**
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided (e.g., baseline decrease in number of plaques, improvement in skin appearance, etc.) **AND**
- ✓ Patient is not receiving medication in combination with other biologic DMARDs or phosphodiesterase 4 (PDE4) inhibitors **AND**
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created criteria for new adalimumab formulations	8.2023

REFERENCE:

1. Adalimumab injection [product monograph]. Kirkland, Quebec, Canada: Pfizer Canada ULC; January 2021.
2. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations: Part II: Topical, intralesional, and systemic medical management. J Am Acad Dermatol. 2019 Jul;81(1):91-101. doi: 10.1016/j.jaad.2019.02.068. Epub 2019 Mar 11. PMID: 30872149; PMCID: PMC9131892.
3. Amjevita (adalimumab) [prescribing information]. Thousand Oaks, CA: Amgen Inc; April 2023
4. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. Arthritis Care Res. 2011; 63(4):465-482.
5. Braun J, van den berg R, et al. 2010 Update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. Am Rheu Dis. 2011; 70:896-904
6. Cyltezo (adalimumab) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; May 2023.
7. Feuerstein JD, Ho EY, Shmidt E, et al; American Gastroenterological Association Institute Clinical Guidelines Committee. AGA clinical practice guidelines on the medical management of moderate to severe luminal and perianal fistulizing Crohn's disease. Gastroenterology 2021;160:2496-2508. (https://doi.org/10.1053/j.gastro.2021.04.022)
8. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology. 2020 Apr;158(5):1450-1461. doi: 10.1053/j.gastro.2020.01.006. Epub 2020 Jan 13. PMID: 31945371; PMCID: PMC7175923.
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10. Hadlima and Hadlima PushTouch (adalimumab) [product monograph]. Kirkland, Quebec, Canada: Organon Canada Inc; December 2022.
11. Hulio (adalimumab) [product monograph]. Etobicoke, Ontario, Canada: BGP Pharma ULC; May 2023.
12. Humira Prescribing Information. North Chicago, IL: AbbVie, Inc.; January 2019. Available at: http://www.rxabbvie.com/pdf/humira.pdf. Accessed February 26, 2019.
13. Hyrimoz (adalimumab) [product monograph]. Boucherville, Québec, Canada: Sandoz Canada Inc; September 2021.
14. Idacio (adalimumab) [product monograph]. Toronto, Ontario, Canada: Fresenius Kabi Canada Ltd; October 2020.
15. Kolasinski SL, Neogi T, Hochberg MC, etc. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee. Arthritis Care Res (Hoboken). 2020 Feb;72(2):149-162. doi: 10.1002/acr.24131. Epub 2020 Jan 6. Erratum in: Arthritis Care Res (Hoboken). 2021 May;73(5):764. PMID: 31908149.
16. Kornbluth A, Sachar DB. Ulcerative Colitis Practice Guidelines in Adults: American College of Gastroenterology, Practice Parameters Committee. Am J Gastroenterol. 2010; 105:501-523.

17. Lichtenstein GR, Loftus Jr. EV, Isaacs KI, Regueiro MD, Gerson LB, and Sands BE. ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2018; 113:481-517.
18. Magrey MN, Danve AS, Ermann J, Walsh JA. Recognizing Axial Spondyloarthritis: A Guide for Primary Care. Mayo Clin Proc. 2020 Nov;95(11):2499-2508. doi: 10.1016/j.mayocp.2020.02.007. Epub 2020 Jul 29. PMID: 32736944.
19. Menter A, Gottlieb A, Feldman SR, et al. Guidelines for the management of psoriasis and psoriatic arthritis. Section 1: Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol. 2008; 58(5):826-850.
20. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011; 65(1):137-174.
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22. Singh JA, Furst DE, Bharat A, et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. Arthritis Care Res. 2012; 64(5):625-639
23. Smolen JS, Landewé R, Breedveld FC, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2013 update. Ann Rheum Dis. 2014; 73:492-509.
24. Ward MM, Deodhar A, Aki EA, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2015. DOI 10.1002/ART.39298.
25. Yuflyma (adalimumab) [prescribing information]. Jersey City, NJ: Celltrion USA Inc; May 2023.
26. Yuflyma (adalimumab) [product monograph]. Toronto, Ontario, Canada: Celltrion Healthcare Canada Limited; December 2021.

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Prior Authorization Criteria for CYSTADANE® (betaine anhydrous for oral solution)

1. Patient has diagnosis of homocystinuria **AND**
2. Dosage and direction of use: 3 grams twice daily **AND**
3. Quantity requested does not exceed: 20 grams/day **AND**
4. Patient has one of the following types of homocystinuria confirmed by genetic testing:
    a. Cystathionine beta-synthase deficiency **OR**
    b. 5,10-methylenetetrahydrofolate reductase deficiency **OR**
    c. Cobalamin cofactor metabolism defect **AND**
5. Prescribed by or in consultation with a specialist such as a geneticist or metabolic disease specialist

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 12 months.
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided
- ✓ Approval duration for renewal: 12 months.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual review	No changes	2.2024

REFERENCE:

1. Cystadane (betaine powder). [Prescribing information]. Memphis, TN: AnovoRx Distribution, LLC. July 2014.

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Prior Authorization Criteria for CYSTAGON® (cysteamine bitartrate IR)

1. Patient has a diagnosis of nephropathic cystinosis **AND**
2. Dosage and Direction for Use: Confirm the dosage is within FDA recommended dosing or dose is supported by compendia or medical literature.
    a. Initial dose is 1/6 to 1/4 of maintenance dose; titrate slowly upward over 4 to 6 weeks
    b. Maintenance dose:
        - For age < 12 years old: 1.30 g/m^2/day given in four divided doses. Max dose 1.95gm/m^2/day
        - For age ≥ 12 years old: 2.0 g/day in four divided doses. Max dose 1.95gm/m^2/day **AND**
3. Quantity requested does not exceed: 1.95 g/m2 per day **AND**
4. Patient has one of the following:
    a. Increased leukocyte cystine concentration above the upper limit of the normal reference range for the reporting laboratory (normal concentration: < 0.2 nmol half cystine/mg protein) **OR**
    b. Cystinosin, lysosomal cystine transporter (CTNS) gene mutation **AND**
5. Patient will not be using cystagon and procysbi concurrently **AND**
6. Prescribed by a physician experienced in management of nephropathic cystinosis, such as an endocrinologist, nephrologist, or urologist.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Patient is responding positively to therapy as evidenced by improvement in the leukocyte cystine concentration
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA Criteria created based on CAB 3.12.2020	3.2020
Annual reviewed	No Change	3.2021
Annual reviewed	No Change	3.2022
Annual review	Updated dosing; removed eye exam from diagnostic requirement; added reference	4.2023
Updated	Created separate criteria from Procysbi	9.2023
Annual review	Updated criteria verbiage to include “Patient will not be using cystagon and procysbi concurrently”	4.2024

REFERENCE:

1. American Academy of Pediatrics Committee on Drugs. "Inactive" ingredients in pharmaceutical products: update (subject review). Pediatrics. 1997;99(2):268-278.[PubMed 9024461]
2. Belldina EB, Huang MY, Schneider JA, et al. Steady-state pharmacokinetics and pharmacodynamics of cysteamine bitartrate in paediatric nephropathic cystinosis patients. Br J Clin Pharmacol. 2003;56(5):520-525.[PubMed 14651726]
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4. Cystagon (cysteamine) [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals; January 2019.

5. Dohil R, Fidler M, Gangoiti JA, et al, "Twice-Daily Cysteamine Bitartrate Therapy for Children With Cystinosis," J Pediatr, 2010, 156(1):71-75.e1-3.[PubMed 19775699]
6. Emma F, Nesterova G, Langman C, et al. Nephropathic cystinosis: an international consensus document. Nephrol Dial Transplant. 2014;29 Suppl 4:87-94.[PubMed 25165189]
7. Gahl WA, Thoene JG, and Schneider JA, "Cystinosis," N Engl J Med, 2002, 347(2):111-21.[PubMed 12110740]
8. Langman CB, Greenbaum LA, Sarwal M, et al, "A Randomized Controlled Crossover Trial With Delayed-Release Cysteamine Bitartrate in Nephropathic Cystinosis: Effectiveness on White Blood Cell Cystine Levels and Comparison of Safety," Clin J Am Soc Nephrol, 2012, 7(7):1112-20.[PubMed 22554716]
9. Procysbi (cysteamine) [prescribing information]. Lake Forest, IL: Horizon Pharma USA; May 2019.
10. Shehab N, Lewis CL, Streetman DD, Donn SM. Exposure to the pharmaceutical excipients benzyl alcohol and propylene glycol among critically ill neonates. Pediatr Crit Care Med. 2009;10(2):256-259.[PubMed 19188870]
11. Zar T, Graeber C, Perazella MA. Recognition, treatment, and prevention of propylene glycol toxicity. Semin Dial. 2007;20(3):217-219.[PubMed 17555487]
12. Baumner, Soren, Weber, Lutz T. Nephropathic Cystinosis: Symptoms, Treatment,, and Perspectives of a Systemic Disease. Front Pediatr. March 2018.

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Prior Authorization Criteria for CYSTARAN™ (cysteamine hcl 0.44% ophthalmic solution)

1. Patient has diagnosis of cystinosis **AND**
2. Dosage and direction of use: One drop in each eye every hour while awake (1 bottle/week) **AND**
3. Quantity requested does not exceed: 4 bottles/28 days **AND**
4. Patient has documentation of corneal cysteine crystal deposits **AND**
5. Prescribed by or in consultation with an ophthalmologist.

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 1 year

RENEWALS

✓ Patient has been evaluated and has seen improvement
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created from CAB 9.24.2020	9.2020
Annual Review	No changes	9.2021
Annual Review	No changes	7.2022
Annual Review	No changes	7.2023
Updated	Created separate criteria for cysteamine drops	8.2023
Annual Review	No changes	8.2024

REFERENCE:

1. Cystaran (cysteamine) [prescribing information]. Gaithersburg, MD: Leadiant Biosciences; April 2020.

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Prior Authorization Criteria for CAYSTON® (aztreonam for inhalation)

1. Patient has diagnosis of cystic fibrosis **AND**
2. Patient is 7 years of age or older **AND**
3. Dosage and direction of use: 1 vial administered three times daily for 28 day course, followed by 28 day off period **AND**
4. Quantity requested does not exceed: 1 (28 day) kit/56 days **AND**
5. Patient has a positive culture of Pseudomonas aeruginosa in the airway **AND**
6. Patient has FEV between 25% to 75% predicted **AND**
7. Prescribed by or in consultation with a pulmonologist

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 12 months.

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided
- ✓ Approval duration for renewal: 12 months.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023

REFERENCE:

1. Cayston [package insert]. Foster City, CA: Gilead Sciences, Inc.; December 2021.

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Prior Authorization Criteria for KALYDECO™ (ivacaftor)

1. Patient has diagnosis of Cystic Fibrosis (CF) **AND**
2. Patient is 1 month or older **AND**
3. Dosage and direction of use:

Dosage of KALYDECO				
Age	**Body Weight**	**Dosage**	**Total Daily Dose**	**Administration**
1 month to less than 2 month	3 kg or greater	One 5.8 mg packet every 12 hours	11.6 mg/day	Mixed with one teaspoon (5 ml) of soft food or liquid and administered orally with fat containing food
2 months to less than 4 months	3 kg or greater	One 13.4 mg packet every 12 hours	25 mg/day	
4 months* to less than 6 months+	5 kg or greater	One 25 mg packet every 12 hours	50 mg/day	
6 months to less than 6 years	5 kg to less than 7 kg	One 25 mg packet every 12 hours	50 mg/day	
	7 kg to less than 14 kg	One 50 mg packet every 12 hours	100 mg/day	
	14 kg or greater	One 75 mg packet every 12 hours	150 mg/day	
6 years and older	-	One 150 mg tablet every 12 hours	300 mg/day	Taken orally with fat containing food

*KALYDECO is not recommended for use in children under 1 month of age.
+KALYDECO is not recommended for use in children aged 1 month to less than 6 months born at a gestational age less than 37 weeks has not been evaluated

4. Quantity requested does not exceed: 56 tablets/28 days (one ivacaftor 150 mg tablet every 12 hours) OR 56 packets/28 days **AND**
5. Patient has at least one of the following mutation in the CFTR gene that is responsive to ivacaftor (*See Full List in Appendix*): A1067T, A455E, D110E, D110H, D1152H, D1270N, D579G, E193K, E56K, E831X, F1052V, F1074L, F508del*, K1060T, L206W, P67L, R1070W, R117C, R347H, R352Q, R74W, S945L, S977F, 2789+5G -> A, 3272-26A->G, 3489+10kbC->T, 711+3A->G **AND**
6. Patient has CFTR gene mutation confirmed by a FDA-cleared CF mutation test followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use (provide documentation and indicate patient's mutation in the CFTR gene) **AND**
7. Patient **DOES NOT** have homozygous F508del mutation in the CFTR gene **AND**
8. Patient is not taking another CFTR potentiator (i.e., Orkambi, Symdeko, or Trikafta) **AND**
9. Prescribed by or in consultation with a specialist such as pulmonologist or a physician who specializes in the treatment of CF.

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 6 months

RENEWALS

✓ Documentation of positive response to therapy (e.g. stable or improvement of ppFEV1 from baseline, decrease in pulmonary exacerbations, pulmonary infections, or hospitalizations).
✓ Approval duration for renewal: 6 months to 1 year

APPENDIX

Table 1: List of CFTR Gene Mutations That Are Responsive to Kalydeco® (ivacaftor)

711+3A→G	F311del	I148T	R75Q	S589N
2789+5G→A	F311L	I175V	R117C	S737F
3272-26A→G	F508C	I807M	R117G	S945L
3849+10kbC→T	F508C; S1251N[†]	I1027T	R117H	S977F
A120T	F1052V	I1139V	R117L	S1159F
A234D	F1074L	K1060T	R117P	S1159P
A349V	G178E	L206W	R170H	S1251N
A455E	G178R	L320V	R347H	S1255P
A1067T	G194R	L967S	R347L	T338I
D110E	G314E	L997F	R352Q	T1053I
D110H	G551D	L1480P	R553Q	V232D
D192G	G551S	M152V	R668C	V562I
D579G	G576A	M952I	R792G	V754M
D924N	G970D	M952T	R933G	V1293G
D1152H	G1069R	P67L	R1070Q	W1282R
D1270N	G1244E	Q237E	R1070W	Y1014C
E56K	G1249R	Q237H	R1162L	Y1032C
E193K	G1349D	Q359R	R1283M	
E822K	H939R	Q1291R	S549N	
E831X	H1375P	R74W	S549R	

+Complex/compound mutations where a single allele of the CFTR gene has multiple mutations; these exist independent of the presence of mutations on the other allele.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA Criteria created based on CAB 11.4.19	12.2019
Update	PA criteria update	1.2020
Update	Update patient age indication/ usage with new dose	6.2021
Update	Updated denial comments	8.2021
Annual Review	Added appendix section with complete list of mutations covered by Kaledyco. Updated expanded indication to include patients 4 months or older. Separated Kaledyco from the CF group criteria.	8.2022
Annual Review	Updated criteria to include expanded indication for patients 1 month old and older; Updated dosage and denial message	8.2023
Annual Review	No criteria updates	2.2024

REFERENCE:

1. Kalydeco (ivacaftor) [prescribing information]. Boston, MA: Vertex Pharmaceuticals Inc; May 2023.
2. Accurso FJ, Rowe SM, Clancy JP, et al. Effect of VX-770 in persons with cystic fibrosis and the G551DCFTR mutation. N Engl J Med. Nov 18 2010;363(21):1991-2003.
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7. Kapnadak SG, Dimango E, Hadjiliadis D, Hempstead SE, Tallarico E, Pilewski JM, Faro A, Albright J, Benden C, Blair S, Dellon EP, Gochenour D, Michelson P, Moshiree B, Neuringer I, Riedy C, Schindler T, Singer LG, Young D, Vignola L, Zukosky J, Simon RH. Cystic Fibrosis Foundation consensus guidelines for the care of individuals with advanced cystic fibrosis lung disease. J Cyst Fibros. 2020 May;19(3):344-354. doi: 10.1016/j.jcf.2020.02.015. Epub 2020 Feb 27. PMID: 32115388.

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Prior Authorization Criteria for ORKAMBI® (lumacaftor/ivacaftor) tablets and oral granules

1. Patient has diagnosis of Cystic Fibrosis (CF) **AND**
2. Patient is 1 year of age or older **AND**
3. Dosage and direction of use:

Recommended Dosage in Patients Aged 1 Year and Older				
Age	**Weight**	**Dose**	**Total/Day**	**Administration**
1 year through 2 years	7 kg to < 9 kg	1 packet of lumacaftor 75 mg/ivacaftor 94 mg granules	2 packets/day	Mixed with one teaspoon (5 ml) of soft food or liquid and administered orally **every 12 hours** with fat containing food
	9 kg to < 14 kg	1 packet of lumacaftor 100 mg/ivacaftor 125 mg granules	2 packets/day	
	≥14 kg	1 packet of lumacaftor 150 mg/ivacaftor 188 mg granules	2 packets/day	
2 through 5 years	≤14 kg	1 packet of lumacaftor 100 mg/ivacaftor 125 mg granules	2 packets/day	
	≥14 kg	1 packet of lumacaftor 150 mg/ivacaftor 188 mg granules	2 packets/day	
6 through 11 years	--	2 tablets of lumacaftor 100 mg/ivacaftor 125 mg (lumacaftor 200 mg/ivacaftor 250 mg per dose)	4 tablets/day	Taken orally **every 12 hours** with fat containing food
12 years and older	--	2 tablets of lumacaftor 200 mg/ivacaftor 125 mg (lumacaftor 400 mg/ivacaftor 250 mg per dose)	4 tablets/day	

4. Quantity requested does not exceed: 112 tablets/28 days (two tablets of lumacaftor 200 mg/ivacaftor 125 mg every 12 hours) or 56 packets/28 days.
    a. Note: tablets come in 112-count tablet box containing a 4-week supply and packets come in 56-count carton **AND**
5. Patient has homozygous F508del mutation in the CFTR gene confirmed by an FDA-cleared CF mutation test (provide documentation and indicate patient's mutation in the CFTR gene). If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene **AND**
6. Patient is not taking another CFTR potentiator (i.e., Kalydeco, Symdeko, or Trikafta) **AND**
7. Prescribed by or in consultation with a specialist such as pulmonologist or a physician who specializes in the treatment of CF.

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 6 months

RENEWALS

✓ Documentation of positive response to therapy (e.g. stable or improvement of ppFEV1 from baseline, decrease in pulmonary exacerbations, pulmonary infections, or hospitalizations).

✓ Approval duration for renewal: 6 months to 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA Criteria created based on CAB 11.4.19	12.2019
Annual Review	Combined with other CF medications.	8.2020
Annual Review	Update patient age indication/ usage with new dose	8.2021
Annual Review	Annual Review: added quantity per day and max dose for tablets and oral granule packets; separated Orkambi from group CF criteria	8.2022
Update	Criteria update to include expanded indication for patients age 1 year of age and older; added dosing chart	10.2022
Annual Review	Removed documented weight requirement; Updated denial message and format.	8.2023
Annual Review	Updated verbiage to require verification of patient's genotype via FDA-cleared CF mutation test if genotype is unknown	2.2024

REFERENCE:

1. Orkambi (lumacaftor/ivacaftor) [prescribing information]. Boston, MA: Vertex Pharmaceuticals Incorporated; August 2023.
2. Orkambi ((lumacaftor/ivacaftor) [product monograph]. Toronto, Ontario, Canada: Vertex Pharmaceuticals (Canada) Incorporated; December 2018.
3. Trimble A, McKinzie C, Terrell M, Stringer E, Esther CR Jr. Measured fetal and neonatal exposure to lumacaftor and ivacaftor during pregnancy and while breastfeeding. *J Cyst Fibros.* 2018;17(6):779-782. doi: 10.1016/j.jcf.2018.05.009.
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Prior Authorization Criteria for PULMOZYME® (dornase alfa)

1. Patient has diagnosis of cystic fibrosis **AND**
2. Patient is 5 years of age or older **AND**
3. Dosage and direction of use: 2.5 mg single-use ampule inhaled once daily using a recommended nebulizer **AND**
4. Quantity requested does not exceed: 28 ampules/28 days **AND**
5. Medication is used in conjunction with standard therapies for the management of cystic fibrosis (CF) (e.g., antimicrobials, bronchodilators, mucolytics, chest physiotherapy) **AND**
6. Prescribed by or in consultation with a pulmonologist.

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 1 year

RENEWALS

✓ Documentation of positive clinical response to therapy has been proven
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	1.2021
Annual Review	No Change	1.2022
Annual Review	No Change	1.2023
Updated	Updated format and renamed document	8.2023
Annual Review	Updated criteria to include “medication is used in conjunction with standard therapies for the management of cystic fibrosis”.	1.2024

REFERENCE:

1. Pulmozyme (dornase alfa) [prescribing information]. South San Francisco, CA: Genentech; August 2020.
2. Pulmozyme (dornase alfa) [prescribing information]. South San Francisco, CA: Genentech Inc; July 2021.
3. Accurso FJ, Rowe SM, Clancy JP, et al. Effect of VX-770 in persons with cystic fibrosis and the G551DCFTR mutation. N Engl J Med. Nov 18 2010;363(21):1991-2003.
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6. Kapnadak SG, Dimango E, Hadjiliadis D, Hempstead SE, Tallarico E, Pilewski JM, Faro A, Albright J, Benden C, Blair S, Dellon EP, Gochenour D, Michelson P, Moshiree B, Neuringer I, Riedy C, Schindler T, Singer LG, Young D, Vignola L, Zukosky J, Simon RH. Cystic Fibrosis Foundation consensus guidelines for the care of individuals with advanced cystic fibrosis lung disease. J Cyst Fibros. 2020 May;19(3):344-354. doi: 10.1016/j.jcf.2020.02.015. Epub 2020 Feb 27. PMID: 32115388.

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Prior Authorization Criteria for SYMDEKO® (tezacaftor/ivacaftor)

1. Patient has diagnosis of Cystic fibrosis (CF) **AND**
2. Patient is 6 years of age or older **AND**
3. Dosage and direction of use:

Recommended Dosage of Symdeko				
Age	**Morning (one tablet)**	**Evening (one tablet)**	**Total/Day**	**Administration**
6 to < 12 years weighing <30 kg	one tablet (tezacaftor 50 mg/ivacaftor 75 mg)	one tablet (ivacaftor 75 mg)	2 tablets/day	Taken orally **every 12 hours** with fat containing food
6 to < 12 years weighing ≥ 30 kg	one tablet (tezacaftor 100 mg/ivacaftor 150 mg)	one tablet (ivacaftor 150 mg)	2 tablets/day	
≥ 12 years of age and older	one tablet (tezacaftor 100 mg/ivacaftor 150 mg)	one tablet (ivacaftor 150 mg)	2 tablets/day	

4. Quantity requested does not exceed: 54 tablets/28 days; Each box contains 4 weekly wallets. Each wallet contains 14 tablets. Max: 100 tezacaftor/300 mg ivacaftor per a day (1 tablet tezacaftor/ivacaftor and 1 tablet ivacaftor 150mg per day) **AND**
5. Patient has one of the following:
    a. Mutation in one of the CFTR gene that is responsive to Symdeko: A1067T, A455E, D110E, D110H, D1152H, D1270N, D579G, E193K, E56K, E831X, F1052V, F1074L, F508del*, K1060T, L206W, P67L, R1070W, R117C, R347H, R352Q, R74W, S945L, S977F, 2789+5G -> A, 3272-26A->G, 3489+10kbC->T, 711+3A->G (*See Full List in Appendix*) **OR**
    b. Patient has homozygous F508del mutation in the CFTR gene confirmed by a FDA-cleared CF mutation test followed by verification with bi-directional sequencing when recommended by the mutation test (provide documentation and indicate patient's mutation in the CFTR gene) **AND**
6. Patient is not taking another CFTR potentiator (i.e., Kalydeco®, Orkambri®, or Trikafta) **AND**
7. Prescribed by or in consultation with a specialist such as pulmonologist or gastroenterologist or other prescriber with certification or extensive experience treating cystic fibrosis.

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 6 months

RENEWALS

✓ Documentation of positive response to therapy (e.g. stable or improvement of ppFEV1 from baseline, decrease in pulmonary exacerbations, pulmonary infections, or hospitalizations).
✓ Approval duration for renewal: 6 months to 1 year

Appendix: List of CFTR Gene Mutations That Are Responsive to Symdeko® (tezacaftor/ivacaftor)

546insCTA	E92K	G576A	L346P	R117G	S589N
711+3A→G	E116K	G576A; R668C†	L967S	R117H	S737F
2789+5G→A	E193K	G622D	L997F	R117L	S912L
3272-26A→G	E403D	G970D	L1324P	R117P	S945L
3849+10kbC→T	E588V	G1069R	L1335P	R170H	S977F
A120T	E822K	G1244E	L1480P	R258G	S1159F
A234D	E831X	G1249R	M152V	R334L	S1159P
A349V	F191V	G1349D	M265R	R334Q	S1251N
A455E	F311del	H939R	M952I	R347H	S1255P
A554E	F311L	H1054D	M952T	R347L	T338I
A1006E	F508C	H1375P	P5L	R347P	T1036N
A1067T	F508C; S1251N†	I148T	P67L	R352Q	T1053I
D110E	F508del^	I175V	P205S	R352W	V201M
D110H	F575Y	I336K	Q98R	R553Q	V232D
D192G	F1016S	I601F	Q237E	R668C	V562I
D443Y	F1052V	I618T	Q237H	R751L	V754M
D443Y; G576A; R668C†	F1074L	I807M	Q359R	R792G	V1153E
D579G	F1099L	I980K	Q1291R	R933G	V1240G
D614G	G126D	I1027T	R31L	R1066H	V1293G
D836Y	G178E	I1139V	R74Q	R1070Q	W1282R
D924N	G178R	I1269N	R74W	R1070W	Y109N
D979V	G194R	I1366N	R74W; D1270N†	R1162L	Y161S
D1152H	G194V	K1060T	R74W; V201M†	R1283M	Y1014C
D1270N	G314E	L15P	R74W; V201M; D1270N†	R1283S	Y1032C
E56K	G551D	L206W	R75Q	S549N	
E60K	G551S	L320V	R117C	S549R	

^ A patient must have two copies of the F508del mutation or at least one copy of a responsive mutation present in the table.

† Complex/compound mutations where a single allele of the CFTR gene has multiple mutations; these exist independent of the presence of mutations on the other allele.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA Criteria created based on CAB 11.4.19	12.2019
Update	Combined with other CF medications.	6.2020
Update	Update patient age indication/ usage with new dose	8.2021
Annual Review	Updated Max quantity; added appendix section with complete list of mutations covered by Symdeko. Separated Symdeko from the CF group criteria.	8.2022
Annual Review	Updated format and dosing chart and denial message	8.2023

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1. Accurso FJ, Rowe SM, Clancy JP, et al. Effect of VX-770 in persons with cystic fibrosis and the G551DCFTR mutation. N Engl J Med. Nov 18 2010;363(21):1991-2003.
2. Boucher RC, Knowles MR, Yankaskas JR. Cystic Fibrosis. In: Mason RJ, Broaddus VC, Martin TR, et al., eds. Murray and Nadel's Textbook Of Respiratory Medicine. 5th ed. St. Louis, MO: W.B. Saunders; 2010:985-1022.
3. Institute for Safe Medication Practices. Safety briefs: strength confusion. ISMP Medication Safety Alert! Acute Care Edition. 2016;21(9):3,5.
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6. Symdeko Prescribing Information. Boston, MA: Vertex Pharmaceuticals Incorporated; June 2019. Available at: https://www.symdeko.com/. Accessed Nov 4, 2019.
7. Ren CL, Morgan RL, Oermann C, et al. Cystic Fibrosis Foundation pulmonary guidelines: Use of cystic fibrosis transmembrane conductance regulator modulator therapy in patients with cystic fibrosis. Ann Am Thorac Soc. 2018; 15(3): 271-280.
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11. Accurso FJ, Rowe SM, Clancy JP, et al. Effect of VX-770 in persons with cystic fibrosis and the G551DCFTR mutation. N Engl J Med. Nov 18 2010;363(21):1991-2003.
12. Boucher RC, Knowles MR, Yankaskas JR. Cystic Fibrosis. In: Mason RJ, Broaddus VC, Martin TR, et al., eds. Murray and Nadel's Textbook Of Respiratory Medicine. 5th ed. St. Louis, MO: W.B. Saunders; 2010:985-1022.
13. Institute for Safe Medication Practices. Safety briefs: strength confusion. ISMP Medication Safety Alert! Acute Care Edition. 2016;21(9):3,5
14. Wright CC, Vera YY. Cystic fibrosis. In: Dipiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey LM, eds. Pharmacotherapy: A Pathophysiologic Approach. 8th ed. New York, NY: McGraw Hill Medical; 2011:525-537.Yu H, Burton B, Huang CJ, et al. Ivacaftor potentiation of multiple CFTR channels with gating mutations. J Cyst Fibros. Jan 30 2012.

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Prior Authorization Criteria TOBRAMYCIN inhalation (Bethkis®, Kitabis Pak®, TOBI®, TOBI Podhaler®)

1. Patient has a diagnosis of cystic fibrosis **AND**
2. Patient is 6 years of age or older **AND**
3. Dosage and Direction for Use:
    a. Inhalation solution (Bethkis, Kitabis Pak, TOBI): one ampule (300 mg) twice a day (600 mg per day) by oral inhalation administered on a 28 days on/28 days off cycle
    b. Inhalation powder (TOBI Podhaler): 224 mg (four-28 mg capsules) twice a day administered via Podhaler device only on a 28 days on/28 days off cycle **AND**
4. Quantity requested does not exceed: 56/28 days (one single-dose ampoule (300 mg) twice daily) or 224 capsules/28 days **AND**
5. Confirm that patient has lung infection with positive culture demonstrating *Pseudomonas aeruginosa* infection **AND**
6. If request is for brand medication, patient must have had an adequate trial of generic tobramycin **AND**
7. Prescribed by or in consultation with a specialist such as pulmonologist, gastroenterologist, an infectious disease specialist, or other prescriber with certification or extensive experience treating cystic fibrosis.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 12 months

RENEWALS

✓ Provided documentation demonstrating positive response
✓ Approval duration for renewal: 12 months

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Updated criteria	11.2021
Annual Review	No changes	11.2022
Updated	Combined criteria for tobramycin inhalations: Bethkis, Kitabis Pak, TOBI, TOBI Podhaler.	8.2023
Annual Review	No criteria changes	2.2024

REFERENCE:

1. Bethkis Prescribing Information. Woodstock, IL: Catalent Pharm Solutions, LLC; December 2019.
2. Bethkis (tobramycin) [prescribing information]. Woodstock, IL: Chiesi USA Inc; February 2023.
3. Kitabis Pak (tobramycin inhalation solution) [prescribing information]. Woodstock, IL: Catalent Pharma Solutions LLC; April 2023.
4. Tobi (tobramycin) [prescribing information]. Morgantown, WV: Mylan Specialty LP; February 2023.
5. Tobi Podhaler (tobramycin) [prescribing information]. Morgantown, WV: Mylan Specialty LP; February 2023.
6. Treggiari MM, Retsch-Bogart G, Mayer-Hamblett N, et al; Early Pseudomonas Infection Control (EPIC) Investigators. Comparative efficacy and safety of 4 randomized regimens to treat early Pseudomonas aeruginosa infection in children with cystic fibrosis. Arch Pediatr Adolesc Med. 2011;165(9):847-856. doi:10.1001/archpediatrics.2011.136[PubMed 21893650]
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8. Uwaydah M, Bibi S, and Salman S, "Therapeutic Efficacy of Tobramycin - A Clinical and Laboratory Evaluation," J Antimicrob Chemother, 1975, 1(4):429-37.[PubMed 1107297]
9. Cystic Fibrosis Foundation: Clinical Care Guidelines. Available at: https://www.cff.org/medical-professionals/clinical-care-guidelines. Accessed July 25, 2023.
10. Kapnadak SG, Dimango E, Hadjiliadis D, et al. Cystic Fibrosis Foundation consensus guidelines for the care of individuals with advanced cystic fibrosis lung disease. J Cyst Fibros 2020 May;19(3):344-354. doi: 10.1016/j.jcf.2020.02.015.

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Prior Authorization Criteria for TRIKAFTA™ (elexacaftor, tezacaftor and ivacaftor)

1. Patient has diagnosis of Cystic fibrosis (CF) **AND**
2. Patient is 2 years of age or older **AND**
3. Dosage and direction of use:

Recommended Dosage for Adult and Pediatric Patients Aged 2 Years and Older for TRIKAFTA				
Age	**Weight**	**Morning Dose**	**Evening Dose**	**Total Dose/day**
2 to less than 6 years	Less than 14 kg	One packet containing elexacaftor 80 mg/tezacaftor 40 mg/ivacaftor 60 mg oral granules	One packet containing ivacaftor 59.5 mg oral granules	2 packets/day
	14 kg or more	One packet containing elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg oral granules	One packet containing ivacaftor 75 mg oral granules	2 packets/day
6 to less than 12 years	Less than 30 kg	Two tablets, each containing elexacaftor 50 mg/tezacaftor 25 mg/ivacaftor 37.5 mg	One tablet of ivacaftor 75 mg	3 tablets/day
	30 kg or more	Two tablets, each containing elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg	One tablet of ivacaftor 150 mg	3 tablets/day
12 years and older		Two tablets, each containing elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg	One tablet of ivacaftor 150 mg	3 tablets/day

4. Quantity requested does not exceed: 84 tablets/28 days. A blister pack contains 84-count tablets **AND**
5. Patient has one of the following:
    a. At least one mutation in the CFTR gene that is responsive to Trikafta (*See Full List in Appendix)* ***OR***
    b. Patient has at least one F508del mutation in the CFTR gene confirmed by an FDA-cleared CF mutation test (provide documentation and indicate patient's mutation in the CFTR gene). If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one F508del mutation or a mutation that is responsive based on in vitro data **AND**
6. Patient is not taking another CFTR potentiator (i.e., Kalydeco, Orkambi, or Symdeko) **AND**
7. Prescribed by or in consultation with a specialist such as pulmonologist or a physician who specializes in the treatment of CF.

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 6 months

RENEWALS

✓ Documentation of positive response to therapy (e.g. stable or improvement of ppFEV1 from baseline, decrease in pulmonary exacerbations, pulmonary infections, or hospitalizations).

✓ Approval duration for renewal: 6 months to 1 year

Appendix: List of CFTR Gene Mutations That Are Responsive to Trikafta® (elexacaftor/tezacaftor/ivacaftor)

3141del9	E822K	G1069R	L967S	R117L	S912L
546insCTA	F191V	G1244E	L997F	R117P	S945L
A46D	F311del	G1249R	L1077P	R170H	S977F
A120T	F311L	G1349D	L1324P	R258G	S1159F
A234D	F508C	H139R	L1335P	R334L	S1159P
A349V	F508C; S1251N†	H199Y	L1480P	R334Q	S1251N
A455E	F508del*	H939R	M152V	R347H	S1255P
A554E	F575Y	H1054D	M265R	R347L	T338I
A1006E	F1016S	H1085P	M952I	R347P	T1036N
A1067T	F1052V	H1085R	M952T	R352Q	T1053I
D110E	F1074L	H1375P	M1101K	R352W	V201M
D110H	F1099L	I148T	P5L	R553Q	V232D
D192G	G27R	I175V	P67L	R668C	V456A
D443Y	G85E	I336K	P205S	R751L	V456F
D443Y; G576A; R668C†	G126D	I502T	P574H	R792G	V562I
D579G	G178E	I601F	Q98R	R933G	V754M
D614G	G178R	I618T	Q237E	R1066H	V1153E
D836Y	G194R	I807M	Q237H	R1070Q	V1240G
D924N	G194V	I980K	Q359R	R1070W	V1293G
D979V	G314E	I1027T	Q1291R	R1162L	W361R
D1152H	G463V	I1139V	R31L	R1283M	W1098C
D1270N	G480C	I1269N	R74Q	R1283S	W1282R
E56K	G551D	I1366N	R74W	S13F	Y109N
E60K	G551S	K1060T	R74W; D1270N†	S341P	Y161D
E92K	G576A	L15P	R74W; V201M†	S364P	Y161S
E116K	G576A; R668C†	L165S	R74W; V201M; D1270N†	S492F	Y563N
E193K	G622D	L206W	R75Q	S549N	Y1014C
E403D	G628R	L320V	R117C	S549R	Y1032C
E474K	G970D	L346P	R117G	S589N	
E588V	G1061R	L453S	R117H	S737F	

*F508del is a responsive CFTR mutation based on both clinical and in vitro data

† Complex/compound mutations where a single allele of the CFTR gene has multiple mutations; these exist independent of the presence of mutations on the other allele

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA Criteria created based on CAB 11.4.19	12.2019
Update	Update patient age indication/ usage with new dose	6.2021
Annual Review	Added appendix section with complete list of mutations covered by Trikafta, updated administration and denial message for Trikafta	8.2022
Annual Review	Added expanded indication for patients 2 years of age and older; Updated format and denial message	8.2023
Annual Review	Updated verbiage to require verification of patient's genotype via FDA-cleared CF mutation test if genotype is unknown	2.2024

REFERENCE:

1. Trikafta (elexacaftor/tezacaftor/ivacaftor) [prescribing information]. Boston, MA: Vertex Pharmaceuticals Incorporated; October 2019.
2. Trimble A, McKinzie C, Terrell M, Stringer E, Esther CR Jr. Measured fetal and neonatal exposure to lumacaftor and ivacaftor during pregnancy and while breastfeeding. J Cyst Fibros. 2018;17(6):779-782. doi: 10.1016/j.jcf.2018.05.009.[PubMed 29866531]
3. Accurso FJ, Rowe SM, Clancy JP, et al. Effect of VX-770 in persons with cystic fibrosis and the G551DCFTR mutation. N Engl J Med. Nov 18 2010;363(21):1991-2003.
4. Boucher RC, Knowles MR, Yankaskas JR. Cystic Fibrosis. In: Mason RJ, Broaddus VC, Martin TR, et al., eds. Murray and Nadel's Textbook Of Respiratory Medicine. 5th ed. St. Louis, MO: W.B. Saunders; 2010:985-1022.
5. Institute for Safe Medication Practices. Safety briefs: strength confusion. ISMP Medication Safety Alert! Acute Care Edition. 2016;21(9):3,5.
6. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Cystic fibrosis pulmonary guidelines: Chronic medications for maintenance of lung health. Am J Respir Crit Care Med. 2013; 187(7): 680-689.

7. Ren CL, Morgan RL, Oermann C, et al. Cystic Fibrosis Foundation pulmonary guidelines: Use of cystic fibrosis transmembrane conductance regulator modulator therapy in patients with cystic fibrosis. Ann Am Thorac Soc. 2018; 15(3): 271-280.
8. Trikafta (elexacaftor/tezacaftor/ivacaftor) [prescribing information]. Boston, MA: Vertex Pharmaceuticals Incorporated; October 2019.
9. Trimble A, McKinzie C, Terrell M, Stringer E, Esther CR Jr. Measured fetal and neonatal exposure to lumacaftor and ivacaftor during pregnancy and while breastfeeding. J Cyst Fibros. 2018;17(6):779-782. doi: 10.1016/j.jcf.2018.05.009.
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Prior Authorization Criteria for DARAPRIM® (pyrimethamine)

1. Patient has diagnosis of toxoplasmosis **AND**
2. Dosage and direction of use:
    a. Adult: 50-75 mg daily for 1-3 weeks; then reduce dose to one-half and continue for 4-5 weeks
    b. Pediatric: 1 mg/kg/day for 2-4 days; then reduce dose to one-half and continue for approximately 1 month **AND**
3. Requested medication is being used in combination with a sulfonamide **AND**
4. Patient has had trial and failure, intolerance to, or contraindication to trimethoprim-sulfamethoxazole (TMP-SMX **AND**
5. Prescribed by or in consultation with an infectious disease specialist or physician who specializes in treatment of HIV

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 6 months.
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation of positive clinical response to therapy and continued need has been provided
- ✓ Approval duration for renewal: 12 months.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual review	Updated references	2.2024

REFERENCE:

1. Daraprim (pyrimethamine). [Prescsribing Information]. New York, NY: Vyera Pharmaceuticals. October 2023.

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Prior Authorization Criteria for DAURISMO™ (glasdegib)

1. Patient has a diagnosis of newly diagnosed acute myeloid leukemia (AML) **AND**
2. Patient meets one of the following criteria:
    1) 75 years of age or older OR
    2) Patient is 18 years or older and has comorbidities that preclude use of intensive induction chemotherapy
3. Dosage and direction of use: 100mg orally once daily **AND**
4. Quantity does not exceed: 30 tabs / 30 days **AND**
5. Confirm Daurismo is prescribed in combination with low-dose cytarabine **AND**
6. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
7. Prescribed by or in consultation with an oncologist or hematologist.

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on existed criteria	3.2019
Update	Update Format/Add Denial Message	3.2020
Annual Review	No Change	3.2021
Annual Review	No Change	3.2022
Annual Review	No change	3.2023
Annual Review	Updated indication to be newly diagnosed per package insert; updated format of age requirement; added requested medication follows appropriate sequence per NCCN guidelines; updated duration to 1 year	2.2024

REFERENCE:

1. Cortes JE, Douglas Smith B, Wang ES, et al. Glasdegib in combination with cytarabine and daunorubicin in patients with AML or high-risk MDS: Phase 2 study results. Am J Hematol. 2018;93(11):1301-1310.[PubMed 30074259]
2. Daurismo (glasdegib) [prescribing information]. New York, NY: Pfizer Labs; March 2020.
3. US Department of Health and Human Services; Centers for Disease Control and Prevention; National Institute for Occupational Safety and Health. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings 2016. http://www.cdc.gov/niosh/topics/antineoplastic/pdf/hazardous-drugs-list_2016-161.pdf. Updated September 2016. Accessed November 28, 2018.
4. Walterhouse DO, Yoon JW, Iannaccone PM. Developmental pathways: Sonic hedgehog-Patched-GLI. Environ Health Perspect. 1999;107(3):167-171.[PubMed 10064544]
5. National Comprehensive Cancer Network. Acute Myeloid Leukemia (Version 2.2022). https://www.nccn.org/professionals/physician_gls/pdf/aml_blocks.pdf. Accessed January 19, 2023.

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Prior Authorization Criteria for DEMSER® (metyrosine)

1. Patient has diagnosis of pheochromocytoma **AND**
2. Patient is 12 years of age or older **AND**
3. Dosage and direction of use: 250 mg four times daily **AND**
4. Quantity requested does not exceed: 4 gm/day **AND**
5. Patient has had an adequate trial and failure of an alpha blockade (terazosin, doxazosin, and prazosin, phenoxybenzamine) **AND**
6. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
7. Prescribed by or in consultation with an oncologist or endocrinologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated duration of approval to 1 year; added endocrinologist to prescriber type	3.2024

REFERENCE:

1. Demser (metyrosine). [Prescribing information]. Bridgewater, NJ: Bausch Health; July 2020.
2. NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (version 1.2023 – August 2, 2023). Available at: http://www.nccn.org/. Accessed on August 14, 2023.

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Prior Authorization Criteria for desmopressin acetate nasal spray

1. Patient has diagnosis of:
   - Hemophilia A with Factor VIII coagulant activity levels greater than 5% OR
   - Von Willebrand's disease (type I) **AND**
2. Patient is 11 months of age or older **AND**
3. Dosage and direction of use:
   - Patient weight <50 kg: 150 mcg (1 spray) in a single nostril **OR**
   - Patient weight ≥50 kg: 150 mcg spray once in each nostril (total dose of 300mcg) per day **AND**
4. Quantity requested does not exceed: 150 mcg spray once in each nostril (total dose of 300mcg) per day **AND**
5. Prescribed by or in consultation with a hematologist.

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 1 year

RENEWALS

✓ Documentation of positive clinical response to therapy has been proven
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	1.2021
Annual Review	No Changes	1.2022
Annual Review	No Changes	1.2023
Annual Review	Updated recommended dose. Stimate has been discontinued - updated criteria document name to desmopressin acetate nasal spray.	1.2024

REFERENCE:

1. Stimate (desmopressin acetate) nasal spray [prescribing information]. King of Prussia, PA: CSL Behring; June 2013.
2. Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. Haemophilia. Jan 2013; 19(1): e1-47.
3. Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF): Database of treatment guidelines. Available at https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-ScientificAdvisory-Council-MASAC/MASAC-Recommendations. Accessed November 29, 2017.

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Prior Authorization Criteria for Dextenza®
(dexamethasone ophthalmic insert)

FDA-APPROVED INDICATIONS

- For the treatment of ocular inflammation and pain following ophthalmic surgery.
- For the treatment of ocular itching associated with allergic conjunctivitis.

1. Patient has diagnosis of
    a. Ocular inflammation and pain following ophthalmic surgery **AND**
    b. Ocular itching associated with allergic conjunctivitis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: insert 0.4 mg Intracanalicular **AND**
4. Quantity requested does not exceed: 1 insert per treatment **AND**
5. Patent has had adequate trial of corticosteroid eye drops such as dexamethasone ophthalmic solution AND
6. *For allergic conjunctivitis:* patient has had an adequate trial of ophthalmic antihistamine (i.e., azelastine, olopatadine, ketotifen) and/or mast cell stabilizer (i.e., cromolyn) **AND**
7. Documentation provided with medical justification on why eye drops cannot be used **AND**
8. Prescribed or in consultation with an ophthalmologist.

APPROVALS

✓ Initial approval for 1 time only if criteria met

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2019
Update	Add Denial Message	8.2020
Annual Review	No Change	8.2021
Updated	Added expanded indication: ocular itching associated with allergic conjunctivitis; Added denial message	1.2022/7.2022
Annual Review	Updated format	8.2023
Annual Review	Updated references	1.2024

REFERENCE:

1. Dextenza (dexamethasone) [prescribing information]. Bedford, MA: Ocular Therapeutix Inc; June 2019.
2. Dexycu (dexamethasone) [prescribing information]. Watertown, MA: EyePoint Pharmaceuticals US Inc; December 2018.
3. Hodzic-Hadzibegovic D, Ba-Ali S, Valerius M, Lund-Andersen H. Quantification of fluid resorption from diabetic macular oedema with foveal serous detachment after dexamethasone intravitreal implant (Ozurdex®) in a pregnant diabetic. Acta Ophthalmol. 2017;95(3):324-325. doi: 10.1111/aos.13282.[PubMed 27778454]

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Prior Authorization Criteria for DIACOMIT® (stiripentol)

1. Patient has diagnosis of seizures associated with Dravet syndrome **AND**
2. Patient is 6 months of age or older **AND**
3. Dosage and direction of use: 50 mg/kg orally in 2 or 3 divided doses, up to 3g/day **AND**
4. Quantity requested does not exceed: 180 capsules or packets (500 mg capsules) /30 days (3g /day); please optimize quantity based on prescribed dosing schedule **AND**
5. Confirm patient is 7 kg or more **AND**
6. Patient is currently taking clobazam **AND**
7. Requested medication will not be used as monotherapy **AND**
8. Prescribed by or in consultation with a neurologist.

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 6 months.

RENEWALS

✓ If patient is demonstrating a positive response to therapy, a renewal will be granted for 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	5.2019
Update	Update Format / Add Denial Message	5.2020
Annual Review	No Change	5.2021
Annual Review	Update expanded indication to include patient's age and weight	7.2022
Annual Review	Updated format	7.2023
Annual Review	Reformatted requirement criteria	2.2024

REFERENCE:

1. Diacomit (stiripentol) [prescribing information]. Beauvais, France; Biocodex; July 2022.
2. Chiron C, Marchand MC, Tran A, et al. Stiripentol in severe myoclonic epilepsy in infancy: a randomised placebo-controlled syndrome-dedicated trial. STICLO study group. Lancet. 2000;356 (9242):1638-1642.
3. Fabio Nascimento, MD, Danielle Andrade, MD, MSC, FRCPC, Dravet Syndrome: Management and Prognosis. UpToDate: Apr 2019.
4. Wirrell, E, Laux L, Donner E, et all. Optimizing the Diagnosis and Management of Dravet Syndrome: Recommendations From a North American Consensus Panel. Pediatr Neurol 2017; 68: 18-34

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Prior Authorization Criteria for DIBENZYLINE® (phenoxybenzamine)

1. Patient has a diagnosis of sweating and hypertension associated with pheochromocytoma prior to pheochromocytoma resection/removal **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: Initial: 10 mg twice daily; dose should be increased every other day, usually to 20 to 40 mg 2 or 3 times a day, until an optimal dosage is obtained, as judged by blood pressure control **AND**
4. Quantity requested does not exceed: vary depending on prescribed dose **AND**
5. Patient has had an adequate trial and failure of an alpha-1 selective adrenergic receptor blocker (e.g. doxazosin, terazosin, or prazosin) **AND**
6. Blood pressure is being monitored regularly; **AND**
7. Prescribed by or in consultation with a specialist such as an endocrinologist

INITIAL APPROVALS

✓ Initial approval will be for a period of 1 year

RENEWALS

✓ Confirm patient has had a positive response to treatment
✓ Renewal approval: 6 months to 1 year.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2019
Update	Added example for alternatives; added Denial Message	6. 2020
Annual Review	No Change	6.2021
Annual Review	No Change	6.2022
Annual Review	Updated format	6.2023
Annual Review	Updated approval duration	5.2024

REFERENCE:

1. Dibenzyline (phenoxybenzamine) [prescribing information]. St. Michael, Barbados: Concordia Pharmaceuticals Inc; April 2020.
2. Hack HA. The perioperative management of children with phaeochromocytoma. Paediatr Anaesth. 2000.10(5):463-476.[PubMed 11012949]
3. Lenders JWM, Duh QY, Eisenhofer G, et al. Pheochromocytoma and paraganglioma: an Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2014;99(6):1915-1942.
4. Hack HA, Brown TC. Preoperative management of phaeochromocytoma--a paediatric perspective. Anaesth Intensive Care. 1999;27(1):112-113.[PubMed 10050231]
5. Kinney MA, Narr BJ, and Warner MA, "Perioperative Management of Pheochromocytoma," J Cardiothorac Vasc Anesth, 2002, 16(3):359-69.[PubMed 12073213]

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Prior Authorization Criteria for DOPTELET® (avatrombopag maleate)

FDA-Approved Indications

- Treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure
- Treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment

Diagnosis: Thrombocytopenia with chronic liver disease

1. Patient has diagnosis of thrombocytopenia with chronic liver disease **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use:
    a. Platelet count <40,000/µL: 60 mg (3 tablets) for 5 days
    b. Platelet count 40,000/µL-50,000/µL: 40 mg (2 tablets) for 5 days **AND**
4. Quantity requested does not exceed: 15 tablets/5 days **AND**
5. Patient is scheduled to undergo a procedure **AND**
6. Requested medication will be initiated 10-13 days prior to the procedure **AND**
7. Patient has a platelet count of <50,000/µL

Diagnosis: Chronic Immune thrombocytopenia

1. Patient has diagnosis of chronic immune thrombocytopenia **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 20 mg daily. Dose adjustments should be made based on platelet counts **AND**
4. Patient had insufficient response to previous treatment **AND**
5. Prescribed by or in consultation with a hematologist

INITIAL APPROVALS

- ✓ Chronic liver disease: Initial authorization will be granted for a period of 1 fill
- ✓ Chronic immune thrombocytopenia: Initial authorization will be granted for 6 months

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided
- ✓ Chronic immune thrombocytopenia: Initial authorization will be granted for 12 months

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	No changes	3.2024

REFERENCE:

1. Doptelet [Prescribing Information]. Durham, NC. AkaRx, Inc: July 2021.

Prior Authorization Criteria for DUPIXENT® (dupilumab)

FDA-APPROVED INDICATIONS

- Atopic dermatitis: Patients aged 6 months and older with moderate-to severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
- Moderate to Severe Asthma: Patients age 6 years and older of moderate to severe asthma with an eosinophilic phenotype or with oral corticosteroid dependent asthma
- Chronic Rhinosinusitis Nasal polyposis: Adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis.
- Eosinophilic Esophagitis: Patients age 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE).
- Prurigo Nodularis: Adult patients with prurigo nodularis (PN).

Diagnosis: for Atopic Dermatitis

1. Patient has diagnosis of moderate-to-severe Atopic Dermatitis **AND**
2. Patient is 6 months of age or older **AND**
3. Dosage and direction of use:
    a. Pediatric patients 6 months to 17 years old:

Age	Body Weight	Initial Loading Dose (LD)	Subsequent Dosage
6 months to 5 years old	5 to less than 15 kg	200 mg (one 200 mg injection) every 4 weeks	
	15 to less than 30 kg	300 mg (one 300 mg injection) every 4 weeks	
6 years – 17 years old	15 to less than 30 kg	600 mg (two-300 mg injections)	300 mg every 4 weeks
	30 to less than 60 kg	400 mg (two-200 mg injections)	200 mg every other week (Q2W)
	60 kg or more	600 mg (two-300 mg injections)	300 mg every other week (Q2W)

    b. Adult patients (18 years and older): an initial dose of 600 mg (two 300-mg injections), followed by 300 mg given every other week (Q2W) **AND**
4. Quantity requested does not exceed: Initial dose: 4 mL (two-300 mg injections)/ 14 days; Maintenance dose: 4 mL (2-300 mg injections)/28 days **AND**
5. Failure of all of the following, unless contraindicated or clinically significant adverse effects are experienced:
    a) Two formulary medium to very high potency topical corticosteroids, each used for at least 2 weeks **AND**
    b) One non-steroidal topical therapy: topical calcineurin inhibitor (e.g., tacrolimus 0.03% ointment, pimecrolimus 1% cream) or Eucrisa, each used for at least 4 weeks **AND**
    c) One or more of the following systemic agents: corticosteroids, azathioprine, methotrexate, mycophenolate mofetil, or cyclosporine **AND**
6. Prescribed by or in consultation with a dermatologist.

Diagnosis: for Asthma

1. Patient has diagnosis of Asthma and one of the following:
    a) Absolute blood eosinophil count ≥ 150 cells/mcL within the past 3 months
    b) Currently receiving maintenance treatment with systemic glucocorticoids and has received treatment for at least 4 weeks **AND**
2. Patient is 6 years of age or older **AND**
3. Dosage and direction of use:

Age	Body Weight	Initial and Subsequent Dosage
6 to 11 years of age	15 to less than 30 kg	100 mg every other week (Q2W) **OR** 300 mg every 4 weeks
	> 30 kg	200 mg every other week (Q2W)

Age	Initial Dose	Subsequent Dosage
12 years and older	400 mg (two-200 mg injections)	200 mg every other week (Q2W)
	OR	
	600 mg (two-300 mg injections)	300 mg every other week (Q2W)
12 years and older with oral corticosteroid-dependent asthma or with co-morbid moderate-to-severe atopic dermatitis or adults with comorbid chronic rhinosinusitis with nasal polyposis	600 mg (two-300 mg injections)	300 mg every other week (Q2W)

4. Quantity requested does not exceed: Initial dose: 4 mL (two-300 mg injections)/14 days; Maintenance dose: 4 mL (2 – 300 mg injections)/28 days **AND**
5. Patient has been adherent to the use of controller therapy (i.e., medium- to high-dose inhaled corticosteroid (e.g. Flovent, Pulmicort, Qvar) plus either a long-acting beta2 agonist (e.g. Serevent) or leukotriene modifier (e.g. Singulair, Accolate) **AND**
6. Patient has uncontrolled asthma despite adherent use of optimized doses of therapy requiring any of the following:
    a. Two or more exacerbations requiring oral/systemic corticosteroid treatment (or increase in dose if already on oral corticosteroid) in the past 12 months **OR**
    b. Urgent care visit or hospital admission in the past 12 months **OR**
    c. Use of maintenance oral corticosteroids for asthma control **AND**
7. Dupixent is prescribed concomitantly with an ICS plus either a LABA or LTRA **AND**
8. Dupixent will not be used concomitantly with other biologic product such as Cinqair, Fasenra, Nucala, Tezpsire, or Xolair **AND**
9. Prescribed by or in consultation with a/an allergist, immunologist, or pulmonologist.

Diagnosis: for Chronic Rhinosinusitis with Nasal Polyposis

1. Patient has diagnosis of Chronic Rhinosinusitis with Nasal Polyposis for at least 12 weeks **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 300 mg given every other week **AND**
4. Quantity requested does not exceed: 4 mL (2 injections)/ 28 days **AND**
5. Patient has two or more of the following symptoms for 12 weeks or more:
    a. Nasal blockage/congestion **OR**
    b. Nasal discharge **OR**
    c. Facial pain/pressure **OR**
    d. Reduction of smell **AND**
6. Patient had an inadequate treatment response, intolerance, or contraindication to a two- month trial of a saline nasal irrigation and TWO nasal corticosteroid sprays (i.e., mometasone, fluticasone, budesonide, or triamcinolone) **AND**
7. Patient has one of the following:
    a. An inadequate treatment response, intolerance, or contraindication to a 5 day or more treatment course of oral corticosteroids in the past 2 years **OR**
    b. Patient has had a prior surgery for nasal polyps **AND**
8. Patient is currently on and will continue current maintenance therapy with intranasal corticosteroids, unless contraindicated
9. Dupixent will not be used concomitantly with other biologic product such as Cinqair, Fasenra, Nucala, Tezpsire, or Xolair **AND**
10. Prescribed by or in consultation with an otolaryngologist, allergist, or immunologist

Diagnosis: for Eosinophilic Esophagitis

1. Patient has documented diagnosis of Eosinophilic Esophagitis **AND**
2. Patient is 1 year of age or older AND weigh at least 15 kg **AND**
3. Dosage and direction of use:
    a. 15 to < 30 kg: 200 mg every other week (Q2W) **OR**

   b. 30 to < 40 kg: 300 mg every other week (Q2W) **OR**
   c. ≥ 40 kg: 300 mg given every week **AND**
4. Quantity requested does not exceed: 8 mL (four – 300 mg injections)/28 days **AND**
5. Patient has ≥15 intraepithelial eosinophils per high-power field (eos/hpf) following a treatment course of a PPI **AND**
6. Patient experienced at least two or more episodes of dysphagia per week (i.e., pain while swallowing, drooling, sensation of food getting stuck in the throat or chest) **AND**
7. Patient has inadequate response (8-week trial) or intolerance/contraindication to high-dose PPI therapy or swallowed respiratory corticosteroids **AND**
8. Prescribed by or in consultation with allergist, immunologist, or otolaryngologist.

Diagnosis: Prurigo Nodularis

1. Patient has documented diagnosis of Prurigo Nodularis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: an initial dose of 600 mg (two - 300 mg injections), followed by 300 mg given every other week (Q2W) **AND**
4. Quantity requested does not exceed: : maintenance dose of 4 mL (2 injections)/ 28 days **AND**
5. Patient has severe or very severe itch (WI-NRS score ≥7) reported within the past week **AND**
6. Patient has presence of at least 20 PN lesions in total on both legs and/or both arms and/or trunk **AND**
7. Patient has inadequate response or intolerance/contraindication to at least one medium- to super high-potency topical corticosteroid (TCS) **AND**
8. Prescribed by or in consultation with an allergist, immunologist, or dermatologist.

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 12 months.

RENEWALS

✓ Atopic Dermatitis - Member is responding positively to therapy (e.g., reduction in itching/scratching); if request is for a dose increase, new dose does not exceed 300 mg given every other week.
   - Approval duration: 12 months.

✓ Asthma - Demonstrated adherence to asthma controller therapy that includes an ICS plus either a LABA or LTRA, if request is for a dose increase, new dose does not exceed 300 mg every other week.
   - Approval duration: 12 months.

✓ Chronic Rhinosinusitis with Nasal Polyposis- Member is responding positively to therapy (e.g., improve in sino-nasal symptoms, decrease utilization of oral corticosteroids, patient has been compliant with Dupixent treatment); if request is for a dose increase, new dose does not exceed 300 mg given every other week.
   - Approval duration: 12 months.

✓ Eosinophilic Esophagitis - Member is responding positively to therapy, if request is for a dose increase, new dose does not exceed 300 mg every week.
   - Approval duration: 12 months.

✓ Prurigo Nodularis - Member is responding positively to therapy, if request is for a dose increase, new dose does not exceed 300 mg every other week.
   - Approval duration: 12 months

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	11.2017
Updated	Created criteria for asthma indication; updated age for atopic dermatitis	11.2018
Updated	Created criteria for chronic rhinosinuis with nasal polysis	8.2019
Updated	Update age for atopic dermatitis to ≥ 6 years per new expanded indication; Add Denial Message	6.2020
Reviewed	No Change	6.2021
Reviewed	Annual Review: update age to include children 6 to 11 years of age for severe Asthma.	6.2022
Updated	Updated expanded indication/ age and dosage for atopic dermatitis for 6 months and older; Added a new diagnosis requirement to the criteria sections: Eosinophilic Esophagitis	7.2022
Updated	Updated criteria to include new expanded indication of Prurigo Nodularis	10.2022
Annual Review	Updated references Asthma: updated severe asthma dx requirements, added Tezspire to excluded concomitant meds; added requirement to continue maintenance treatment CRSwNP: Added diagnostic criteria; added t/f of 2 nasal steroids; separated t/f criteria; updated prescriber requirements; added requirement for maintenance therapy; added exclusion for concomitant meds EE: Updated prescriber specialties to allergist, immunologist, or otolarygnologist PN: Updated prescriber specialties to allergist, immunologist, or dermatologist; updated quantity exceed limit to 4ml/28 days	6.2023
Updated	Updated criteria to include expanded indication for Eosinophilic Esophagitis to now include patients 1 year of age and older weighing at least 15 kg. Updated denial message and format.	2.2024

REFERENCE:

1. Dupixent (dupilumab) [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals; July 2023.
2. Isaksson M, Jansson L. Contact allergy to Tween 80 in an inhalation suspension. Contact Dermatitis. 2002;47(5):312-313.[PubMed 12534540]
3. Jorge E, Clark J. Dupilumab for off-label treatment of moderate to severe childhood atopic dermatitis. Cutis. 2018;102(3):201-204.[PubMed 30372706]
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5. Bredenoord AJ, et al. Disease burden and unmet need in eosinophilic esophagitis. Am J Gastroenterol. Published online April 13, 2022. doi:10.14309/ajg.0000000000001777.
6. Dellon ES, et al. Clinical and histological improvements with weekly dupilumab treatment in adult and adolescent patients with eosinophilic esophagitis at Week 24: weekly and every 2 weeks' results from Part B of the 3-Part LIBERTY EoE TREET study. Paper presented at: Digestive Disease Week 2022 Annual Meeting; May 24, 2022; San Diego, CA. Presentation number 867a.
7. Johnston DT. Examining unmet needs in the management of eosinophilic esophagitis. Am J Manag Care. 2021;27:S311- S318. doi:10.37765/ajmc.2021.88756.
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9. Huang AH, et al. Real-world prevalence of prurigo nodularis and burden of associated diseases. J Invest Dermatol. 2020;140(2):480-483.e4. doi:10.1016/j.jid.2019.07.697
10. Ständer S, et al. IFSI-guideline on chronic prurigo including prurigo nodularis. Itch. 2020;5(4):e42. doi:10.1097/itx.0000000000000042
11. Ständer S, et al. Prevalence of prurigo nodularis in the United States of America: a retrospective database analysis. JAAD Int. 2020;2:28-30. doi:10.1016/j.jdin.2020.10.009
12. Satoh T, Yokozeki H, Murota H. 2020 guidelines for the diagnosis and treatment of prurigo. J Dermatol. 2021 Sep;48(9):e414-e431. doi: 10.1111/1346-8138.16067. Epub 2021 Jul 27. PMID: 34314056.
13. Global Initiative for Asthma: Global strategy for asthma management and prevention (2023 update). Available at: https://ginasthma.org/wp-content/uploads/2023/05/GINA-2023-Full-Report-2023-WMS.pdf/. Accessed May 24, 2023.

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Prior Authorization Criteria for EMCYT (estramustine phosphate sodium)

FDA-Approved Indications

- Palliative treatment of patients with metastatic and/or progressive carcinoma of the prostate.

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated duration of approval; added FDA approved dx and age	5.2024

REFERENCE:

1. Emcyt (estramustine phosphate sodium). [Prescribing Information]. New York, NY: Pfizer Laboratories. May 2023.

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Prior Authorization Criteria for EMFLAZA® (deflazacort)

1. Patient has a diagnosis of Duchenne Muscular Dystrophy (DMD) confirmed by genetic testing demonstrating a mutation in the DMD gene or muscle biopsy demonstrating lack of muscle dystrophin **AND**
2. Patient is 2 years of age and older **AND**
3. Dosage and Direction for Use: 0.9 mg/kg taken orally once daily **AND**
4. Quantity requested does not exceed: Dosed by weight, please optimize quantity based on prescribed dosing scheduling **AND**
5. Patient has had trial and failure of a generic corticosteroid such as prednisone **AND**
6. Prescribed by or in consultation with a specialist such as a neurologist with expertise in the treatment of DMD.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Approval duration for renewal: 1 year
✓ Patient has a positive response to therapy (documentation provided)

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	5.2024

REFERENCE:

1. Emflaza (deflazacort) [prescribing information]. South Plainfield, NJ: PTC Therapeutics Inc; June 2021.

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Prior Authorization Criteria for EMPAVELI™ (pegcetacoplan)

1. Patient has a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: 1,080 mg by subcutaneous infusion twice weekly via a commercially available pump **AND**
4. Quantity requested does not exceed: 1,080 mg by subcutaneous infusion twice weekly **AND**
5. Patient has laboratory documentation of a detectable GPI-deficient hematopoietic clones via Flow Cytometry to confirm diagnosis of PNH **AND**
6. Patient has been vaccinated against encapsulated bacteria, including Streptococcus pneumoniae, Nesseria meningitidis, and Haemophilus influenzae type B (at least 2 weeks prior to treatment, if not previously vaccinated) when clinically appropriate **AND**
7. Patient has signs and symptoms attributed to PNH (e.g., abdominal pain, anemia, dyspnea, extreme fatigue, smooth muscle dystonia, unexplained/unusual thrombosis, hemolysis/hemoglobinuria, kidney disease, pulmonary hypertension) **AND**
8. Empaveli is not prescribed concurrently with another FDA-approved product for PNH (e.g., Soliris, Ultomiris), unless the member is in a 4-week period of cross-titration between Soliris and Empaveli; the prescriber attests that these medications will be discontinued within 4 weeks after starting Empaveli **AND**
9. Prescribed by or in consultation with a specialist such as a hematologist or oncologist.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 6 months

RENEWALS

✓ Patient has positive response to therapy (e.g., decrease in transfusions, increase in hemoglobin levels, normalization in LDH levels)
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 6.3.2021	6.2021
Annual Review	Updated format	6.2022
Annual Review	Updated criteria to include: patient has PNH confirmed by flow cytometry showing the absence of glycosylphosphatidylinositol-anchored proteins on at least two cell lineages; updated vaccination verbiage to include patient is vaccinated against encapsulated bacteria, including Streptococcus pneumoniae, Nesseria meningitidis, and Haemophilus influenzae type B; Added Empaveli is not prescribed concurrently with other medications for PNH; updated denial message.	6.2023
Annual Review	Updated approval duration to 6 months to standardize drug class; Updated diagnosis wording	6.2024

REFERENCE:

1. Empaveli (pegcetacoplan) [prescribing information]. Waltham, MA: Apellis Pharmaceuticals Inc; February 2024.
2. Hillmen P, Szer J, Weitz I, et al. Pegcetacoplan versus eculizumab in paroxysmal nocturnal hemoglobinuria. N Engl J Med. 2021;384(11):1028-1037. doi:10.1056/NEJMoa2029073[PubMed 33730455]
3. Hill A, et al. The incidence and prevalence of paroxysmal nocturnal hemogloninuria (PNH) and survival of patients in Yorkshire. Blood. 2006; 108 (11):985. doi:10.1182/blood.V108.11.985.985.
4. Peffault de Latour R, et al. Forty-Eight Week Efficacy and Safety of Pegcetacoplan in Adult Patients with Paroxysmal Nocturnal Hemoglobinuria and Suboptimal Response to Prior Eculizumab Treatment. Abstract S174. EHA 2021.
5. Parker CJ. Update on the diagnosis and management of paroxysmal nocturnal hemogloinuria. Hematology Am Soc Hematol Edu Program. 2016;2016(1):208-216.

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Prior Authorization Criteria for EMVERM (mebendazole)

1. Patient has diagnosis of one of the following infections:
   a. Ancylostoma duodenale (hookworm) **OR**
   b. Ascaris lumbricoides (roundworm) **OR**
   c. Enterobius vermicularis (pinworm) **OR**
   d. Necator americanus (hookworm) **OR**
   e. Trichuris trichiura (whipworm) **AND**
2. Patient is 2 years of age or older **AND**
3. Dosage and direction of use:
   a. Pinworm: 1 tablet once
   b. Hookworm/Roundworm/Whipworm: 1 tablet twice daily for 3 days **AND**
4. Quantity requested does not exceed:
   a. Pinworm: 1 tablet
   b. Hookworm/Roundworm/Whipworm: 6 tablets

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of one fill.

RENEWALS

✓ Documentation of need for continued therapy due to patient not being cured
✓ Approval duration for renewal: 1 fill

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Annual review	No changes	3.2024

REFERENCE:

1. Emverm [package insert]. Horsham, PA: Amedra Pharmaceuticals LLC; August 2021.

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Prior Authorization Criteria for ENBREL® (etanercept)

FDA-APPROVED INDICATIONS

- Rheumatoid arthritis (RA): Adult patients with moderately to severely active rheumatoid arthritis
- Juvenile idiopathic arthritis (JIA): Patients age 2 years or older with moderately to severely active polyarticular juvenile idiopathic arthritis
- Psoriatic arthritis (PsA):
    - Adult patients with psoriatic arthritis
    - Pediatric patients 2 years and older with active juvenile psoriatic arthritis
- Ankylosing spondylitis (AS): Adult patients with active ankylosing spondylitis
- Plaque psoriasis (PP): Patients 4 years or older with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy

Diagnosis: for Rheumatoid Arthritis (RA)

1. Patient has diagnosis of moderate to severe rheumatoid arthritis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 50 mg once weekly **AND**
4. Quantity requested does not exceed: 4 pens (50mg per pen)/28 days **AND**
5. Patient has had an inadequate response or has contraindications to at least one non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide) **AND**
6. Patient is not receiving Enbrel in combination with other biologic DMARDs **AND**
7. Prescribed by or in consultation with a rheumatologist

Diagnosis: for Polyarticular Juvenile Idiopathic Arthritis (JIA)

1. Patient has diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis **AND**
2. Patient is 2 years of age or older **AND**
3. Dosage and direction of use: maximum of 50 mg per week (may vary due to weight)
4. Quantity requested does not exceed: 4 pens/28 days
5. Patient's weight is provided **AND**
6. Patient has had an inadequate response or has contraindications to at least one non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide) **AND**
7. Patient is not receiving Enbrel in combination with other biologic DMARDs **AND**
8. Prescribed by or in consultation with a rheumatologist

Diagnosis: for Psoriatic Arthritis (PsA)

1. Patient has diagnosis of psoriatic arthritis **AND**
2. Patient is 2 years of age or older **AND**
3. Dosage and direction of use: maximum of 50 mg per week (may vary due to weight) **AND**
4. Quantity requested does not exceed: 4 pens (50mg per pen)/28 days **AND**
5. Patient has had an inadequate response or has contraindications to at least one non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide) **AND**
6. Patient is not receiving requested medication in combination with other biologic DMARDs **AND**
7. Prescribed by or in consultation with a rheumatologist

Diagnosis: for Ankylosing Spondylitis (AS)

1. Patient has diagnosis of ankylosing spondylitis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 50 mg once weekly **AND**
4. Quantity requested does not exceed: 4 pens (50mg per pen)/28 days **AND**

5. Patient has had trial and failure of TWO scheduled/maintenance NSAIDs, each used for a duration of at least four weeks **AND**
6. Patient is not receiving Enbrel in combination with other biologic DMARDs **AND**
7. Prescribed by or in consultation with a rheumatologist

Diagnosis: for Plaque Psoriasis (PP)

1. Patient has diagnosis of moderate to severe chronic plaque psoriasis **AND**
2. PP is affecting more than 3% of body surface area (BSA) or affecting crucial body areas (e.g., hands, feet, face, or genitals) **AND**
3. Patient is 4 years of age or older **AND**
4. Dosage and direction of use:
    a. ≥18 years of age: initial dosing of 50 mg twice weekly for 3 months, followed by 50 mg once weekly
    b. <18 years of age: maximum of 50 mg per week (may vary due to weight) **AND**
5. Quantity requested does not exceed: Initial: 8 pens (50mg per pen)/28 days for 3 months; maintenance: 4 pens/28 days
6. Patient has had an adequate trial and failure of UV or systemic therapy (i.e., methotrexate, acitretin, cyclosporine) **AND**
7. Patient has had an adequate trial and failure to topical therapy (i.e., corticosteroids, calcipotriene, calcitriol, tazarotene, tacrolimus) **AND**
8. Patient is not receiving Enbrel in combination with other biologic **AND**
9. Prescribed by or in consultation with a dermatologist

INITIAL APPROVALS

- ✓ Prescriber attestation that labs/notes indicate patient has the disease or requires the medication
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided **AND**
- ✓ Patient is not receiving medication in combination with other biologic DMARDs **AND**
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Reviewed	Reviewed	10.2017
Reviewed	Reviewed	10.2018
Revised	Updated criteria for plaque psoriasis, formatted to new template	8.2019
Updated	Updated criteria for AS/PsA	10.2019
Updated	Added default denial message	12.2019
Reviewed	Reviewed under Jan 2020 CAB meeting, no change.	1.2020
Updated	Updated criteria for PP (updated age cutoff and no longer require Humira); Updated criteria for JIA, removed NSAIDs to ensure patient t/f non-biologic DMARDs	12.2020
Annual Review	Annual Review for PsA and AS: updated t/f criteria to include: non-steroidal anti-inflammatory drugs (NSAIDs) or non-biologic DMARDs (i.e., methotrexate or leflunomide). Updated denial message	2.2022
Updated	Removed TB test exclusion criteria; Separated out denial message by indication; Updated references; removed PDE4 exclusion based on package insert RA/PJIA: Updated t/f wording for consistency PsA: Separated criteria; Removed t/f of NSAID option per guidelines AS: Separate critera; Changed t/f requirements to trial of two NSAIDs per guidelines Plaque psoriasis: Updated BSA to 3% per guidelines; separated out t/f criteria	6.2023

Updated	Updated history section and removed “completed by” section	8.2023
Annual Review	Updated dosing for psoriatic arthritis and plaque psoriasis; updated age to 2 years and older for psoriatic arthritis	6.2024

REFERENCE:

1. Enbrel Prescribing Information. Thousand Oaks, CA: Immunex Corporation: December 2023. Available at: http://pi.amgen.com/~/media/amgen/repositorysites/pi-amgencom/enbrel/enbrel_pi.ashx. Accessed February 27, 2018.
2. Ward MM, Deodhar, A, Gensler, LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis & Rheumatology. 2019; 71(10): 1599-1613.
3. Singh, JA, Guyatt, G, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis & Rheumatology. 2019; 71(1): 5-32.
4. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol 2008; 58(5):826-50.
5. Menter A, Strober BE, Kaplan DH, etc. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019 Apr;80(4):1029-1072. doi: 10.1016/j.jaad.2018.11.057. Epub 2019 Feb 13. PMID: 30772098.
6. Gossec L, et al; European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update, Ann Rheum Dis 2016;75:499-510.
7. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res (Hoboken). 2021 Jul;73(7):924-939. doi: 10.1002/acr.24596. Epub 2021 Jun 8. PMID: 34101387; PMCID: PMC9273041.
8. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Recommendations for Nonpharmacologic Therapies, Medication Monitoring, Immunizations, and Imaging. Arthritis Care Res (Hoboken). 2022 Apr;74(4):505-520. doi: 10.1002/acr.24839. Epub 2022 Mar 1. PMID: 35233989; PMCID: PMC10231687.
9. Coates, L.C., Soriano, E.R., Corp, N. et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. Nat Rev Rheumatol 18, 465–479 (2022). https://doi.org/10.1038/s41584-022-00798-0

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Prior Authorization Criteria for ENDARI ™ (L-glutamine oral powder)

1. Patient has diagnosis of sickle cell disease **AND**
2. Patient is 5 years of age or older **AND**
3. Dosage and Direction for Use: 5 grams to 15 grams orally, twice daily based on body weight:
    a. **Weight <30 kg:** 10 grams (2 packets/day)
    b. **Weight 30 to 65 kg**: 20 grams/day (4 packets/day)
    c. **Weight > 65 kg:** 30 grams/day (6 packets/day) **AND**
4. Quantity requested does not exceed: 5 grams to 15 grams twice daily based on weight per FDA-approved recommendation:
    a. **Weight <30 kg:** Max 10 grams (2 packets/day)
    b. **Weight 30 to 65 kg**: Max 20 grams/day (4 packets/day)
    c. **Weight > 65 kg:** Max 30 grams/day (6 packets/day) **AND**
5. Patient has an adequate trial of hydroxyurea **AND**
6. Prescribing provider is a specialist such as a hematologist.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Patient has experienced a positive response since initiating therapy such as a reduction in number of acute complications (i.e., blood transfusions, sickle cell crisis, hospitalizations).

✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Updated Format and Criteria	4.2020
Annual Review	No Changes	4.2021
Annual Review	No Changes	4.2022
Annual Review	Update Reference	4.2023
Annual Review	Updated initial approval duration	4.2024

REFERENCE:

1. Endari (glutamine) [prescribing information]. Torrance, CA: Emmaus Medical, Inc; October 2020.
2. Institute of Medicine (IOM). Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients). Washington, DC: National Academies Press; 2005.
3. Niihara Y, Miller ST, Kanter J, et al; Investigators of the Phase 3 Trial of l-Glutamine in Sickle Cell Disease. A phase 3 trial of l-glutamine in sickle cell disease. N Engl J Med. 2018;379(3):226-235. doi: 10.1056/NEJMoa1715971.[PubMed 30021096]
4. Yawn BP, Buchanan GR, Afenyi-Annan AN, et al. Management of sickle cell disease: summary of the 2014 evidence-based report by expert panel members. JAMA 2014;312(10):1033-48.
5. U.S. Department of Health and Human Services, National Institutes of Health, National Heart, Lung, and Blood Institute. The Management of Sickle Cell Disease (NIH Publication No. 02-2117). (2002). Retrieved from https://www.nhlbi.nih.gov/files/docs/guidelines/sc_mngt.pdf.
6. Brandow A, Carroll C, Creary S, et al. American Society of Hematology 2020 guidelines for sickle cell disease: management of acute and chronic pain. Blood Advances. 2020;4(12):2656-2701.

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Prior Authorization Criteria for ENSPRYNG® (satralizumab-mwge)

1. Patient has diagnosis of neuromyelitis optica spectrum disorder (NMOSD) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: initial loading dose of 120 mg by subcutaneous injection for the first three administrations at weeks 0, 2 and 4 followed by a maintenance dose of 120 mg every 4 weeks **AND**
4. Quantity requested does not exceed: 120 mg for the first three administrations (three single-dose prefilled syringes)/28 days for initial loading dose then 120mg (one single-dose prefilled syringe)/28 days **AND**
5. Patient is seropositive for aquaporin-4 (AQP4) IgG antibodies **AND**
6. Patient meets **one** of the following criteria:
    a. History of at least one relapse requiring rescue therapy during the previous 12 months **OR**
    b. History of two relapses requiring rescue therapy during the previous 24 months **AND**
7. Patient has had an adequate trial of rituximab **AND**
8. Patient is not taking Enspryng concurrently with rituximab, Soliris, or Uplizna **AND**
9. Prescribed by or in consultation with a neurologist.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Documentation of positive clinical response to therapy has been provided

✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created from CAB 9.10.2020	9.2020
Annual Review	Added additional clinical rules, and updated default message	11.2021
Annual Review	No changes	11.2022
Annual Review	Updated reference; added requirement of history of relapse requiring rescue therapy	10.2023
Annual Review	Removed requirement to verify Hep B and TB status; Removed azathioprine or mycophenolate from t/f treatment option	6.2024

REFERENCE:

1. Borisow N, Hellwig K, Paul F. Neuromyelitis optica spectrum disorders and pregnancy: relapse-preventive measures and personalized treatment strategies. EPMA J. 2018;9(3):249-256. doi:10.1007/s13167-018-0143-9
2. Chang VTW, Chang HM. Review: recent advances in the understanding of the pathophysiology of neuromyelitis optica spectrum disorder. Neuropathol Appl Neurobiol. 2020;46(3):199-218. doi:10.1111/nan.12574[PubMed 31353503]
3. Enspryng (satralizumab) [prescribing information]. South San Francisco, CA: Genentech Inc;. March 2022.
4. Zhu W, Zhang Y, Wang Z, Fu Y, Yan Y. Monoclonal antibody-based treatments for neuromyelitis optica spectrum disorders: from bench to bedside. Neurosci Bull. 2020;10.1007/s12264-020-00525-3. doi:10.1007/s12264-020-00525-3[PubMed 32533450]

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Prior Authorization Criteria for ENTEREG (alvimopan)

1. Patient has had a partial large or small bowel resection surgery with primary anastomosis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 12 mg orally 30 minutes to 5 hours prior to surgery, followed by 12 mg twice daily beginning day after surgery for up to 7 days or until hospital discharge **AND**
4. Quantity requested does not exceed: 15 capsules/8 days *May not exceed 15 doses total* **AND**
5. Requested medication will be used in the hospital **AND**
6. Patient has not taken more than 7 consecutive days of therapeutic doses of opioids immediately prior to receiving requested medication **AND**
7. Prescribed by or in consultation with a specialist

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 8 days (max of 15 capsules)
- ✓ Brand name may be subject to formulary exclusions

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	12.2023

REFERENCE:

1. Entereg (alvimopan). [Prescribing Information]. Rahway, NJ: Merck & Co. May 2022.

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Prior Authorization Criteria for EPIDIOLEX® (cannabidiol)

1. Patient has diagnosis of Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), or tuberous sclerosis complex **AND**
2. Patient is 1 year of age and older **AND**
3. Dosage and Direction for Use:
    a. Seizures Associated with Lennox-Gastaut Syndrome or Dravet Syndrome: 2.5 mg/kg by mouth twice daily (5 mg/kg/day) as the initial starting dose. After one week, the dosage can be increased to a maintenance dosage of 5 mg/kg twice daily (10 mg/kg/day) up to a maximum maintenance dosage of 10 mg/kg twice daily (20 mg/kg/day) based on clinical response and tolerability.
    b. Seizures Associated with Tuberous Sclerosis Complex: 2.5 mg/kg by mouth twice daily (5 mg/kg/day) for the starting dosage. Increase the dose weekly by 2.5 mg/kg twice daily (5 mg/kg/day), as tolerated, to a recommended maintenance dosage of 12.5 mg/kg twice daily (25 mg/kg/day) **AND**
4. Quantity requested does not exceed: 25mg/kg/day **AND**
5. Patient weight (within most recent 2 months) and targeted weight-based dose have been provided **AND**
6. Patient has had an adequate trial of at least two anti-seizure medications (e.g., valproic acid, clobazam, topiramate, clonazepam, levetiracetam, zonisamide, ethosuximide) **AND**
7. Patient has been evaluated for hepatic impairment and appropriately managed **AND**
8. Prescribed by, or in consultation with, a pediatric neurologist or a neurologist with expertise in epilepsy.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Upon receipt of clinical records demonstrating seizure activity abated while on treatment
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	10.2018
Updated	Updated to new format; Added denial message	2.2020
Annual Review	No Changes	2.2021
Update	Criteria update to include expanded indication and dosage for Seizures Associated with Tuberous Sclerosis Complex	8.2022
Annual Review	Added t/f criteria of two anti-seizure medications based on guidelines.	7.2023
Annual Review	Updated initial duration to 1 year	3.2024

REFERENCE:

1. Bertrand KA, Hanan NJ, Honerkamp-Smith G, Best BM, Chambers CD. Marijuana use by breastfeeding mothers and cannabinoid concentrations in breast milk. Pediatrics. 2018;142(3):e20181076. doi:10.1542/peds.2018-1076[PubMed 30150212]

2. Epidiolex (cannabidiol) [prescribing information]. Carlsbad, CA: Greenwich Biosciences LLC; October 2023.
3. Kim J, de Castro A, Lendoiro E, Cruz-Landeira A, López-Rivadulla M, Concheiro M. Detection of in utero cannabis exposure by umbilical cord analysis. Drug Test Anal. 2018;10(4):636-643. doi:10.1002/dta.2307[PubMed 28948698]
4. Moss MJ, Bushlin I, Kazmierczak S, et al. Cannabis use and measurement of cannabinoids in plasma and breast milk of breastfeeding mothers. Pediatr Res. 2021;90(4):861-868. doi:10.1038/s41390-020-01332-2[PubMed 33469174]
5. Cross JH, Auvin S, Falip M, Striano P, Arzimanoglou A. Expert Opinion on the Management of Lennox-Gastaut Syndrome: Treatment Algorithms and Practical Considerations. Front Neurol. 2017 Sep 29;8:505. doi: 10.3389/fneur.2017.00505. PMID: 29085326; PMCID: PMC5649136.
6. Na J-H, Jung DE, Kang HJ, Kang H-C, Kim HD. Treatment strategies for Lennox-Gastaut syndrome: outcomes of multimodal treatment approaches. Therapeutic Advances in Neurological Disorders. 2022;15. doi:10.1177/17562864221108012
7. Strzelczyk A, Schubert-Bast S. A Practical Guide to the Treatment of Dravet Syndrome with Anti-Seizure Medication. CNS Drugs. 2022 Mar;36(3):217-237. doi: 10.1007/s40263-022-00898-1. Epub 2022 Feb 14. PMID: 35156171; PMCID: PMC8927048.
8. Northrup H, Aronow ME, Bebin EM, Bissler J, Darling TN, de Vries PJ, Frost MD, Fuchs Z, Gosnell ES, Gupta N, Jansen AC, Jóźwiak S, Kingswood JC, Knilans TK, McCormack FX, Pounders A, Roberds SL, Rodriguez-Buritica DF, Roth J, Sampson JR, Sparagana S, Thiele EA, Weiner HL, Wheless JW, Towbin AJ, Krueger DA; International Tuberous Sclerosis Complex Consensus Group. Updated International Tuberous Sclerosis Complex Diagnostic Criteria and Surveillance and Management Recommendations. Pediatr Neurol. 2021 Oct;123:50-66. doi: 10.1016/j.pediatrneurol.2021.07.011. Epub 2021 Jul 24. PMID: 34399110.

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Prior Authorization Criteria for EPIVIR HBV® (lamivudine)

1. Patient has diagnosis of chronic hepatitis B infection **AND**
2. Patient is 2 years of age or older **AND**
3. Dosage and direction of use:
    a. Adults: 100 mg once daily
    b. Pediatrics: 3 mg/kg daily **AND**
4. Quantity requested does not exceed: 100 mg/day **AND**
5. Alternative antiviral agent with a higher genetic barrier to resistance (e.g. tenofovir or entecavir) is not available or is not appropriate for the patient **AND**
6. Patient does not have HIV-1 infection and is not using this medication as a single agent for HIV treatment **AND**
7. Prescribed by or in consultation with a specialist such as a gastroenterologist, hepatologist, or infectious disease specialist

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 12 months.

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided
- ✓ Approval duration for renewal: 12 months.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Annual Review	No changes	7.2024

REFERENCE:

1. Epivir HBV (lamivudine) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline LLC; December 2021.
2. Lok, Anna SF. Hepatitis B virus: Overview of management. UpToDate. July 2021. Accessed July 24, 2023.

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Prior Authorization Criteria for ERIVEDGE (vismodegib)

FDA-Approved Indications

- Treatment of adults with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery and who are not candidates for radiation.

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated duration of approval; added FDA approved dx and age	5.2024

REFERENCE:

1. ERIVEDGE. [Prescribing Information]. San Francisco, CA. Genentech USA, Inc: March 2023.

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Prior Authorization Criteria for ERLEADA® (apalutamide)

FDA-APPROVED INDICATIONS

- Treatment of metastatic castration-sensitive prostate cancer
- Treatment of non-metastatic castration-resistant prostate cancer

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist.

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
- ✓ Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA Criteria created 7.13.22	7.2022
Update	Added new direction and maximum dose for the new formulation of 240 mg tablet from CAB 3.9.2023	3.2023
Annual Review	Update references; updated wording for clarity	7.2023
Annual Review	Updated duration of approval; added FDA approved dx and age; updated renewal criteria	5.2024

REFERENCE:

1. Erleada Prescribing Information. Horsham, PA: Janssen Pharmaceutical Companies; February 2023.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 4.2022 – May 10, 2022). © 2022 National Comprehensive Cancer Network. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate_blocks.pdf. Accessed June 4, 2022.

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Prior Authorization Criteria for ESBRIET® (pirfenidone)

1. Patient has diagnosis of idiopathic pulmonary fibrosis (IPF) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use:
    a. Day 1 through 7: 267 mg three times daily (3 capsules or tablets of 267 mg)/day (total of 801 mg/day)
    b. Day 8 through 14: 534 mg three times daily (6 capsules or tablets of 267 mg)/day (total of 1,602 mg/day)
    c. Day 15 and onward: 801 mg three times daily (3 tablets of 801 mg)/day (total of 2,403 mg/day) **AND**
4. Quantity requested does not exceed:
    a. Day 1 through 7: 801 mg/day
    b. Day 8 through 14: 1,602 mg/day
    c. Day 15 and onward: 2,403 mg/day **AND**
5. Diagnosis is confirmed by one of the following (documentation required):
    a. Usual interstitial pneumonia (UIP) patterns from high-resolution computed tomography (HRCT) demonstrated peripheral (subpleural), bibasilar reticular opacities associated with architectural distortion, including honeycomb changes and traction bronchiectasis or bronchiolectasis **OR**
    b. Lung biopsy with pathology confirming UIP **OR**
    c. The combination of HRCT and biopsy pattern are both indicative of probable UIP **AND**
6. Patient does not have any other known causes of interstitial lung disease (e.g., environmental exposure, radiation, systemic lupus erythematosus, and rheumatoid arthritis, HIV, cancer, etc.) **AND**
7. Patient has documentation of a predicted FVC ≥ 50% (mild to moderate lung function) **AND**
8. Patient has diffusion capacity of the lung for carbon monoxide (%DL_{CO}) ≥ 30% **AND**
9. Patient will not be taking Ofev concomitantly **AND**
10. For brand requests, patient has had an adequate trial of generic pirfenidone unless contraindicated **AND**
11. Prescribed by or in consultation with a pulmonologist.

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 1 year

RENEWALS

✓ Documentation of positive clinical response to therapy has been provided
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Revised	Created	9.2019
Updated	Add Denial Message	2.2020
Updated	Updated approval duration to initial approval of 1 year; fixed type on #7	11.2020
Updated	Updated default denial	2.2021

Annual Review	No Change	2.2022
Annual Review	Updated criteria to include trial of generic for brand requests.	2.2023
Annual Review	Removed criteria requirements based on package insert, updated denial message, and updated format	2.2024

REFERENCE:

1. Esbriet (pirfenidone) [prescribing information]. South San Francisco, CA: Genentech USA; February 2022.
2. Noble PW, Albera C, Bradford WZ, et al, "Pirfenidone in Patients With Idiopathic Pulmonary Fibrosis (CAPACITY): Two Randomized Trials," Lancet, 2011, 377(9779):1760-9.[PubMed 21571362]
3. Selman M, King TE, and Pardo A, "Idiopathic Pulmonary Fibrosis: Prevailing and Evolving Hypotheses About Its Pathogenesis and Implications for Therapy," Ann Intern Med, 2001, 134(2):136-51. [PubMed 11177318]
4. Raghu G, Remy-Jardin M, and Richeldi L., Idiopathic Pulmonary Fibrosis (an Update) and Progressive Pulmonary Fibrosis in Adults: An Official ATS/ERS/JRS/ALAT Clinical Practice Guideline. Am J Respir Crit Care Med. 2022 May 1;205(9):e18-e47. doi: 10.1164/rccm.202202-0399ST. PMID: 35486072; PMCID: PMC9851481.
5. Pleasants R, Tighe RM. Management of Idiopathic Pulmonary Fibrosis. Ann Pharmacother. 2019 Dec;53(12):1238-1248. doi: 10.1177/1060028019862497. Epub 2019 Jul 7. PMID: 31280590; PMCID: PMC6745766.

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Prior Authorization Criteria for etoposide capsule

FDA-APPROVED INDICATIONS

- Small Cell lung cancer in combination with other approved chemotherapeutic agents as first line treatment in patients with small cell lung cancer

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year.

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated to oncology template	7.2024

REFERENCE:

1. Etoposide [Prescribing Information]. Morgantown, WV. Mylan Pharmaceuticals Inc.: April 2016.

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Prior Authorization Criteria for EVRYSDI® (risdiplam)

1. Patient has a diagnosis of type 1, 2, or 3 spinal muscular atrophy (SMA) **AND**
2. Dosage and Direction for Use: The recommended dosage is determined by age and body weight and is administered orally once daily after a meal using the provided oral syringe.

Age and Body Weight	Recommended Daily Dosage
Less than 2 months of age	0.15 mg/kg
2 months to less than 2 years of age	0.2 mg/kg
2 years of age and older weighing less than 20 kg	0.25 mg/kg
2 years of age and older weighing 20 kg or more	5 mg

3. Quantity requested does not exceed: dosed by weight, please optimize quantity based on prescribed dosing schedule **AND**
4. Patient has a diagnosis of spinal muscular atrophy confirmed by one of the following: homozygous gene deletion of SMN1 gene, homozygous gene mutation of SMN1 gene or compound heterozygous mutation of SMN1 gene **AND**
5. Patient has documentation of at least one of the following exams to establish baseline motor functions:
    a. Bayley Scales of Infant and Toddler Development, Third Edition (BSID-III)
    b. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
    c. Hammersmith Infant Neurological Examination (HINE) Part 2
    d. Hammersmith Functional Motor Scale Expanded (HFMSE)
    e. Revised Upper Limb Module (RULM)
    f. 6-Minute Walk Test (6MWT) **AND**
6. Patient does not require invasive ventilatory support **AND**
7. Patient is not receiving concurrent treatment or has not previously received gene replacement therapy with Spinraza or Zolgensma **AND**
8. Prescribed by or in consultation with a neurologist or pediatrician with expertise in treating SMA.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 6 months

RENEWALS

✓ Patient responded positively to therapy
✓ Documentation of response to therapy as evidenced by a clinically meaningful improvement in motor function **OR** documentation of disease stabilization or a reduction in normal motor decline in the applicable population.
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 8.28.2020	8.2020
Annual Review	No Change	8.2021
Annual Review	Updated expanded indication to include pediatric patient less than 2 months of age and older; updated diagnosis parameters and baseline motor function exams	8.2022
Annual Review	Removed min age requirement – it is now approved for patients less than 2 months of age and adults.	8.2023
Annual Review	Added ventilatory support exclusion	8.2024

REFERENCE:

1. Evrysdi [package insert]. South San Francisco, CA: Genentech, Inc; February 2024.
2. Kirschner J, Butoianu N, Goemans N, et al. European ad-hoc consensus statement on gene replacement therapy for spinal muscular atrophy. European Journal of Paediatric Neurology. 2020, doi: https://doi.org/10.1016/j.ejpn.2020.07.001.
3. Servais L, Baranello G, Masson R, et al. FIREFISH Part 2: Efficacy and safety of risdiplam (RG7916) in infants with Type 1 spinal muscular atrophy (SMA). Presented at the 2020 Virtual SMA Research & Clinical Care Meeting
4. Day JW, Annoussamy M, Baranello G, et al. SUNFISH Part 1: 24-month safety and exploratory outcomes of risdiplam (RG7916) treatment in patients with Type 2 or 3 spinal muscular atrophy (SMA). Presented at the 2020 Virtual SMA Research & Clinical Care Meeting.
5. Markowitz JA, Singh P, Darras BT. Spinal Muscular Atrophy: A Clinical and Research Update. Pediatric Neurology 46 (2012) 1-12.
6. Finkel RS, Mercuri E, Darras BT, et al. Nusinersen versus Sham Control in InfantileOnset Spinal Muscular Atrophy. N Engl J Med. 2017 Nov 2;377(18):1723-1732.

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Prior Authorization Criteria for EXJADE®, JADENU®, JADENU® Sprinkle (deferasirox)

FDA Approved Indications

- Chronic Iron Overload due to Blood Transfusions
- Non-transfusion-dependent-thalassemia (NTDT) Syndromes

Diagnosis: Chronic Iron Overload due to Blood Transfusions

1. Patient has diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis) **AND**
2. Patient is 2 years of age or older **AND**
3. Dosage and Directions for Use:
    a. *Exjade:* Recommended daily dose is 20 mg/kg body weight, taken on an empty stomach at least 30 minutes before food. Doses above 40 mg per kg are not recommended. Disperse the tablets by stirring in an appropriate amount of water, orange juice, or apple juice. Calculate dose to the nearest whole tablet.
    b. *Jadenu & Jadenu Sprinkle:* Recommended daily dose is 14 mg/kg body weight (calculated to nearest whole tablet or nearest whole sachet content for granules), once daily on an empty stomach or with a low-fat meal. Doses above 28 mg per kg are not recommended **AND**
4. Quantity requested does not exceed:
    a. *Exjade:* Recommended daily dose is 40 mg/kg body weight per day
    b. *Jadenu & Jadenu Sprinkle:* 28 mg/kg body weight per day **AND**
5. Prior to starting therapy, patient has documented:
    a. Transfusion history of ≥ 100 mL/kg of packed red blood cells (e.g., ≥ 20 units of packed red blood cells for a 40 kg person) therapy **AND**
    b. Serum ferritin level > 1,000 mcg/L **AND**
6. Patient is not taking any other iron chelators **AND**
7. If request is for brand, patient has an adequate trial of generic alternatives (e.g., deferasirox) **AND**
8. Patient does not have any of the following labeled contraindications:
    a. Estimated GFR less than 40 mL/min/1.73 m^2 **OR**
    b. Poor performance status **OR**
    c. Advanced malignancies **OR**
    d. High-risk myelodysplastic syndrome (MDS) **OR**
    e. Platelet counts less than 50 x 10^9/L

Diagnosis: Non-transfusion-dependent-thalassemia (NTDT) Syndromes

1. Patient has diagnosis of chronic iron overload due to Non-transfusion-dependent-thalassemia (NTDT) Syndromes **AND**
2. Patient is 10 years of age or older **AND**
3. Dosage and Directions for Use:
    a. *Exjade:* Recommended daily dose is 10 mg/kg body weight, taken on an empty stomach at least 30 minutes before food. Doses above 20 mg per kg are not recommended. Disperse the tablets by stirring in an appropriate amount of water, orange juice, or apple juice. Calculate dose to the nearest whole tablet.
    b. *Jadenu & Jadenu Sprinkle:* Recommended daily dose is 7 mg/kg body weight (calculated to nearest whole tablet or nearest whole sachet content for granules), once daily on an empty stomach or with a low-fat meal. Doses above 14 mg/kg are not recommended **AND**
4. Quantity requested does not exceed:
    a. *Exjade:* Recommended daily dose is 20 mg/kg body weight per day
    b. *Jadenu & Jadenu Sprinkle:* 14 mg/kg body weight per day **AND**
5. Prior to starting therapy, patient has documented liver iron concentration (LIC) of at least 5 mg Fe/g dw and a serum ferritin greater than 300 mcg/L **AND**
6. Patient is not taking any other iron chelators **AND**

7. If request is for brand, patient has an adequate trial of generic alternatives (e.g., deferasirox) **AND**
8. Patient does not have any of the following labeled contraindications:
    a. Estimated GFR less than 40 mL/min/1.73 m^2 **OR**
    b. Poor performance status **OR**
    c. Advanced malignancies **OR**
    d. High-risk myelodysplastic syndrome (MDS) **OR**
    e. Platelet counts less than 50 x 10^9/L

INITIAL APPROVALS

- ✓ Initial approval will be for a period of up to 6 months.
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Individual demonstrates benefit from the iron chelation agent (for example: reduction in the serum ferritin levels, stable disease), as confirmed by the prescribing physician.
- ✓ Renew for period of up to 12 months.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2019
Update	Update Format / Add Denial Message	2.2020
Update	Add Jadenu & Jadenu Sprinkles	8.2020
Annual Review	No Changes	8.2021
Annual Review	No Changes	8.2022
Annual Review	Updated format and contraindications	8.2023
Annual Review	Updated criteria verbiage to include t/f of generic if request is for brand, updated dosage, updated denial message, and updated format	2.2024

REFERENCE:

1. Exjade (deferasirox) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2023.
2. Jadenu (deferasirox) [product monograph]. Dorval, Quebec, Canada: Novartis Pharmaceuticals Canada Inc; August 2022.
3. Cappellini MD, Cohen A, Porter, J, et al. A short guide for the management of transfusion dependent thalassaemia. 3rd Edition. Available at: https://thalassaemia.org.cy/wp-content/uploads/2022/08/TDT-GUIDE-2022-FOR-web.pdf. Accessed on February 13, 2023.
4. Aydinok Y, Kattamis A, Viprakasit V. Current approach to iron chelation in children. Br J Haematol. 2014;165(6):745-755. doi:10.1111/bjh.12825.
5. Olivieri NF, Brittenham GM. Iron-chelating therapy and the treatment of thalassemia [published correction appears in Blood 1997 Apr 1;89(7):2621]. Blood. 1997;89(3):739-761.
6. Farmakis D, Porter J, Taher A, Domenica Cappellini M, Angastiniotis M, Eleftheriou A. 2021 Thalassaemia International Federation Guidelines for the Management of Transfusion-dependent Thalassemia. Hemasphere. 2022 Jul 29;6(8):e732. doi: 10.1097/HS9.0000000000000732. PMID: 35928543; PMCID: PMC9345633.

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Prior Authorization Criteria for EXKIVITY™ (mobocertinib succinate)

FDA-Approved Indications

- Treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
- ✓ Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Approval duration for renewal: 1 year
- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 10.7.2021	10.2021
Annual Review	No changes	10.2022
Annual Review	Updated renewal criteria; updated format; updated denial message	10.2023
Update	Updated duration of approval; added FDA approved dx and age; added FDA indication section	5.2024

REFERENCE:

1. Exkivity (mobocertinib) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America Inc: September 2023.
2. doi:10.1200/JCO.2021.39.15_suppl.9014
3. Zhang SS, et al. Spotlight on mobocertinib (TAK-788) in NSCLC with EGFR exon 20 insertion mutations. Lung Cancer (Auckl). 2021;12:61-65. doi:10.2147/LCTT.S307321.
4. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer (Version 6.2021). https://www.nccn.org/professionals/physician_gls/pdf/nscl_blocks.pdf Accessed October 4, 2021.

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Prior Authorization Criteria for EXSERVAN (riluzole)

1. Patient has a diagnosis of amyotrophic lateral sclerosis (ALS) **AND**
2. Patient is 18 years of age and older **AND**
3. Dosage and Direction for Use: 50 mg twice daily, taken at least 1 hour before or 2 hours after a meal **AND**
4. Quantity requested does not exceed: 60 film packets/30 days **AND**
5. Patient has had an adequate trial of generic riluzole **AND**
6. Documentation of medical necessity for use of oral films instead of riluzole tablets **AND**
7. Prescribed by or in consultation with a specialist such as a neurologist with expertise in ALS.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 6 months

RENEWALS

✓ Patient has a positive response to therapy
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	No changes	5.2024

REFERENCE:

1. Chen JJ. Overview of current and emerging therapies for amytrophic lateral sclerosis. Am J Manag Care. 2020 Aug;26(9 Suppl):S191-S197. doi: 10.37765/ajmc.2020.88483. PMID: 32840332.
2. Exservan (riluzole) oral film [prescribing information]. Warren, NJ: Aquestive Therapeutics; July 2022.
3. Miller RG, Jackson CE, Kasarskis EJ, et al; Quality Standards Subcommittee of the American Academy of Neurology. Practice parameter update: the care of the patient with amyotrophic lateral sclerosis: drug, nutritional, and respiratory therapies (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology [published correction appears in Neurology. 2009;73(24):2134] [published correction appears in Neurology. 2010;74(9):781]. Neurology. 2009;73(15):1218-1226. doi: 10.1212/WNL.0b013e3181bc0141
4. Paganoni S, Macklin EA, Hendrix S, et al. Trial of sodium phenylbutyrate-taurursodiol for amyotrophic lateral sclerosis. N Engl J Med. 2020;383(10):919-930. doi:10.1056/NEJMoa1916945[PubMed 32877582]
5. Paganoni S, Macklin EA, Hendrix S, et al. Trial of sodium phenylbutyrate-taurursodiol for amyotrophic lateral sclerosis. N Engl J Med. 2020 Sep;383(10):919-930. doi:10.1056/NEJMoa1916945.
6. Brown CA, Lally C, Kupelian V, Flanders WD. Estimated prevalence and incidence of amyotrophic lateral sclerosis and SOD1 and C9orf72 genetic variants. Neuroepidemiology. 2021 Jul;55(5):342-353. doi:10.1159/000516752.
7. National Institute of Neurological Disorders and Stroke. Amyotrophic lateral sclerosis (ALS) fact sheet. November 15, 2021. Accessed December 10, 2021. https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Amyotrophic-Lateral-Sclerosis-ALS-Fact-Sheet.
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10. Brotman RG, Moreno-Escobar MC, Joseph J, et al. Amyotrophic Lateral Sclerosis. [Updated 2022 Aug 22]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK556151/

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Prior Authorization Criteria for FABHALTA® (iptacopan)

1. Patient has diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) **AND**
2. Patient is 18 years of age and older **AND**
3. Dosage and direction of use: 200 mg orally twice daily with or without food **AND**
4. Quantity requested does not exceed: 60 tablets/30 days **AND**
5. Patient has laboratory documentation of a detectable GPI-deficient hematopoietic clones via Flow Cytometry to confirm diagnosis of PNH **AND**
6. Patient has signs and symptoms attributed to PNH (e.g., abdominal pain, anemia, dyspnea, extreme fatigue, smooth muscle dystonia, unexplained/unusual thrombosis, hemolysis/hemoglobinuria, kidney disease, pulmonary hypertension) **AND**
7. Patient must have received vaccinations against encapsulated bacteria, including Streptococcus pneumoniae, Neisseria meningitidis (serogroups A, C, W, Y and B), and Haemophilus influenzae type B, according to current ACIP recommendations at least 2 weeks prior to initiation of therapy **AND**
8. Prescribed by or in consultation with a specialist such as hematologist, oncologist, or immunologist.

INITIAL APPROVALS

- ✓ Initial approval will be granted for a period of 6 months

RENEWALS

- ✓ Documentation of positive clinical response to therapy is provided
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created from CAB 12.28.2023	12.2023

REFERENCE:

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2. Risitano AM, Kulasekararaj A, Roeth A, et al. Factor B inhibition with oral iptacopan monotherapy demonstrates sustained long-term efficacy and safety in anti-C5-treated patients (pts) with paroxysmal nocturnal hemoglobinuria (PNH) and persistent anemia: final 48-week results from the multicenter, phase III APPLY-PNH trial. Blood. 2023;142(suppl 1):571. https://doi.org/10.1182/blood-2023-180780.
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Prior Authorization Criteria for FASENRA™ (benralizumab)

FDA-Approved Indications

- Add-on maintenance treatment of adult and pediatric patients aged 6 years and older with severe asthma, and with an eosinophilic phenotype
- Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)

Diagnosis: Asthma

1. Patient has a diagnosis of severe asthma with an eosinophilic phenotype **AND**
2. Patient is 6 years of age or older **AND**
3. Dosage and direction of use:
    a. Patients 12 years and older: 30 mg every 4 weeks for the first 3 doses, followed by once every 8 weeks thereafter **OR**
    b. Patients 6 to 11 years of age:
        i. < 35 kg: 10 mg every 4 weeks for first 3 doses followed by once every 8 weeks thereafter **OR**
        ii. > 35 kg: 30 mg every 4 weeks for first 3 doses followed by once every 8 weeks thereafter
4. Quantity requested does not exceed: initial dose: 1 syringe or pen/28 days for 3 doses, maintenance dose: 1 syringes or pen/ 56 days **AND**
5. Patient has an absolute blood eosinophil count ≥ 150 cells/mcL within the past 3 months **AND**
6. Patient has been adherent to the use of controller therapy (i.e., medium- to high-dose inhaled corticosteroid (e.g. Flovent, Pulmicort, Qvar) plus either a long-acting beta2 agonist (e.g. Serevent) or leukotriene modifier (e.g. Singulair, Accolate) **AND**
7. Patient experienced ≥ 2 exacerbations within the last 12 months despite adherent use of optimized doses of therapy requiring any of the following:
    a. Oral/systemic corticosteroid treatment (or increase in dose if already on oral corticosteroid)
    b. Urgent care visit or hospital admission
    c. Intubation **AND**
8. Fasenra is not prescribed concurrently with Cinqair®, Nucala®, Dupixent®, or Xolair® **AND**
9. Prescribed by or in consultation with a pulmonologist, immunologist, or allergist.

Diagnosis: Eosinophilic granulomatosis with polyangiitis (EGPA)

1. Patient has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 30 mg every 4 weeks **AND**
4. Quantity requested does not exceed: 1 syringe or pen/28 days **AND**
5. Patient has history or presence of asthma **AND**
6. Patient has eosinophilia (1,000 cells/uL or >10% of leukocytes) with EGPA clinical features (e.g., asthma, chronic rhinosinusitis with polyps, eosinophilia, neuropathy, lung infiltrates, eosinophilic cardiomyopathy or gastroenteritis, glomerulonephritis) **AND**
7. Patient has had trial and failure of a 3-month trial of a glucocorticoid (e.g. prednisone, methylprednisolone) or an immunosuppressant (e.g. methotrexate, azathioprine), unless contraindicated or clinically significant adverse events are experienced **AND**
8. Patient has a history of relapsing or refractory disease while being on standard of care therapy (e.g., oral corticosteroid with or without immunosuppressant therapy) **AND**
9. Fasenra is not prescribed concurrently with Cinqair®, Nucala®, Dupixent®, Tezspire, or Xolair® **AND**
10. Prescribed by or in consultation with a pulmonologist, immunologist, or allergist.

INITIAL APPROVALS

- ✓ Initial approval will be for a period of 12 months

RENEWALS

- ✓ Patient respond positively to treatment.
- ✓ Approval duration for renewal: 1 year.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2019
Annual Review	Add Denial Message	6.2020
Annual Review	No Change	6.2021
Annual Review	No Change	6.2022
Annual Review	Updated references	5.2023
Annual Review	Updated criteria to include expanded indication to include patients aged 6 years and older with severe asthma, and with an eosinophilic phenotype	5.2024
Update	Updated criteria to include expanded indication of Eosinophilic granulomatosis with polyangiitis (EGPA)	9.2024

REFERENCE:

1. Fasenra (benralizumab) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2024.
2. National Asthma Education and Prevention Program: Expert panel report III: Guidelines for the diagnosis and management of asthma. Bethesda, MD: National Heart, Lung, and Blood Institute, 2007. (NIH publication no. 08-4051). Available at http://www.nhlbi.nih.gov/healthpro/guidelines/current/asthma-guidelines. Accessed July 10, 2019
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.clinicalpharmacology.com. Accessed July 10, 2019
4. Global Initiative for Asthma: Global strategy for asthma management and prevention (2023 update). Available at: https://ginasthma.org/wp-content/uploads/2023/05/GINA-2023-Full-Report-2023-WMS.pdf/. Accessed May 24, 2023.
5. Chakraborty RK, Aeddula NR. Eosinophilic Granulomatosis With Polyangiitis (Churg-Strauss Syndrome) [Updated 2024 Aug 25]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK537099/
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Prior Authorization Criteria for
FERRIPROX®, FERRIPROX TWICE-A-DAY® (deferiprone)

1. Patient has a diagnosis of transfusional iron overload associated with thalassemia, iron overload associated with sickle cell disease, or other anemias **AND**
2. Patient is:
    a. Oral solution: 3 years of age and older **OR**
    b. Oral Tablets: 8 years of age or older
3. Dosage and Direction for Use:
    a. **Oral solution:** 25 mg/kg to 33 mg/kg actual body weight, orally, three times per day for a total of 75 mg/kg/day. The maximum dose is 33 mg/kg actual body weight, three times per day for a total of 99 mg/kg/day. Round doses to nearest 2.5 mL.
    b. **Tablets (twice a day), 1,000 mg**: starting dosage of 75 mg/kg/day (actual body weight) in two divided doses up to maximum dosage of 99 mg/kg/day (actual body weight) in two divided doses.
    c. **Tablets (three times a day), 1,000 mg**: starting dosage of 75 mg/kg/day (actual body weight) in three divided doses up to maximum dosage of 99 mg/kg/day (actual body weight) in three divided doses.
    d. **Tablets (three times a day), 500 mg:** starting dosage of 75 mg/kg/day (actual body weight) in three divided doses up to maximum dosage of 99 mg/kg/day (actual body weight) in three divided doses **AND**
4. Quantity requested does not exceed: Dosed by weight, please optimize quantity based on prescribed dosing scheduling (max of 99 mg/kg/day) **AND**
5. Confirm patient has transfusion history **AND**
6. Patient's iron overload was due to thalassemia syndromes, sickle cell disease, or other anemias when current chelation therapy is inadequate **AND**
7. Prior to starting therapy, patient has documented serum ferritin level > 1,000 mcg/L **AND**
8. If request is for brand, patient had an adequate trial of generic alternatives (e.g., deferiprone, deferasirox) **AND**
9. Patient is not taking any other iron chelators **AND**
10. For oral solution, patient has documentation of a swallowing disorder **AND**
11. Prescribed by or in consultation with a hematologist.

INITIAL APPROVALS

- ✓ Initial approval will be granted for a period of 1 year
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Confirm patient responds positively from therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 7.16.2020	7.2020
Annual Review	No Changes	7.2021
Annual Review	Updated diagnosis criteria, updated age from 18 to 8 years old, dose, and denial message.	2.2022
Annual Review	Updated dosage for oral tablets and clinical criteria; Added age requirement and clinical criteria for oral solution.	2.2023
Annual Review	Updated criteria - slight updates on criteria verbiage, removed CBC/ANC level requirement, updated denial message, and updated template	2.2024

REFERENCE:

1. Ferriprox (deferiprone) 500 mg tablets [prescribing information]. Cary, NC: Chiesi USA Inc; November 2021.
2. Ferriprox (deferiprone) 1,000 mg tablets [prescribing information]. Cary, NC: Chiesi USA Inc; November 2021.
3. Ferriprox (deferiprone) oral solution [prescribing information]. Cary, NC: Chiesi USA Inc; November 2021.
4. Ferriprox (deferiprone) tablets and oral solution [product monograph]. Woodbridge, Ontario, Canada: Chiesi Canada Corp; October 2021.
5. Ferriprox and Ferriprox MR (deferiprone) tablets and extended-release tablets [product monograph]. Woodbridge, Ontario, Canada: Chiesi Canada Corp; March 2023.
6. Brittenham GM. Iron-chelating therapy for transfusional iron overload. N Engl J Med. 2011;364:146-156.
7. Palmer WC, Vishnu P, Sanchez W, et al. Diagnosis and Management of Genetic Iron Overload Disorders. J Gen Intern Med. 2018 Dec;33(12):2230-2236.
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9. Pennell DJ, Udelson JE, Arai AE, et al. Cardiovascular function and treatment in β-thalassemia major. A consensus statement from the American Heart Association. Circulation. 2013;128:281-308.
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Prior Authorization Criteria for FIRDAPSE® (amifampridine)

1. Confirm patient has a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) **AND**
2. Patient is 6 years of age or older **AND**
3. Dosage and direction of use:
   Recommendation dosage and direction of use for pediatric patients 6 years of age and older:

Age and Body Weigh	Initial Daily Dosage	Titration Regimen	Maximum Single Dose	Maximum Total Daily Maintenance Dosage
Adults (any weight) Pediatric patients weighing 45 kg or more	15 mg to 30 mg daily, in 3 to 4 divided doses	Increase total daily dosage by 5 mg every 3 or 4 days	20 mg	80 mg Given in divided doses
Pediatric patients weighing less than 45 kg	5 mg to 15 mg daily, in 3 to 4 divided doses	Increase total daily dosage by 2.5 mg every 3 or 4 days	10 mg	40 mg Given in divided doses

4. Quantity requested does not exceed: 8 tablets (80 mg/day) **AND**
5. Prescriber attestation that labs/notes indicate that patient has clinical symptoms suggestive of LEMS (i.e. proximal weakness affecting legs, eyes, face, throat) **AND**
6. Patient has documentation of a confirmatory diagnostic test result including one of the following:
   a. Neurophysiology studies **OR**
   b. Positive anti-P/Q type voltage-gated calcium channel antibody test **AND**
7. Patient does not have a history of seizures **AND**
8. Prescribed by or in consultation with a specialist such as a neurologist.

INITIAL APPROVALS

- ✓ Prescriber attestation that labs/notes indicate patient has the disease or requires the medication
- ✓ Initial approval will be for a period of 1 year

RENEWALS

- ✓ Documentation of positive response to therapy as evidenced by clinical symptom improvement and clinical muscle strength assessments (examples may include but are not limited to the QMG score, 3TUG test, T25FW test).
- ✓ Renewal approval: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2019
Update	Add Denial Message; combine criteria with Ruzurgi	7.2020
Annual Review	No Change	7.2021
Annual Review	Remove Ruzurgi for pediatric patients, as this drug is no longer authorized for distribution in the US.	8.2022

Annual Review	Updated expanded indication to include pediatric patients 6 years and older; dosage table and directions of use; Added a criteria requirement to exclude patients with a history of seizures; Updated default denial message and format	7.2023
Annual Review	Updated renewal criteria; removed requirement for initial documentation of strength assessments	6.2024

REFERENCE:

1. Firdapse (amifampridine) [prescribing information]. Coral Gables, FL: Catalyst Pharmaceuticals Inc; May 2023.
2. Firdapse® tablets [prescribing information]. Coral Gables, FL: Catalyst Pharmaceuticals; February 2021
3. Weinberg DH. Lambert-Eaton myasthenic syndrome: Treatment and Prognosis. In: UpToDate, Wen PY, Shefner JM, Eichler AF (Ed), UpToDate, Waltham, MA.2018.
4. Kesner VG, Oh SJ, Dimachkie MM, et al. Lambert-Eaton Myasthenic Syndrome. Neurol Clin. 2018;36(2):379-394.
5. Wirtz PW, Titulaer MJ, Gerven JM, Verschuuren JJ. 3,4-diaminopyridine for the treatment of Lambert-Eaton myasthenic syndrome. Expert Rev Clin Immunol. 2010;6(6):867-874. doi: 10.1586/eci.10.57.[PubMed 20979551]

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Prior Authorization Criteria for FORTEO® (teriparatide) and Teriparatide (Recombinant)

FDA-APPROVED INDICATIONS

- Treatment of postmenopausal women with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy.
- Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy.
- Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy.

1. Patient has diagnosis of Osteoporosis:
   a. Postmenopausal women with osteoporosis at high risk for fracture **OR**
   b. Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture **OR**
   c. Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: 20mcg subcutaneously once a day **AND**
4. Quantity requested does not exceed: 30 doses/30 days. Use of medication for more than 2 years during a patient's lifetime is not recommended **AND**
5. Patient has one of the following:
   a. Patient has a BMD t-score ≤ -2.5 (DXA) at the total hip or femoral neck **OR**
   b. History of fragility (non-traumatic) or osteoporotic fracture **OR**
   c. High FRAX fracture probability: 10-year major osteoporotic facture risk of ≥20% or 10-year probability of hip fracture ≥3% **AND**
6. Patient has tried and failed or has contraindication to oral bisphosphonates **AND**
7. **If request is for Teriparatide**: in addition to the below, patient has also tried and failed Forteo **AND**
8. No concomitant use with other osteoporosis therapy (e.g. bisphosphonates, Prolia, Tymlos, Evenity)

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 6 months to 1 year

RENEWALS

✓ Approval duration for renewal: 1 year
✓ Documentation of positive clinical response to therapy has been provided
✓ Individual will not exceed lifetime maximum of 24 monthly doses of treatment [including previous use of Tymlos (abaloparatide)]

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	3.2017

Update	Update Format: Add Denial Message	4.2020
Annual Review	No Change	4.2021
Annual Review	No Change	4.2022
Annual Review	No Change	4.2023
Annual Review	Added criteria to include high FRAX fracture probability as a criteria option	4.2024

REFERENCE:

1. Body JJ, Gaich GA, Scheele WH, et al, "A Randomized Double-blind Trial to Compare the Efficacy of Teriparatide [Recombinant Human Parathyroid Hormone (1-34)] With Alendronate in Postmenopausal Women With Osteoporosis," J Clin Endocrinol Metab, 2002, 87(10):4528-35.[PubMed 12364430]
2. Bonsity (teriparatide) [prescribing information]. San Diego, CA: Pfenex; October 2019.
3. Buckley L, Guyatt G, Fink HA, et al. 2017 American College of Rheumatology guideline for the prevention and treatment of glucocorticoid-induced osteoporosis [published correction appears in Arthritis Rheumatol. 2017;69(11):2246]. Arthritis Rheumatol. 2017;69(8):1521-1537. doi: 10.1002/art.40137.[PubMed 28585373]
4. Centers for Disease Control and Prevention (CDC). CDC clinical reminder: insulin pens must never be used for more than one person. Centers for Disease Control and Prevention Web site. http://www.cdc.gov/injectionsafety/clinical-reminders/insulin-pens.html. Updated January 5, 2012. Accessed January 9, 2012.
5. Cosman F, de Beur SJ, LeBoff MS, et al. Clinician's guide to prevention and treatment of osteoporosis. Osteoporos Int. 2014;25(10):2359-2381. doi: 10.1007/s00198-014-2794-2.[PubMed 25182228
6. Forteo (teriparatide) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; October 2019.
7. Geusens P, Marin F, Kendler DL, et al. Effects of teriparatide compared with risedronate on the risk of fractures in subgroups of postmenopausal women with severe osteoporosis: the VERO Trial. J Bone Miner Res. 2018;33(5):783-794. doi: 10.1002/jbmr.3384.[PubMed 29329484]
8. Miller PD, Hattersley G, Riis BJ, et al; ACTIVE Study Investigators. Effect of abaloparatide vs placebo on new vertebral fractures in postmenopausal women with osteoporosis: a randomized clinical trial [published correction appears in JAMA. 2017;317(4):442]. JAMA. 2016;316(7):722-733. doi: 10.1001/jama.2016.11136.[PubMed 27533157]
9. Reeve, J, "Recombinant Human Parathyroid Hormone," BMJ, 2002, 324(7335):435-6.[PubMed 11859030]
10. Saag KG, Shane E, Boonen S, et al, "Teriparatide or Alendronate in Glucocorticoid-Induced Osteoporosis," N Engl J Med, 2007, 357(20):2028-39.[PubMed 18003959]

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Prior Authorization Criteria for FULPHILA® (pegfilgrastim-jmdb)

FDA-Approved Indications:

- Prevention of Chemotherapy-Induced Neutropenia

Diagnosis: Prevention of Chemotherapy-Induced Neutropenia

1. Patient diagnosis of prophylaxis or treatment for chemotherapy induced febrile neutropenia **AND**
2. Dosage and Direction for Use:
   a. **Adults:** 6 mg SubQ once per chemotherapy cycle, beginning at least 24 hours after completion of chemotherapy. **Note:** Do not administer in the period between 14 days before and 24 hours after administration of cytotoxic chemotherapy.
   b. **Infants, Children, and Adolescents**: Weight based dosing is used for pediatric patients <45kg. Administer once per chemotherapy cycle, beginning at least 24 hours after completion of chemotherapy. Do not administer in the period between 14 days before and 24 hours after administration of cytotoxic chemotherapy.
      a. <10 kg: SubQ: 0.1 mg/kg (0.01 mL/kg)
      b. 10 to 20 kg: SubQ: 1.5 mg (0.15 mL)
      c. 21 to 30 kg: SubQ: 2.5 mg (0.25 mL)
      d. 31 to <45 kg: SubQ: 4 mg (0.4 mL)
      e. ≥45 kg: SubQ: 6 mg (0.6 mL) **AND**
3. Quantity requested does not exceed: Weight based dosage and direction **AND**
4. Confirm that plan covers MD administered medications. This is administered SubQ by a healthcare provider, but can be given at home with proper training **AND**
5. Patient is currently receiving or will be receiving myelosuppressive chemotherapy **AND**
6. Patient has a non-myeloid malignancy **AND**
7. Patient is not using in combination with another granulocyte colony-stimulating factor (G-CSF) **AND**
8. Prescribing provider is specialist such as an Oncologist.

INITIAL APPROVALS

- ✓ The dose is within FDA recommended dosing or dose is supported by compendia or medical literature.
- ✓ Initial approval will be granted for a period of 6 months

RENEWALS

- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created Criteria to combine all pegfilgrastim medications	2.2020
Updated	Updated Criteria to include new ST edits	12.2020
Updated	Updated Criteria based on ST edits	10.2021

Annual Review	updated NCCN guideline reference	10.2022
Updated	Updated criteria to include Stimufend, biosimilar to Neulasta, for Prevention of Chemotherapy-Induced Neutropenia; Combined Flynetra criteria to biosimilar document; Udenyca was added to diagnosis Hematopoietic Radiation Injury Syndrome per FDA package insert.	2.2023
Updated	Created separate criteria for Ziextenzo and Fulphila and updated format	8.2023
Annual Review	Updated NCCN guideline reference	10.2023

REFERENCE:

1. Fulphila (pegfilgrastim-jmdb) [prescribing information]. Rockford, IL: Mylan Institutional LLC; May 2021.
2. Fylnetra (pegfilgrastim-pbbk) [prescribing information]. Bridgewater, NJ: Amneal Pharmaceuticals Inc; May 2022.
3. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors. Version 1.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf
4. Neulasta (pegfilgrastim) [prescribing information]. Thousand Oaks, CA: Amgen Inc; March 2021.
5. Nyvepria (pegfilgrastim) [prescribing information]. Thousand Oaks, CA: Amgen Inc; June 2020.
6. Smith TJ, Bohlke K, Lyman GH, Carson KR, et al. Recommendations for the use of WBC growth factors: American Society of Clinical Oncology Clinical Practice Guideline Update. J Clin Oncol. 2015;33(28):3199- 3212
7. Stimufend (pegfilgrastim-fpgk) [prescribing information]. Lake Zurich, IL: Fresenius Kabi USA LLC; September 2022.
8. Udenyca (pegfilgrastim-cbqv) [prescribing information]. Redwood City, CA: Coherus BioSciences, Inc; June 2021.
9. Ziextenzo (pegfilgrastim-bmez) [prescribing information]. Princeton, NJ: Sandoz Inc; March 2021.

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Prior Authorization Criteria for FUZEON (enfuvirtide kit)

1. Patient has diagnosis of HIV-1 infection **AND**
2. Dosage and direction of use:
    a. Adults: 90 mg (1 mL) twice daily subcutaneously
    b. Pediatrics (>11 kg): 2 mg/kg twice daily subcutaneously up to a maximum of 90 mg twice daily **AND**
3. Quantity requested does not exceed: 60 vials/30 days **AND**
4. Patient is treatment-experienced **AND**
5. Patient has evidence of HIV-1 replication despite ongoing retroviral therapy **AND**
6. Prescribed by or in consultation with an infectious disease specialist or physician that specializes in HIV

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 12 months.

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided
- ✓ Approval duration for renewal: 12 months.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	No changes	3.2024

REFERENCE:

1. Fuzeon (enfuvirtide). [Prescribing information]. South San Francisco, CA: Genentech USA, Inc. December 2019.

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Prior Authorization Criteria for GALAFOLD (migalastat hcl)

1. Patient must have diagnosis of Fabry Disease **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: 123 mg once every other day **AND**
4. Quantity requested does not exceed: 14 capsules/28 days **AND**
5. Patient has an amenable galactosidase alpha gene variant based on in vitro assay data **AND**
6. Patient is not using concurrently with an ERT (Elfabrio or Fabrazyme) **AND**
7. Prescribed by or in consultation with a specialist in metabolic diseases or geneticist

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Renewals will be granted for a period of 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	12.2023

REFERENCE:

1. Galafold (migalastat). [Prescribing information]. Philadelphia, PA: Amicus Therapeutics, US, LLC. June 2023.
2. Ortiz A, Germain DP, Desnick RJ, et al. Fabry disease revisited: Management and treatment recommendations for adult patients. Mol Genet Metab 2018; 123:416.
3. Wanner C, Arad M, Baron R, et al. European expert consensus statement on therapeutic goals in Fabry disease. Mol Genet Metab 2018; 124:189.

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Prior Authorization Criteria for GATTEX (teduglutide injection)

1. Patient has diagnosis of short bowel syndrome **AND**
2. Patient is 1 year of age or older **AND**
3. Dosage and direction of use: 0.05 mg/kg once daily **AND**
4. Patient is dependent on parenteral support **AND**
5. Prescribed by or in consultation with a specialist such as a gastroenterologist or nutritional support specialist

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 6 months.

RENEWALS

✓ Documentation of positive clinical response to therapy has been provided
✓ Approval duration for renewal: 12 months.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated references	3.2024

REFERENCE:

1. Gattex (teduglutide). [Prescribing Information]. Lexington, MAL Takeda Pharmaceuticals America, Inc. February 2024.

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Prior Authorization Criteria for GAVRETO® (pralsetinib)

FDA-APPROVED INDICATIONS

- Adult patients with metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer as detected by an FDA approved test (NSCLC).
- Adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
- ✓ Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created from CAB 9.24.20	9.2020
Reviewed	Annual Review: No Changes	9.2021
Update	Added a new diagnosis requirement to the criteria sections: advanced or metastatic medullary thyroid cancer (MTC), advanced or metastatic thyroid cancer.	10.2022
Annual Review	Updated format to oncology drug format; removed MTC indication; condensed criteria; updated references	10.2023
Update	Updated duration of approval; added FDA approved age	5.2024

REFERENCE:

1. Gavreto® capsules [prescribing information]. Cambridge, MA: Blueprint Medicines; March 2024
2. Hwang JP, Feld JJ, Hammond SP, et al. Hepatitis B virus screening and management for patients with cancer prior to therapy: ASCO provisional clinical opinion update. J Clin Oncol. 2020;JCO2001757. doi:10.1200/JCO.20.01757[PubMed 32716741]
3. National Comprehensive Cancer Network. Small Cell Lung Cancer (Version 5.2022). https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed October 24, 2022.
4. National Comprehensive Cancer Network. Thyroid Carcinoma (Version 2.2022). https://www.nccn.org/professionals/physician_gls/pdf/thyroid_blocks.pdf. Accessed October 24, 2022.

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Prior Authorization Criteria for GILOTRIF (afatinib)

FDA Indications

- First-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test
- Treatment of patients with metastatic squamous NSCLC progressing after platinum-based chemotherapy

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Updated	Updated duration of approval; added FDA approved age	5.2024
Annual Review	No Changes	7.2024

REFERENCE:

1. Gilotif (afatinib). [Prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc. April 2022.

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Prior Authorization Criteria for GLEEVEC (imatinib)

FDA Indications

- Newly diagnosed adult and pediatric patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase
- Patients with Philadelphia chromosome positive chronic myeloid leukemia in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy
- Adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)
- Pediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy
- Adult patients with myelodysplastic/ myeloproliferative diseases associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements as determined with an FDA-approved test
- Adult patients with aggressive systemic mastocytosis without the D816V c-Kit mutation as determined with an FDA-approved test or with c-Kit mutational status unknown
- Adult patients with hypereosinophilic syndrome and/or chronic eosinophilic leukemia who have the FIP1L1PDGFRα fusion kinase (mutational analysis or FISH demonstration of CHIC2 allele deletion) and for patients with HES and/or CEL who are FIP1L1-PDGFRα fusion kinase negative or unknown
- Adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans
- Patients with Kit (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors
- Adjuvant treatment of adult patients following complete gross resection of Kit (CD117) positive GIST

1. Patient has an FDA approved diagnosis **AND**
2. Patient is
    a. 1 year of age or older for diagnosis of Ph+ CML or Ph+ ALL **OR**
    b. 18 years of age or older for all other indications **AND**
3. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to “Off-Label Use Policy”).
- ✓ Initial authorization will be granted for a period of 1 year
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Annual Review	Updated approval duration to 1 year	5.2024

REFERENCE:

1. Gleevec [Prescribing Information] East Hanover, NJ: Novartis; March 2024.

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Prior Authorization Criteria for GLEOSTINE (lomustine)

FDA Indications

- Brain tumors
  - Treatment of patients with primary and metastatic brain tumors following appropriate surgical and/or radiotherapeutic procedures
- Hodgkin's Lymphoma
  - Used as a component of combination chemotherapy for the treatment of patients with Hodgkin's lymphoma whose disease has progressed following initial chemotherapy

1. Patient has an FDA approved diagnosis **AND**
2. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
3. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
✓ Initial authorization will be granted for a period of 1 year

RENEWALS

✓ Documentation or claim data supports continuation of treatment
✓ Patient is responding positively to therapy and still requires the medication for induction of remission
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Annual review	Updated duration to 1 year	5.2024

REFERENCE:

1. GLEOSTINE [Prescribing Information]. Miami, FL. NextSource Biotechnology, LLC: January 2024.

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Prior Authorization Criteria for GLOPERBA® (colchicine oral solution)

1. Patient has diagnosis of gout **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: 0.6 mg (5 mL) once or twice daily **AND**
4. Quantity requested does not exceed: 1.2 mg/day **AND**
5. Requested medication is being used for prophylaxis of gout flares **AND**
6. Confirm patient does not have renal AND hepatic impairment **AND**
7. Confirm patient with renal or hepatic impairment is not taking GLOPERBA in conjunction with drugs that inhibit both CYP3A4 and P-gp (i.e., clarithromycin, ketoconazole) **AND**
8. Patient had an adequate trial of allopurinol and colchicine tablets or documentation has been provided for why the oral solution is clinically necessary

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA Criteria created based on CAB 11.21.19	12.2019
Annual Review	No Change	6.2021
Annual Review	No Change	6.2022
Annual Review	No Change	5.2023
Annual Review	Updated diagnosis wording	5.2024

REFERENCE:

1. Becker MA, Gaffo AL. Treatment of gout flares. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed October 2, 2019.
2. Becker MA. Treatment of calcium pyrophosphate crystal deposition (CPPD) disease. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed March 15, 2018a.
3. Colcrys (colchicine) [prescribing information]. Deerfield, IL: Takeda; December 2015.
4. Gloperba (colchicine) [prescribing information]. Alpharetta, GA: Avion Pharmaceuticals, LLC; July 2019.
5. Imazio M, Brucato A, Cemin R, et al; CORP (COlchicine for Recurrent Pericarditis) Investigators. Colchicine for recurrent pericarditis (CORP): a randomized trial. *Ann Intern Med.* 2011;155(7):409-414. doi: 10.7326/0003-4819-155-7-201110040-00359.[PubMed 21873705]
6. Mitigare (colchicine) [prescribing information]. Memphis, TN: Hikma Americas Inc; July 2019.

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Prior Authorization Criteria for GLP-1 RAs
BYDUREON BCISE® (exenatide) extended-release injectable suspension & BYETTA® (exenatide) injection

1. Prescriber attestation of diagnosis of Type 2 diabetes mellitus

APPROVALS

✓ Approval will be granted for a period of 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	12.2019
Updated	Added Rybelsus; Updated Trulicity in "Dosage and Administration" section due to recent expanded indication" If additional glycemic control is needed, may further increase to 3 mg once weekly after at least 4 weeks on the 1.5 mg weekly dose and then to a maximum of 4.5 mg once weekly after at least 4 weeks on the 3 mg weekly dose."; added additional requirement "Patient is not on concomitant use with a DPP-4 inhibitors such as Januvia® (sitaglitpin), Onglyza® (saxagliptin), Tradjenta®(linagliptin), or Nesina® (alogliptin)" due to lack of additive glycemic benefit, avoid concomitant use with a dipeptidyl peptidase-4 inhibitor (ADA/EASD [Davies 2018]).	10.2020
Updated	Updated PA criteria based on 2021 ADA Guidelines. Added GLP-1 RA are preferred after metformin If the patient has a compelling indication Established ASCVD, Indicators of high ASCVD risk, CKD, or compelling need to minimize weight gain or promote weight loss	3.2021
Updated	Added new indications for Victoza, Ozempic, Rybelsus, Trulicity; updated denial statement	8.2021
Updated	Remove trial criteria of at least one other oral diabetic agent and removed criteria of a trial a preferred GLP-1 RA; updated age indication for Bydureon Bcise & Trulicity.	12.2022
Updated	Updated criteria include A1C value and updated denial message.	3.2023
Updated	Created separate criteria documents for GLP1-RAs: Bydurean and Byetta to align with FAEs	5.2023
Updated	Remove "Patient is not on concomitant use with a DPP-4 inhibitor", updated compelling indications to include only "minimize weight gain/promote weight loss", add "Prescriber attestation that patient is enrolled in a diet and exercise program", "For continuation of use" under initial approvals, add "Patient has a positive response to therapy"; Updated denial messages.	7.2023
Updated	Added documentation of diagnosis requirements; removed attestation of diet and exercise program	3.2024
Updated	Updated criteria to prescriber attestation of diagnosis	6.2024

REFERENCE:

1. Bydureon BCise (exenatide) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2022.
2. Byetta (exenatide) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2022.
3. American Diabetes Association (ADA). Standards of medical care in diabetes–2022. Diabetes Care. 2022;45(suppl 1):S1-S258. https://diabetesjournals.org/care/issue/45/Supplement_1. Accessed December 14, 2022.
4. Wexler DJ. Initial management of blood glucose in adults with type 2 diabetes mellitus. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed May 14, 2019
5. ElSayed NA, Aleppo G, Aroda VR, et al., American Diabetes Association. 2. Classification and diagnosis of diabetes: *Standards of Care in Diabetes—2023*. Diabetes Care 2023;46 (Suppl. 1):S19–S40. Accessed March 30, 2023.
6. ElSayed NA, Aleppo G, Aroda VR, et al., American Diabetes Association. 9. Pharmacologic approaches to glycemic treatment: Standards of Care in Diabetes—2023. Diabetes Care 2023;46 (Suppl. 1):S140–S157. Accessed March 30, 2023.

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Prior Authorization Criteria for GLP-1 RAs – RYBELSUS (semaglutide) tablets

FDA Indication

- An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus

Diagnosis: Type 2 diabetes

1. Patient has diagnosis of Type 2 diabetes mellitus A1c of 6.5% or greater (in conjunction with diet and exercise) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Administration: 14 mg orally once daily (max dose) **AND**
4. Quantity should not exceed: 30 tab/30 days **AND**
   **Please note: QLs are in accordance with FDA approved max dose
5. Patient has an A1c of 7% or greater measured within the last 90 days (clinical documentation of A1C must be provided) **AND**
6. Patient has had an adequate trial of metformin and has not been able to obtain, or maintain adequate A1c control along with diet and exercise programs **AND**
7. Patient is not currently taking a DPP-4 inhibitor such as Januvia (sitagliptin), Onglyza (saxagliptin), Tradjenta (linagliptin), or Nesina (alogliptin)

INITIAL APPROVALS

- ✓ Type 2 diabetes: Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Patient has confirmed diagnosis of Type 2 diabetes with A1c of 6.5% or greater measured within the previous 365 days (clinical documentation of A1c must be provided) **OR**
- ✓ Clinical documentation of positive response to therapy (e.g., chart notes/labs are provided to confirm improvement in A1c levels and type 2 diabetes) **AND**
- ✓ Patient is not currently taking a DPP-4 inhibitor such as Januvia (sitagliptin), Onglyza (saxagliptin), Tradjenta (linagliptin), or Nesina (alogliptin) **AND**
- ✓ Approval will be granted for a period of 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	10.2023

REFERENCE:

1. Rybelsus (semaglutide) [product monograph]. Mississauga, Ontario, Canada: Novo Nordisk Canada Inc; February 2023.
2. American Diabetes Association (ADA). Standards of medical care in diabetes–2022. Diabetes Care. 2022;45(suppl 1):S1-S258. https://diabetesjournals.org/care/issue/45/Supplement_1. Accessed December 14, 2022.
3. Wexler DJ. Initial management of blood glucose in adults with type 2 diabetes mellitus. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed May 14, 2019
4. ElSayed NA, Aleppo G, Aroda VR, et al., American Diabetes Association. 2. Classification and diagnosis of diabetes: *Standards of Care in Diabetes—2023*. Diabetes Care 2023;46 (Suppl. 1):S19–S40. Accessed March 30, 2023.
5. ElSayed NA, Aleppo G, Aroda VR, et al., American Diabetes Association. 9. Pharmacologic approaches to glycemic treatment: Standards of Care in Diabetes—2023. Diabetes Care 2023;46 (Suppl. 1):S140–S157. Accessed March 30, 2023.

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Prior Authorization Criteria for GLP-1 RAs – OZEMPIC (semaglutide) injection

FDA Indication

- An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
- To reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease.

Diagnosis: Type 2 diabetes

1. Patient has diagnosis of Type 2 diabetes mellitus A1c of 6.5% or greater **OR** medication is prescribed to reduce the risk of cardiovascular events including cardiovascular death, non-fatal myocardial infarction, and non-fatal stroke in adults with type 2 diabetes and cardiovascular disease **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Administration: 2 mg SQ once weekly (max dose) **AND**
4. Quantity should not exceed: 3mL (1 pen)/month **AND**
   **Please note: QLs are in accordance with FDA approved max dose
5. Patient has an A1c of 7% or greater measured within the last 90 days (clinical documentation of A1C must be provided) **AND**
6. Patient has one of the following:
   a. Patient has had an adequate trial of metformin and has not been able to obtain, or maintain adequate A1c control along with diet and exercise programs **OR**
   b. Patient has established atherosclerotic cardiovascular disease (ASCVD), indicators of high ASCVD risk (age >55 years with coronary, carotid, or lower extremity artery stenosis >50%, left ventricular hypertrophy, retinopathy, or multiple CV risk factors), or Chronic Kidney Disease (CKD) (Documentation must be provided) **AND**
7. Patient is not currently taking a DPP-4 inhibitor such as Januvia (sitagliptin), Onglyza (saxagliptin), Tradjenta (linagliptin), or Nesina (alogliptin)

INITIAL APPROVALS

- ✓ Type 2 diabetes: Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Patient has confirmed diagnosis of Type 2 diabetes mellitus with an A1c of 6.5% or greater measured within the previous 365 days (clinical documentation of A1c must be provided) **OR** medication is prescribed to reduce the risk of cardiovascular events including cardiovascular death, non-fatal myocardial infarction, and non-fatal stroke in adults with type 2 diabetes and cardiovascular disease **OR**
- ✓ Clinical documentation of positive response to therapy (e.g., chart notes/labs are provided to confirm improvement in A1c levels and Type 2 diabetes) **AND**
- ✓ Patient is not currently taking a DPP-4 inhibitor such as Januvia (sitagliptin), Onglyza (saxagliptin), Tradjenta (linagliptin), or Nesina (alogliptin) **AND**
- ✓ Approval will be granted for a period of 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	10.2023

REFERENCE:

1. Ozempic (semaglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; October 2022.
2. American Diabetes Association (ADA). Standards of medical care in diabetes–2022. Diabetes Care. 2022;45(suppl 1):S1-S258. https://diabetesjournals.org/care/issue/45/Supplement_1. Accessed December 14, 2022.
3. Wexler DJ. Initial management of blood glucose in adults with type 2 diabetes mellitus. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed May 14, 2019
4. ElSayed NA, Aleppo G, Aroda VR, et al., American Diabetes Association. 2. Classification and diagnosis of diabetes: *Standards of Care in Diabetes—2023*. Diabetes Care 2023;46 (Suppl. 1):S19–S40. Accessed March 30, 2023.
5. ElSayed NA, Aleppo G, Aroda VR, et al., American Diabetes Association. 9. Pharmacologic approaches to glycemic treatment: Standards of Care in Diabetes—2023. Diabetes Care 2023;46 (Suppl. 1):S140–S157. Accessed March 30, 2023.

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Prior Authorization Criteria for TRULICITY® (dulaglutide)

FDA Indication

- As an adjunct to diet and exercise to improve glycemic control in patients 10 years and older with type 2 diabetes mellitus.
- To reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factors.

Diagnosis: Type 2 diabetes

1. Patient has diagnosis of Type 2 diabetes mellitus A1c of 6.5% or greater **OR** medication is prescribed to reduce the risk of cardiovascular events including cardiovascular death, non-fatal myocardial infarction, and non-fatal stroke in adults with type 2 diabetes and cardiovascular disease **AND**
2. Patient must meet the following age limit (one of the following):
    a. To improve glycemic control: Patient is 10 years of age or older **OR**
    b. To reduce risk of major adverse cardiovascular events: Patient is 18 years of age or older **AND**
3. Dosage and Administration: 4.5 mg SQ once weekly (max dose) **AND**
4. Quantity should not exceed: 2mL (4 pens)/month **AND**
   **Please note: QLs are in accordance with FDA approved max dose
5. Patient has an A1c of 7% or greater measured within the last 90 days (clinical documentation of A1C must be provided) **AND**
6. Patient has one of the following:
    a. Patient has had an adequate trial of metformin and has not been able to obtain, or maintain adequate A1c control along with diet and exercise programs **OR**
    b. Patient has established atherosclerotic cardiovascular disease (ASCVD), indicators of high ASCVD risk (age >55 years with coronary, carotid, or lower extremity artery stenosis >50%, left ventricular hypertrophy, retinopathy, or multiple CV risk factors), or Chronic Kidney Disease (CKD) (Documentation must be provided) **AND**
7. Patient is not currently taking a DPP-4 inhibitor such as Januvia (sitagliptin), Onglyza (saxagliptin), Tradjenta (linagliptin), or Nesina (alogliptin)

INITIAL APPROVALS

✓ Type 2 diabetes: Initial approval will be granted for a period of 1 year

RENEWALS

✓ Patient has confirmed diagnosis of Type 2 diabetes mellitus with an A1c of 6.5% or greater measured within the previous 365 days (clinical documentation of A1c must be provided) **OR** medication is prescribed to reduce the risk of cardiovascular events including cardiovascular death, non-fatal myocardial infarction, and non-fatal stroke in adults with type 2 diabetes and cardiovascular disease **OR**

✓ Clinical documentation of positive response to therapy (e.g., chart notes/labs are provided to confirm improvement in A1c levels and type 2 diabetes) **AND**

✓ Patient is not currently taking a DPP-4 inhibitor such as Januvia (sitagliptin), Onglyza (saxagliptin), Tradjenta (linagliptin), or Nesina (alogliptin) **AND**

✓ Approval will be granted for a period of 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created criteria	10.2023

REFERENCE:

1. Trulicity (dulaglutide) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; December 2022.
2. ElSayed NA, Aleppo G, Aroda VR, et al., American Diabetes Association. 2. Classification and diagnosis of diabetes: *Standards of Care in Diabetes—2023*. Diabetes Care 2023;46 (Suppl. 1):S19–S40. Accessed March 30, 2023.
3. ElSayed NA, Aleppo G, Aroda VR, et al., American Diabetes Association. 9. Pharmacologic approaches to glycemic treatment: Standards of Care in Diabetes—2023. Diabetes Care 2023;46 (Suppl. 1):S140–S157. Accessed March 30, 2023.

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Prior Authorization Criteria for OMNITROPE®
(somatropin, human growth hormone)

FDA-APPROVED INDICATIONS

- Pediatric:
  - Pediatric Growth Hormone Deficiency (GHD)
  - Turner Syndrome (TS)
  - Idiopathic Short Stature (ISS)
  - Prader-Willi Syndrome (PWS)
  - Growth Failure in Children Small for Gestational Age (SGA)
- Adults: Treatment of adults with either adult onset or childhood onset GHD

Diagnosis: for Pediatric Growth Hormone Deficiency

1. Patient has a diagnosis of Growth Hormone Deficiency (including pituitary dwarfism) **AND**
2. Pediatric patient < 18 years of age **AND**
3. Confirm the dosage is within FDA recommended dosing or dose is supported by compendia or medical literature **AND**
4. Patient meets **one** of the following auxologic evaluation (stature and growth velocity data)
   a. Current height is more than 2 standard deviations below the mid-parental height percentile for gender and age **OR**
   b. Current height is more than 3 standard deviations below their age and gender **OR**
   c. Growth velocity is > 2 SD below mean for age and gender **OR**
   d. Bone age is > 2 years behind chronological age **AND**
5. Diagnosis must be confirmed by **one** of the following criteria:
   a. Diagnosis confirmed by 2 provocative stimulation tests producing peak growth hormone concentrations <10 ng/mL (e.g. clonidine, glucagon, insulin, L-arginine, levodopa, propranolol) **OR**
   b. Patient has significant structural abnormality affecting the pituitary and 1 provocative stimulation test producing peak growth hormone concentrations below the reference range < 10ng/ml (e.g. brain MRI or CT imaging demonstrated empty sella syndrome, interruption of pituitary stalk, hypoplasia of the pituitary gland, craniofacial developmental defects, pituitary or hypothalamic tumors, etc.) **OR**
   c. Patient has panhypopituitarism, defined as at least 3 pituitary hormone deficiencies **OR**
   d. Insulin growth factor-1 (IGF-1) a.k.a. somatomedin C, or IGF binding protein-3 (IGFBP-3) levels greater than or equal to two standard deviations below normal range (reference range) for age and gender **AND**
6. Confirm open growth plates (epiphyses) in patients over 12 years of age confirmed by X-ray **AND**
7. Patient does not have any of the labeled contraindications **AND**
8. For non-preferred growth hormone formulations, patient has had an adequate trial of one preferred growth hormone formulation **AND**
9. Prescribed by or in consultation with a specialist such as an endocrinologist or neonatologist.

Diagnosis: for Adult Growth Hormone Deficiency

1. Patient has a diagnosis of Growth Hormone Deficiency **AND**
2. Patient is over 18 years of age or older **AND**
3. Confirm the dosage is within FDA recommended dosing or dose is supported by compendia or medical literature **AND**
4. Patient has ONE of the following:
   a. Patient has had 1 pretreatment pharmacologic provocative GH test and demonstrated GH level <

5 ng/mL, as a result of childhood onset growth hormone deficiency, pituitary or hypothalamic disease, surgery or radiation therapy, or trauma **OR**

b. Patient has had 1 pretreatment pharmacologic provocative GH test demonstrated GH level < 5 ng/mL and has pretreatment IGF – 1 level that is low per age and gender **OR**

c. Patient has a documented structural abnormality of the hypothalamus or pituitary and ≥ 3 documented pituitary hormone deficiency (e.g. brain MRI or CT imaging) **AND**

5. For non-preferred growth hormone formulations, patient has had an adequate trial of one preferred growth hormone formulation **AND**
6. Prescribed by or in consultation with a specialist such as an endocrinologist.

Diagnosis: for small for gestational age (SGA)

1. Patient has a diagnosis of small for gestational age (SGA) **AND**
2. Patient is ≥ 2 years of age **AND**
3. Confirm the dosage is within FDA recommended dosing or dose is supported by compendia or medical literature **AND**
4. Patient failed to manifest catch up growth by 2 years of age, defined as height more than 2 standard deviations below the mean for age and gender **AND**
5. Patient was born small for gestational age, defined as weight or length at birth more than two standard deviations below the mean for gestational age **AND**
6. Patient does not have any of the labeled contraindications **AND**
7. For non-preferred growth hormone formulations, patient has had an adequate trial of one preferred growth hormone formulation **AND**
8. Prescribed by or in consultation with an endocrinologist or neonatologist.

Diagnosis: for Turner syndrome (TS)

1. Patient has diagnosis of Turner syndrome **AND**
2. Patient is pediatric (18 years or younger) **AND**
3. Confirm the dosage is within FDA recommended dosing or dose is supported by compendia or medical literature **AND**
4. Patient is female **AND**
5. Patient current heights is more than 2 standard deviations below the mean for age and gender **AND**
6. Diagnosis was confirmed by karyotyping **AND**
7. Epiphysis is open **AND**
8. Patient does not have any of the labeled contraindications **AND**
9. For non-preferred growth hormone formulations, patient has had an adequate trial of one preferred growth hormone formulation **AND**
10. Prescribed by or in consultation with an endocrinologist or neonatologist.

Diagnosis: for Prader-Willi Syndrome (PWS)

1. Patient has a diagnosis of Prader-Willi Syndrome **AND**
2. Patient is pediatric (18 years or younger) **AND**
3. Confirm the dosage is within FDA recommended dosing or dose is supported by compendia or medical literature **AND**
4. Confirm by genetic testing any of the following
   a. Deletion in the chromosomal 15q11.2-q13 region **OR**
   b. Maternal uniparental disomy chromosome 15 **OR**
   c. Imprinting defects or translocations involving chromosome 15 **AND**
5. Patient meets one of the following auxologic evaluation (stature and growth velocity data):
   a. Individual's height is more than two standards of deviation (SD) below average for the population mean height for age and sex, AND a height velocity measured over one year is more than one SD below the mean for chronological age **OR**

   b. for children over two years of age, there is a decrease in height SD of more than 0.5 over one year **OR**
   c. individual's height velocity measured over one year is more than two SD below the mean for age and sex **OR**
   d. individual's height velocity measured over one year is more than 1.5 SD below the mean sustained over two years **AND**
6. Patient does not have any of the labeled contraindications **AND**
7. For non-preferred growth hormone formulations, patient has had an adequate trial of one preferred growth hormone formulation **AND**
8. Prescribed by or in consultation with an endocrinologist.

Diagnosis: for Idiopathic Short Stature (ISS)*

1. ISS may not be a covered indication by plans. Check with plan design to ensure coverage of non-disease indications.
2. Patient has a diagnosis of Idiopathic Short Stature **AND**
3. Confirm the dosage is within FDA recommended dosing or dose is supported by compendia or medical literature **AND**
4. Patient current height is below -2.25 standard deviations of the mean and a predicted adult height that is below the normal range; this corresponds to an adult height of less than 65 inches for males, and less than 59 inches for females **AND**
5. Epiphyses is open **AND**
6. Patient does not have any of the labeled contraindications **AND**
7. For non-preferred growth hormone formulations, patient has had an adequate trial of one preferred growth hormone formulation **AND**
8. Prescribed by or in consultation with an endocrinologist or neonatologist.

INITIAL APPROVALS

- ✓ *Please review formulary for current preferred growth hormone products. All non-formulary growth hormone formulations must first try and fail a preferred formulary growth hormone formulation
- ✓ Initial approval will be granted for a period of 1 year
- ✓ Confirm patient's current height, weight recent bone age, growth velocity, adult height of both parents (if known) and growth charts are provided for prior authorization request

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided, examples include:
  - For pediatric patients:
    - Expected final height is not achieved (i.e., at the height percentile corresponding to the mid-parental height) **AND**
    - Growth plate (epiphyses) is open in patients 12 years of age determined by X-ray **AND**
    - Member is responding positively to therapy as evidenced by Growth velocity > 2 cm/year over baseline in first year
    - Bone age is
      - Patient is male and bone age < 17 years measured in the past 12 months **OR**
      - Patient is female and bone age < 15 years measured in the past 12 months
    - Documentation of expected adult height goal (e.g. genetic potential)
  - Adult: medical necessity for continuation of therapy Chart documentation demonstrating that the

member continues to benefit from growth hormone therapy. Specific examples of benefit must be included (e.g. normalization of IGF-1 levels, improvements in cardiovascular risk markers, bone mineral density, body composition, physical exercise tolerance, quality of life, etc.)
    - Evaluation of whether or not there have been any major changes in clinical status affecting the medical necessity of GH supplementation
    - Verification that the member continues to be compliant with GH therapy and recommended follow-up with provider
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on existing criteria	6.2019
Updated	Patients are now directed to try/ fail two of preferred first line product. Reviewed under Jan' 2020 CAB meeting (2nd part).	1.2020
Annual Review	No changes	1.2021
Updated	**Pediatric GHD**: auxologic evaluation requiring height stature based on percentile now based on standard deviation, addition of growth velocity requirement, and open growth plates confirmed by x-ray. **Renewals**: Expected final height based on mid-parental height and height velocity requirement as a positive response to therapy from baseline	02.2022
Updated	Added new denial statements	3.2022
Updated	**Pediatric GHD:** Removed 2 normal stimulation tests as diagnosis option; IGF levels now based on standard deviation **HIV cachexia**: Antiretroviral therapy requirement; removed age range **SBS**: Age range updated to over 18; nutritional supplement requirement added; removed height based requirements; initial duration now 4 weeks, no renewals **SGA**: Age range updated to 2 years of age and older **TS**: auxologic evaluation requirements removed **CKD**: Age range now less than 18 years of age **ISS**: Added plan design verification for coverage of non-disease indications	4.2023
Updated	Created separate criteria for growth hormone drugs; Added trial and failure of preferred product	8.2023
Annual Review	Updated dosage to standard verbiage	4.2024

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5. Murray PG, Dattani MT, Clayton PE. Controversies in the diagnosis and management of growth hormone deficiency in childhood and adolescence. Arch Dis Child. 2016 Jan;101(1):96-100. doi: 10.1136/archdischild-2014-307228. Epub 2015 Jul 7. PMID: 26153506.
6. Grimberg A, DiVall SA, Polychronakos C, Allen DB, Cohen LE, Quintos JB, Rossi WC, Feudtner C, Murad MH; Drug and Therapeutics Committee and Ethics Committee of the Pediatric Endocrine Society. Guidelines for Growth Hormone and Insulin-Like Growth Factor-I Treatment in Children and Adolescents: Growth Hormone Deficiency, Idiopathic Short Stature, and Primary Insulin-Like Growth Factor-I Deficiency. Horm Res Paediatr. 2016;86(6):361-397. doi: 10.1159/000452150. Epub 2016 Nov 25. PMID: 27884013.

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Prior Authorization Criteria for H.P. ACTHAR® (repository corticotropin), ACTHAR® (corticotropin)

FDA-APPROVED INDICATIONS

- Infantile Spasms (West Syndrome)
- Multiple Sclerosis with Acute Exacerbation
- Rheumatic disorders (may be used, but not indicated) - **ACTHAR® (corticotropin)**
- Opthalmic disorders (may be used, but not indicated) **– ACTHAR® (corticotrophin)**

Diagnosis: for Infantile Spasms (West Syndrome) (IS)

1. Patient has diagnosis of Infantile Spasms (West Syndrome)- clinical documentation **AND**
2. Patient is < 2 years of age **AND**
3. Dosage and direction for use: 150 U/m^2 divided into twice-daily intramuscular injections of 75 U/m^2. After 2 weeks of treatment, dosing should be gradually tapered and discontinued over a 2-week period **AND**
4. Quantity requested does not exceed: dose calculated by body surface area (BSA) **AND**
5. Confirmation patient does not have a suspected congenital infection **AND**
6. H.P. Acthar® will be used as monotherapy **AND**
7. Requested dose and duration must be consistent with FDA product labeling or dose is supported by compendia or medical literature **AND**
8. Prescribed by or in consultation a Neurologist or Pediatrician

Diagnosis: for Multiple Sclerosis with Acute Exacerbation in Adults (MS)

1. Patient has diagnosis of Multiple Sclerosis with Acute Exacerbation **AND**
2. Patient is 18 years and older **AND**
3. Dosage and direction for use: 80-120 units intramuscular or subcutaneous daily for 2-3 weeks. May be necessary to taper the dose **AND**
4. Member has no contraindications to glucocorticoid effects **AND**
5. Patient has an adequate trial and failure to one high dose oral AND one high dose IV corticosteroid therapy* (ex. oral prednisone, IV methylprednisolone)
    a) High dose corticosteroid therapy =
        1. Three to seven day courses of intravenous methylprednisolone 500-1000 mg daily
        2. Three to seven day course of oral prednisone 625-1250 mg daily **AND**
6. Requested medication is not being prescribed as pulse therapy on monthly basis **AND**
7. Requested dose and duration must be consistent with FDA product labeling or dose is supported by compendia or medical literature **AND**
8. Prescribed by or in consultation with a neurologist

Diagnosis: Rheumatic disorders – for ACTHAR® (corticotropin)

1. Patient has diagnosis of Rheumatic Disorders (Psoriatic arthritis; Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy); Ankylosing spondylitis) **AND**
2. Patient is 18 years and older **AND**
3. Dosage and direction for use: 40-80 units given intramuscularly or subcutaneously every 24-72 hours. May be necessary to taper the dose **AND**
4. Member has no contraindications to glucocorticoid effects **AND**
5. Patient has an adequate trial and failure to one high dose oral AND one high dose IV corticosteroid therapy
    a) High dose corticosteroid therapy =
        1. Three to seven day courses of intravenous methylprednisolone 500-1000 mg daily
        2. Three to seven day course of oral prednisone 625-1250 mg daily **AND**
6. Patient has an adequate trial and failure to **two** DMARDS (i.e. methotrexate, sulfasalazine) unless contraindicated **AND**
7. Patient has an adequate trial and failure to **two** biologic agents from different drug classes (i.e., TNF blocker (i.e., Humira), IL-17 inhibitors (i.e., Stelara), IL-23 inhibitors (i.e., Tremfya), or JAK inhibitors (i.e., Xeljanz)) **AND**
8. Therapy is used as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation)
9. Requested dose and duration must be consistent with FDA product labeling or dose is supported by compendia or medical literature **AND**

10. Prescribed by or in consultation with a specialist such as a Rheumatologist.

Diagnosis: Opthalmic disorders – for ACTHAR® (corticotropin)

1. Patient has diagnosis of Opthalmic Disorders (severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, and anterior segment inflammation) **AND**
2. Patient is 2 years and older **AND**
3. Dosage and direction for use: 40-80 units given intramuscularly or subcutaneously every 24-72 hours. May be necessary to taper the dose **AND**
4. Patient has an adequate trial and failure of ALL the following:
    a. Systemic glucocorticoids (prednisone) unless contraindicated **AND**
    b. IV glucocorticoids unless contraindicated **AND**
    c. Steroid-sparing immunosuppressive agents (e.g., azathioprine, mycophenolate, or methotrexate) unless contraindicated **AND**
    d. Nonsteroidal anti-inflammatory drugs (NSAIDs) **AND**
5. Patient has no contraindications to glucocorticoid effects **AND**
6. Prescribed by or in consultation with a specialist such as an Ophthalmologist.

APPROVALS

✓ Approval will be granted for one time for the duration of the following indications:

- Infantile Spasms (West Syndrome) will be granted for up to 4 weeks
- Multiple Sclerosis with Acute Exacerbation will be granted for up to 3 weeks
- Rheumatic disorders will be granted up to 4 weeks
- Opthalmic disorders will be granted up to 4 weeks

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Reviewed	Reviewed based on existing criteria; no change	5.2018
Updated	Added IV corticosteroid therapy criteria for MS indication; added; default denial message; Added to new template	1.2020
Annual Review	No Change	1.2021
Annual Review	No Change	1.2022
Updated	Update to include expanded indication of Rheumatic disorders; collagen diseases – for ACTHAR® (corticotropin)	10.2022
Annual Review	No Change	1.2023
Annual Review	Update to include approval length for Rheumatic disorders for 4 weeks; updated rheumatic disorder trial and failure to 1 oral and 1 IV corticosteroid	1.2024; 9.2024
Update	Indication and criteria added for ophthalmic disorders	10.2024

REFERENCE:

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2. Coates, L.C., Soriano, E.R., Corp, N. et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. Nat Rev Rheumatol 18, 465–479 (2022). https://doi.org/10.1038/s41584-022-00798-0.
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Prior Authorization Criteria for FIRAZYR®, sajazir (icatibant)

FDA-Approved Indications:

- For the treatment of acute attacks of hereditary angioedema (HAE) in adolescent and adult patients

1. Patient has diagnosis of acute attacks of hereditary angioedema (HAE) **AND**
   2. Diagnosis is confirmed by one of the following:
      a. Documentation of presence of mutation in the C1-INH gene altering protein synthesis and/or function **OR**
      b. Both of the following
         i. Documentation of low C4 levels **AND**
         ii. Low C1-INH functional level OR low C1 inhibitor levels **AND**
3. Patient is 18 years of age or older **AND**
4. Dosage and direction of use: 30 mg administered subcutaneously upon HAE attack
   a. If symptoms recur, or response is inadequate, additional injections of 30 mg may be administered at intervals of at least 6 hours. Max 3 injections in 24 hours **AND**
5. Quantity requested does not exceed: 3 doses (30mg/3ml vial)/28 days or 90 mg/day **AND**
6. Confirm requested medication is being used for acute treatment of HAE attacks **AND**
7. For new starts: patient has had an adequate trial of generic icatibant **AND**
8. Confirm patient is not taking other medications for acute HAE attacks (i.e., Berinert, Kalbitor, Ruconest) **AND**
9. Prescribed by or in consultation with a specialist such as an immunologist, hematologist, or allergist.

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 6 months
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided **AND**
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	2.2021
Updated	Updated Criteria and combined all HAE medications	5.2021
Annual Review	No Changes	5.2022
Annual Review	Created separate criteria document for Firazyr for acute treatment of HAE	2.2023
Annual Review	Added confirmation of diagnosis requirement; added requirement that medication is being used for acute treatment	12.2023

REFERENCE:

1. Firazyr (icatibant) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America, Inc; October 2022.
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5. Orladeyo (berotralstat) [prescribing information]. Durham, NC: BioCryst Pharmaceuticals Inc; December 2020.
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8. Aygören-Pürsün E, et al. P507 BCX7353: An effective and safe oral prophylaxis against attacks of hereditary angioedema. APeX-1 final results. Ann Allergy Asthma Immunol. 2017. doi: 10.1016/j.anai.2017.09.073

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Prior Authorization Criteria for HAEGARDA®

(C1 esterase inhibitor subcutaneous [human])

FDA-Approved Indications:

- For the routine prophylaxis against angioedema attacks in patients 6 years of age older with HAE

1. Patient has diagnosis of hereditary angioedema (HAE) **AND**
   2. Diagnosis is confirmed by one of the following:
      a. Documentation of presence of mutation in the C1-INH gene altering protein synthesis and/or function **OR**
      b. Both of the following
         i. Documentation of low C4 levels **AND**
         ii. Low C1-INH functional level OR low C1 inhibitor levels **AND**
3. Patient is 6 years of age or older **AND**
4. Dosage and direction of use: 60 units/kg/dose subcutaneously (SQ) every 3 or 4 days (twice weekly) **AND**
5. Quantity requested does not exceed: 60 units/kg/dose every 3 or 4 days (twice weekly) **AND**
6. Patient has a history of at least one high severity and/or frequency HAE attack per month such as airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, or painful facial distortion **AND**
7. Confirm that Haegarda is prescribed for prophylaxis of HAE attacks **AND**
8. Confirm patient is not taking other medications for HAE prophylaxis (e.g. Orladeyo, Cinryze, Takhzyro) **AND**
9. Prescribed by or in consultation with a specialist such as an immunologist, hematologist, or allergist.

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 6 months

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided **AND**
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	2.2021
Updated	Updated Criteria and combined all HAE medications	5.2021
Annual Review	No Changes	5.2022
Annual Review	Created separate criteria document for Haegarda and added new criteria "Confirm that Haegarda is prescribed for prophylaxis of HAE attacks"	1.2023
Annual Review	Added confirmation of diagnosis requirements	12.2023

REFERENCE:

1. Busse PJ, Christiansen SC, Riedl MA, Banerji A, Bernstein JA, Castaldo AJ, Craig T, Davis-Lorton M, Frank MM, Li HH, Lumry WR, Zuraw BL. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema. J Allergy Clin Immunol Pract. 2021 Jan;9(1):132-150.e3. doi: 10.1016/j.jaip.2020.08.046. Epub 2020 Sep 6. PMID: 32898710.
2. Haegarda (C1 Esterase Inhibitor [Human]) [prescribing information]. Kankakee, IL: CSL Behring LLC; October 2017.
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Prior Authorization Criteria for ORLADEYO® (berotralstat hcl)

FDA-Approved Indications:

- For the routine prophylaxis against angioedema attacks in adults and pediatric patients 12 years and older with HAE

1. Patient has diagnosis of hereditary angioedema (HAE) **AND**
2. Diagnosis is confirmed by one of the following:
    a. Documentation of presence of mutation in the C1-INH gene altering protein synthesis and/or function **OR**
    b. Both of the following
        i. Documentation of low C4 levels **AND**
        ii. Low C1-INH functional level OR low C1 inhibitor levels **AND**
3. Patient is 12 years of age or older **AND**
4. Dosage and direction of use: One capsule (150 mg) taken orally once daily with food **AND**
5. Quantity requested does not exceed: 28 capsules/28 days **AND**
6. Patient has a history of at least one moderate to severe acute attack per month such as airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, or painful facial distortion **AND**
7. Confirm that Orladeyo is prescribed for prophylaxis of HAE attacks **AND**
8. Confirm patient is not taking other medications for HAE prophylaxis (e.g. Cinryze, Haegarda, Takhzyro) **AND**
9. Prescribed by or in consultation with an immunologist.

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 6 months

RENEWALS

✓ Documentation of positive clinical response to therapy has been provided **AND**
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 12.31.2020	1.2021
Annual review	No changes	1.2022
Annual review	Created separate criteria document for Orladeyo and added new criteria "Confirm that Orladeyo is prescribed for prophylaxis of HAE attacks"	1.2023
Annual Review	Added confirmation of diagnosis requirements	12.2023

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Prior Authorization Criteria TAKHZYRO® (lanadelumab-flyo injection)

FDA-Approved Indications:

- For the routine prophylaxis against angioedema attacks in adults and pediatric patients 2 years and older with HAE

TAKHZYRO® (lanadelumab-flyo injection)

1. Patient has diagnosis of hereditary angioedema (HAE) **AND**
2. Diagnosis is confirmed by one of the following:
    a. Documentation of presence of mutation in the C1-INH gene altering protein synthesis and/or function **OR**
    b. Both of the following
        i. Documentation of low C4 levels **AND**
        ii. Low C1-INH functional level OR low C1 inhibitor levels **AND**
3. Patient is 2 years of age or older **AND**
4. Dosage and direction of use:
    a. 2 to less than 6 years of age: 150 mg subcutaneously (SQ) once every 4 weeks
    b. 6 to less than 12 years of age: 150 mg subcutaneously (SQ) once every 2 weeks (or 4 weeks if well controlled for >6 months)
    c. 12 years of age and older: 300 mg subcutaneously (SQ) once every 2 weeks (or 4 weeks if well controlled for >6 months) **AND**
5. Quantity requested does not exceed:
    a. 2 to less than 6 years of age: 1 dose (150 mg/ml syringe)/28 days
    b. 6 to less than 12 years of age: 2 doses (150 mg/ml syringe)/28 days
    c. 12 years of age and older: 2 doses (300mg/2ml vial)/28 days **AND**
6. Patient has a history of at least one high severity and/or frequency HAE attack per month such as airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, or painful facial distortion **AND**
7. Confirm that Takhzyro is prescribed for prophylaxis of HAE attacks **AND**
8. Confirm patient is not taking other medications for HAE prophylaxis (e.g. Orladeyo, Cinryze, Haegarda) **AND**
9. Prescribed by or in consultation with a specialist such as an immunologist, hematologist, or allergist.

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 6 months

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided **AND**
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	2.2021
Updated	Updated Criteria and combined all HAE medications	5.2021
Annual Review	No Changes	5.2022
Annual Review	Created separate criteria document for Takhzyro and added new criteria "Confirm that Takhzyro is prescribed for prophylaxis of HAE attacks"	1.2023
Annual Review	Updated age range to 2 years of age and older; updated dosing; added diagnosis confirmation requirements	12.2023

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2. Aygören-Pürsün E, et al. P507 BCX7353: An effective and safe oral prophylaxis against attacks of hereditary angioedema. APeX-1 final results. Ann Allergy Asthma Immunol. 2017. doi: 10.1016/j.anai.2017.09.073
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Prior Authorization Criteria for HARVONI® (ledipasvir/sofosbuvir)

FDA-APPROVED INDICATIONS

For the treatment of chronic hepatitis C virus (HCV) in adults and pediatric patients 3 years of age and older:

- Genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis **OR**
- Genotype 1 infection with decompensated cirrhosis, in combination with ribavirin **OR**
- Genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin

1. Patient has diagnosis of Chronic Hepatitis C Virus (HCV) Genotype 1, 4, 5, or 6 **AND**
2. Patient is 3 years and older **AND**
3. Patient is one of the following:
   a. Treatment-naïve **OR**
   b. Treatment-experienced: If patient is treatment-experienced, confirm patient's prior treatment history includes either peginterferon alfa +/- ribavirin with or without a hepatitis C virus protease inhibitor **AND**
4. One of the following:
   a. Patient does not have cirrhosis **OR**
   b. Patient has compensated cirrhosis (Child-Pugh A) **OR**
   c. Patient has decompensated cirrhosis (Child-Pugh B and C) **AND**
5. Dosage and Directions for Use:
   a. For adults patients with Genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis: one tablet (90 mg ledipasvir and 400 mg sofosbuvir) taken orally once daily (28 tablets/28 days) with or without food.
   b. For pediatric patients 3 years of age and older with Genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis: dosage is based on weight.

Body Weight (kg)	Dosing of Harvoni tablets or oral pellets	Harvoni Daily Dose
At least 35	one 90 mg/400 mg tablet once daily **or** two 45 mg/200 mg tablets once daily **or** two 45 mg/200 mg packets of pellets once daily	90 mg/400 mg per day
17 to less than 35	one 45 mg/200 mg tablet once daily **or** one 45 mg/200 mg packet of pellets once daily	45 mg/200 mg per day
Less than 17	one 33.75 mg/150 mg packet of pellets once daily	33.75 mg/150 mg per day

   c. For adult and pediatric patients with decompensated cirrhosis, the above regimens are taken in combination with ribavirin (weight-based). Please check dose.
6. Quantity requested does not exceed: See table above **AND**
7. Patient has confirmed positive HCV viral load and HCV RNA test (Documentation of baseline quantitative HCV RNA test result (viral load within 6 months of beginning therapy)) **AND**
8. Patient must have no cirrhosis or compensated cirrhosis (Child-Pugh A) if one of the following:
   a. Patient has HCV genotype 1 or 4 and is liver transplant recipient
   b. Patient has HCV genotype 4, 5, or 6 AND
9. Prescribed by or in consultation with a specialist such as a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

INITIAL APPROVALS

✓ Approval Duration:

Patient population	Approval Duration
Genotype 1 – Treatment-naïve with or without compensated (Child Pugh A) cirrhosis; Treatment-experienced without cirrhosis	Harvoni 12 weeks; Harvoni for 8 weeks can be considered in treatment-naïve patients without cirrhosis who have pretreatment HCV RNA < 6 million IU/mL
Genotype 1 – Treatment-experienced with compensated (Child Pugh A) cirrhosis	Harvoni 24 weeks
Genotype 1 – Treatment-naïve and treatment-experienced with decompensated (Child-Pugh B or C) cirrhosis.	Harvoni + ribavirin 12 weeks
Genotype 1 or 4 – Transplant recipients without cirrhosis, or with compensated (Child-Pugh A) cirrhosis	Harvoni + ribavirin 12 weeks
Genotype 4, 5, or 6 – Treatment-naïve and treatment-experienced with or without compensated (Child-Pugh A) cirrhosis	Harvoni 12 weeks

✓ Generic may be subject to formulary exclusions

RENEWALS

1. **Patient Has Been Started on Harvoni (brand or generic).** Approve for an indication or condition addressed as an approval in the Recommended Authorization Criteria section (FDA-Approved Indications). Approve the duration described above to complete a course therapy (e.g., a patient who should receive 12 weeks, and has received 3 weeks should be approved for 9 weeks to complete their 12-week course).
2. **Patient had a prior null response, prior partial response, or had relapse after prior treatment.** Approve for the hepatitis C medication indicated for specific treatment-experienced patients. Approve the duration described above to complete a course therapy (e.g., a patient who should receive 12 weeks, and has received 3 weeks should be approved for 9 weeks to complete their 12-week course).

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on existing criteria	6.2019
Updated	Patients are now directed to try/ fail two of preferred first line product. Reviewed under Jan' 2020 CAB meeting (2nd part).	1.2020
Updated	Added all Hep C drugs to one policy and updated references and preferred agents; removed Daklinza and Technivie due to market removal and updated the criteria according to the change.	2.2020
Updated	Updated dosing/duration table to include Harvoni/Sovaldi's pellet pack	6.2020
Updated	Updated dosing/duration table to include Epclusa's pellet pack	6.2021
Updated	Updated format	6.2022
Updated	Updated criteria to include expanded indication and dosage of Epclusa and Mavyret to include patients 3 years of age and older; Updated expanded indication for Zepatier to include patients 12 years of age and older; Added dosage and directions of use for Epclusa, Harvoni, Mavyret, Sovaldi, Viekira Pak, Vosevi, and Zepatier.	2.2023
Updated	Separated hepatitis C criteria; Updated format; removed requirement for documentation of baseline lab results and liver damage	10.2023

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Prior Authorization Criteria for EPCLUSA® (velpatasvir/sofosbuvir)

FDA-APPROVED INDICATIONS

- Treatment of adults and pediatric patients 3 years of age and older with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis
- Treatment of adults and pediatric patients 3 years of age and older with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection with decompensated cirrhosis for use in combination with ribavirin.

1. Patient has a diagnosis of Chronic Hepatitis C Virus (HCV) Genotype 1, 2, 3, 4, 5, or 6 **AND**
2. Patient is 3 years and older **AND**
3. Patient is one of the following:
   a. Treatment-naïve **OR**
   b. Treatment-experienced: If patient is treatment-experienced, confirm the patient's prior treatment history includes peginterferon alfa/ribavirin with or without an HCV NS3/4A protease inhibitor (Victrelis (boceprevir), Olysioi (simeprevir), or Incivek (telaprevir)) **AND**
4. One of the following:
   a. Patient does not have cirrhosis **OR**
   b. Patient has compensated cirrhosis (Child-Pugh A) **OR**
   c. Patient has decompensated cirrhosis (Child-Pugh B and C) and one of the following:
      i. Requested medication will be used in combination with ribavirin **OR**
      ii. Patient is ribavirin ineligible **AND**
5. Dosage and Directions for Use:
   a. For adult patients without cirrhosis or with compensated cirrhosis: one tablet (400mg/100 mg) taken orally once daily (28 tablets/28 days)
   b. For patients 3 years of age and older without cirrhosis or with compensated cirrhosis: dosage is based on weight.

Body Weight (kg)	EPCLUSA Daily Dose	Dosing Of EPCLUSA Oral pellets	Dosing of EPCLUSA Tablet
less than 17	150 mg/37.5 mg per day	one 150 mg/37.5 mg packet of pellets once daily	N/A
17 to less than 30	200 mg/50 mg per day	one 200 mg/50 mg packet of pellets once daily	one 200 mg/50 mg tablet once daily
at least 30	400 mg/100 mg per day	two 200 mg/50 mg packets of pellets once daily	one 400 mg/100 mg tablet once daily*

* Two 200 mg/50 mg tablets once daily can be used for patients who cannot swallow the 400 mg/100 mg tablet.

   c. For adult and pediatric patients with decompensated cirrhosis, the above regimens are taken in combination with ribavirin (weight-based). Please check dose **AND**
6. Quantity requested does not exceed: See table above **AND**
7. Patient has confirmed positive HCV viral load and HCV RNA test (Documentation of baseline quantitative HCV RNA test result withing the last 6 months) **AND**
8. Prescribed by or in consultation with a specialist such as a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

INITIAL APPROVALS

✓ Approval Duration:

Patient population	Approval Duration
Genotype 1, 2, 3, 4, 5, or 6, Treatment-naïve and treatment-experienced with No Cirrhosis or Compensated Cirrhosis (Child-Pugh A):	Approve Epclusa for 12 weeks
Genotype 1, 2, 3, 4, 5, or 6, Treatment-naïve and treatment-experienced with Decompensated Cirrhosis (Child-Pugh B or C)	**1.** The patient is ribavirin-eligible, according to the prescribing physician: Approve Epclusa for **12 weeks**, if Epclusa is prescribed **in combination with ribavirin**; OR **2.** The patient is ribavirin-ineligible, according to the prescribing physician: Approve Epclusa for **24 weeks**.

✓ Generic may be subject to formulary exclusions

RENEWALS

1. **Patient Has Been Started on Epclusa (brand or generic).** Approve for an indication or condition addressed as an approval in the Recommended Authorization Criteria section (FDA-Approved Indications). Approve the duration described above to complete a course therapy (e.g., a patient who should receive 12 weeks, and has received 3 weeks should be approved for 9 weeks to complete their 12-week course)
2. **Patient had a prior null response, prior partial response, or had relapse after prior treatment.** Approve for the hepatitis C medication indicated for specific treatment-experienced patients. Approve the duration described above to complete a course therapy (e.g., a patient who should receive 12 weeks, and has received 3 weeks should be approved for 9 weeks to complete their 12-week course).

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on existing criteria	6.2019
Updated	Patients are now directed to try/ fail two of preferred first line product. Reviewed under Jan' 2020 CAB meeting (2nd part).	1.2020
Updated	Added all Hep C drugs to one policy and updated references and preferred agents; removed Daklinza and Technivie due to market removal and updated the criteria according to the change.	2.2020
Updated	Updated dosing/duration table to include Harvoni/Sovaldi's pellet pack	6.2020
Updated	Updated dosing/duration table to include Epclusa's pellet pack	6.2021
Updated	Updated format	6.2022
Updated	Updated criteria to include expanded indication and dosage of Epclusa and Mavyret to include patients 3 years of age and older; Updated expanded indication for Zepatier to include patients 12 years of age and older; Added dosage and directions of use for Epclusa, Harvoni, Mavyret, Sovaldi, Viekira Pak, Vosevi, and Zepatier.	2.2023
Updated	Separated hepatitis C criteria; Updated format; removed requirement for documentation of baseline lab results and liver damage	10.2023

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Prior Authorization Criteria for SOVALDI® (sofosbuvir)

FDA-APPROVED INDICATIONS

- Treatment of adult patients with genotype 1, 2, 3 or 4 chronic HCV infection without cirrhosis or with compensated cirrhosis as a component of a combination antiviral treatment regimen
- Treatment of Pediatric patients 3 years of age and older with genotype 2 or 3 chronic HCV infection without cirrhosis or with compensated cirrhosis in combination with ribavirin.

1. Confirm diagnosis of Chronic Hepatitis C Virus (HCV) Genotype 1, 2, 3, or 4 **AND**
2. Patient is 18 years and older **OR** 3 years and older with genotype 2 or 3 HCV without cirrhosis or with compensated cirrhosis **AND**
3. Patient is one of the following:
   a. Treatment-naïve **OR**
   b. Treatment-experienced: If patient is treatment-experienced, confirm patient's prior treatment history includes interferon-based regimen with or without ribavirin **AND**
4. One of the following
   a. Patient does not have cirrhosis **OR**
   b. Patient has compensated cirrhosis (Child-Pugh A)
      i. Note: The safety or efficacy in patients with decompensated cirrhosis has not been evaluated.
5. Dosage and Directions for Use:
   a. For adult patients with genotype 1, 2, 3 or 4 chronic HCV infection without cirrhosis or with compensated cirrhosis: one 400 mg tablet, taken orally, once daily (28 tablets/28 days) with or without food in combination with ribavirin or in combination with pegylated interferon and ribavirin **OR**
   b. For patients 3 years of age and older with genotype 2 or 3 chronic HCV infection without cirrhosis or with compensated cirrhosis: dosage is based on weight taken in combination with ribavirin. Ribavirin dose is weight-based. Please check dose.

Body Weight (kg)	Dosing of SOVALDI Tablets or Oral Pellets	SOVALDI Daily Dose
At least 35	one 400 mg tablet once daily **or** two 200 mg tablets once daily **or** two 200 mg packets of pellets once daily	400 mg per day
17 to less than 35	one 200 mg tablet once daily **or** one 200 mg packet of pellets once daily	200 mg per day
Less than 17	one 150 mg packet of pellets once daily	150 mg per day

6. Quantity requested does not exceed: See table above **AND**
7. Confirmed positive HCV viral load and HCV RNA test (Documentation of baseline quantitative HCV RNA test result (viral load within 6 months of beginning therapy)) **AND**
8. Documentation provided if patient has hepatocellular carcinoma and is awaiting liver transplant **AND**
9. Patient will be using requested medication in combination with ribavirin **AND**
10. If patient is genotype 1 or 4, confirm patient is interferon eligible; if not, see below:
    a. If patient is genotype 1 and interferon ineligible: see specific approval duration under "Initial Approval" section **OR**
    b. If patient is genotype 4 and interferon ineligible: please deny for other hep C medications (e.g. Harvoni or Epclusa) **AND**
11. Prescribed by or in consultation with a specialist such as a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

INITIAL APPROVALS

✓ Approval Duration:

Patient population	Approval Duration
Genotype 1 or 4 – treatment- naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Solvaldi + peginterferon alfa + ribavirin for 12 weeks; for genotype 1 who are interferon ineligible: Sovaldi + ribavirin for 24 weeks.
Genotype 2- treatment-naïve and treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin for 12 weeks
Genotype 3- treatment-naïve and treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin for 24 weeks
Adult patients with hepatocellular carcinoma waiting for liver transplant	Sovaldi + ribavirin for up to 48 weeks or until liver transplantation, whichever occurs first.

RENEWALS

1. **Patient Has Been Started on Sovaldi.** Approve for an indication or condition addressed as an approval in the Recommended Authorization Criteria section (FDA-Approved Indications). Approve the duration described above to complete a course therapy (e.g., a patient who should receive 12 weeks, and has received 3 weeks should be approved for 9 weeks to complete their 12-week course).
2. **Patient had a prior null response, prior partial response, or had relapse after prior treatment.** Approve for the hepatitis C medication indicated for specific treatment-experienced patients. Approve the duration described above to complete a course therapy (e.g., a patient who should receive 12 weeks, and has received 3 weeks should be approved for 9 weeks to complete their 12-week course).

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on existing criteria	6.2019
Updated	Patients are now directed to try/ fail two of preferred first line product. Reviewed under Jan' 2020 CAB meeting (2nd part).	1.2020
Updated	Added all Hep C drugs to one policy and updated references and preferred agents; removed Daklinza and Technivie due to market removal and updated the criteria according to the change.	2.2020
Updated	Updated dosing/duration table to include Harvoni/Sovaldi's pellet pack	6.2020
Updated	Updated dosing/duration table to include Epclusa's pellet pack	6.2021
Updated	Updated format	6.2022
Updated	Updated criteria to include expanded indication and dosage of Epclusa and Mavyret to include patients 3 years of age and older; Updated expanded indication for Zepatier to include patients 12 years of age and older; Added dosage and directions of use for Epclusa, Harvoni, Mavyret, Sovaldi, Viekira Pak, Vosevi, and Zepatier.	2.2023
Updated	Separated Hep C drugs; removed requirement for extent of liver damage and baseline labs	10.2023

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Prior Authorization Criteria for VOSEVI™ (sofosbuvir/velpatasvir/voxilaprevir)

FDA-APPROVED INDICATIONS

- Treatment of adult patients with chronic HCV infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor.
- Treatment of adult patients with chronic HCV infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor

1. Confirm diagnosis of Chronic Hepatitis C Virus (HCV) Genotype 1a, 1b, 2, 3, 4, 5, or 6 **AND**
2. Patient is 18 years and older **AND**
3. Patient must be treatment-experienced and meet **ONE** of the following criteria:
   a. If patient has genotype 1b, 2, 4, 5, or 6, confirm patient has an adequate trial and failure of an HCV regimen containing NS5A inhibitor (e.g. Daklinza {daclatasvir tablets}, Epclusa {sofosbuvir/velpatasvir tablets brand or generics}, Harvoni {ledipasvir/sofosbuvir tablets brand or generics}, Mavyret™ {glecaprevir/pibrentasvir tablets}, Technivie {ombitasvir/paritaprevir/ritonavir tablets}, Viekira Pak {ombitasvir/paritaprevir/ritonavir tablets; dasabuvir tablets, co-packaged}, Viekira XR {dasabuvir/ombitasvir/ paritaprevir/ritonavir extended-release tablets}, Zepatier {elbasvir/grazoprevir tablets}
   b. If patient has genotype 1a or 3, confirm ONE of the following:
      i. Patient has an adequate trial and failure of an HCV regimen containing NS5A inhibitor (e.g. Daklinza {daclatasvir tablets}, Epclusa {sofosbuvir/velpatasvir tablets brand or generics}, Harvoni {ledipasvir/sofosbuvir tablets brand or generics}, Mavyret™ {glecaprevir/pibrentasvir tablets}, Technivie {ombitasvir/paritaprevir/ritonavir tablets}, Viekira Pak {ombitasvir/paritaprevir/ritonavir tablets; dasabuvir tablets, co-packaged}, Viekira XR {dasabuvir/ombitasvir/ paritaprevir/ritonavir extended-release tablets}, Zepatier {elbasvir/grazoprevir tablets} **OR**
      ii. Patient has an adequate trial and failure of an HCV regimen containing Sovaldi (sofobusvir) WITHOUT an NS5A inhibitor (see above for NS5A inhibitor examples).
4. Patient has one of the following:
   a. Patient does not have cirrhosis **OR**
   b. Patient has compensated cirrhosis (Child-Pugh A) **AND**
      i. Note: Vosevi is not recommended in patients with moderate to severe (Child-Pugh B or C) hepatic impairment.
5. Dosage and Directions for Use: One tablet (400 mg of sofosbuvir, 100 mg of velpatasvir, and 100 mg of voxilaprevir) taken orally, once daily with food **AND**
6. Quantity requested does not exceed: 1 tabs/day or 28 tabs/28 days **AND**
7. Patient has confirmed positive HCV viral load and HCV RNA test (Documentation of baseline quantitative HCV RNA test result (viral load within 6 months of beginning therapy)) **AND**
8. Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

INITIAL APPROVALS

✓ Approval Duration: 12 weeks

RENEWALS

1. **Patient Has Been Started on Vosevi.** Approve for an indication or condition addressed as an approval in the Recommended Authorization Criteria section (FDA-Approved Indications). Approve the duration described above to complete a course therapy (e.g., a patient who should receive 12 weeks, and has received 3 weeks should be approved for 9 weeks to complete their 12-week course).
2. **Patient had a prior null response, prior partial response, or had relapse after prior treatment.** Approve for the hepatitis C medication indicated for specific treatment-experienced patients. Approve the duration described above to complete a course therapy (e.g., a patient who should receive 12 weeks, and has received 3 weeks should be approved for 9 weeks to complete their 12-week course).

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on existing criteria	6.2019
Updated	Patients are now directed to try/ fail two of preferred first line product. Reviewed under Jan' 2020 CAB meeting (2nd part).	1.2020
Updated	Added all Hep C drugs to one policy and updated references and preferred agents; removed Daklinza and Technivie due to market removal and updated the criteria according to the change.	2.2020
Updated	Updated dosing/duration table to include Harvoni/Sovaldi's pellet pack	6.2020
Updated	Updated dosing/duration table to include Epclusa's pellet pack	6.2021
Updated	Updated format	6.2022
Updated	Updated criteria to include expanded indication and dosage of Epclusa and Mavyret to include patients 3 years of age and older; Updated expanded indication for Zepatier to include patients 12 years of age and older; Added dosage and directions of use for Epclusa, Harvoni, Mavyret, Sovaldi, Viekira Pak, Vosevi, and Zepatier.	2.2023
Updated	Separated hepatitis C criteria; Updated format; removed requirement for documentation of baseline lab results and liver damage	10.2023

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Prior Authorization Criteria for HEPSERA® (adefovir dipivoxil)

1. Patient has diagnosis of chronic hepatitis B infection **AND**
2. Patient is 12 years of age or older **AND**
3. Dosage and direction of use: 10 mg once daily **AND**
4. Quantity requested does not exceed: 30 tablets/30 days **AND**
5. Patient has had a trial and failure to, intolerance to, or contraindication to tenofovir or entecavir **AND**
6. Prescribed by or in consultation with a specialist such as a gastroenterologist, hepatologist, or infectious disease specialist

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 12 months.

RENEWALS

✓ Documentation of positive clinical response to therapy has been provided
✓ Approval duration for renewal: 12 months.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Annual Review	No Changes	6.2024

REFERENCE:

1. Hepsera (adefovir dipivoxil) [prescribing information]. Foster City, CA: Gilead Sciences, Inc; December 2018.
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Prior Authorization Criteria for HETLIOZ® HETLIOZ LQ (tasimelteon)

FDA Approved Indications

- Non-24-Hour Sleep-Wake Disorder (Non-24) in adults
- Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in patients 16 years of age and older (Hetlioz capsules) or 3-15 years of age (Hetlioz LQ oral suspension)

Diagnosis: Non-24-Hour Sleep-Wake Disorder (Non-24)

1. Patient has diagnosis of non-24 hour sleep-wake disorder (N24SWD) confirmed by ONE of the following:
    - Assessment of at least one physiologic circadian phase marker (e.g. measurement of urinary melatonin levels, dim light melatonin onset [as measured by blood or saliva], assessment of core body temperature) OR
    - If assessment of at least one physiologic circadian phase marker cannot be done, the diagnosis must be confirmed by the evaluation of sleep logs recorded for at least one month **AND**
2. Patient is at least 18 years of age (capsules) **AND**
3. Dosage and direction of use: 20mg one hour prior to bedtime without food **AND**
4. Quantity requested does not exceed: 30 capsules/30 days **AND**
5. The individual is totally blind (no light perception) **AND**
6. Documented failure or inadequate response, contraindication per FDA label, intolerance, or not a candidate for at least 6 months of continuous therapy (i.e., 6 consecutive months of daily treatment) with melatonin under the guidance of a physician who specializes in the treatment sleep disorders **AND**
7. Prescribed by or in consultation with a neurologist or sleep specialist.

Diagnosis: Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)

1. Patient has diagnosis of Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)
2. Patient is
    - 16 years of age or older (capsules) OR
    - 3 years to 15 years of age (liquid oral suspension only) **AND**
3. Dosage and direction of use:
    - Capsules: 20mg/day before bedtime one hour prior to bedtime
    - Oral suspension:
        - ≤ 28kg: 0.7mg/kg one hour before bedtime without food OR
        - >28 kg: 20mg one hour before bedtime without food **AND**
4. Quantity requested does not exceed: 30 capsules/30 days or 20mg (5ml)/day (150ml/30 days ~ one 158ml bottle) **AND**
5. Documented failure or inadequate response, contraindication per FDA label, intolerance, or not a candidate for at least 6 months of continuous therapy (i.e., 6 consecutive months of daily treatment) with melatonin under the guidance of a physician who specializes in the treatment sleep disorders **AND**
6. Prescribed by or in consultation with a neurologist or sleep specialist.

INITIAL APPROVALS

- ✓ Initial approval will be for a period of 1 year
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ May renew in up to 1 year with current chart notes and other pertinent information demonstrate continued efficacy.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Revised	Created	5.2018; 5.2019
Update	Update Format/Add Denial Message	3.2020
Updated	Expanded Indication	10.2021
Annual Review	No Change	10.2022
Annual Review	Update reference; updated FDA approved indication section; added brand name may be subject to formulary exclusion language	10.2023

REFERENCE:

1. Auger RR, Burgess HJ, Emens JS, et al. Clinical practice guideline for the treatment of intrinsic circadian rhythm sleep-wake disorders: advanced sleep-wake phase disorder (ASWPD), delayed sleep-wake phase disorder (DSWPD), non-24-hours sleep-wake rhythm disorder (N24SWD), and irregular sleep-wake rhythm disorder (ISWRD). An update for 2015. J Clin Sleep Med. 215;11(10):1199-1236.
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Prior Authorization Criteria for HUMIRA® (adalimumab)

FDA-APPROVED INDICATIONS

- Rheumatoid arthritis (RA): Adult patients with moderately to severely active rheumatoid arthritis
- Juvenile idiopathic arthritis (JIA): Polyarticular Juvenile Idiopathic Arthritis: Pediatric patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis
- Psoriatic arthritis (PsA): Adult patients with active psoriatic arthritis
- Ankylosing spondylitis (AS): Adult patients with active ankylosing spondylitis
- Plaque Psoriasis (PP): Adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate
- Crohn's disease (CD): Pediatric patients 6 years of age and older with moderately to severely active Crohn's disease
- Ulcerative colitis (UC): Pediatric patients 5 years of age and older with moderately to severely active ulcerative colitis
- Hidradenitis suppurativa (HS): Moderate to severe hidradenitis suppurativa in patients 12 years of age and older
- Uveitis (UV): Adults and pediatric patients 2 years of age and older with non-infectious intermediate, posterior, and panuveitis

Diagnosis: for Rheumatoid Arthritis (RA)

1. Patient has diagnosis of moderate to severe rheumatoid arthritis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 40 mg every other week, 40 mg every week or 80 mg every other week for patients that are not receiving methotrexate **AND**
4. Quantity requested does not exceed: 4 pens (40mg per pen)/28 days or 2 pens (80mg per pen)/28 days **AND**
5. Patient has had an inadequate response or has contraindications to at least one non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide) **AND**
6. Patient is not receiving medication in combination with other biologic DMARDs **AND**
7. For non-preferred Adalimumab formulations, patient has had an adequate trial of ALL preferred Adalimumab formulations **AND**
8. Prescribed by or in consultation with a rheumatologist.

Diagnosis: for Polyarticular Juvenile Idiopathic Arthritis (JIA)

1. Patient has diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis **AND**
2. Patient is 2 years of age or older **AND**
3. Dosage and direction of use:

Pediatric Weight 2 Years of Age and Older	Recommended Dosage
10 kg (22 lbs) to less than 15 kg (33 lbs)	10 mg every other week
15 kg (33 lbs) to less than 30 kg (66 lbs)	20 mg every other week
30 kg (66 lbs) and greater	40 mg every other week

AND

4. Quantity requested does not exceed: 2 pens (10, 20, or 40mg per pen)/28 days **AND**
5. Patient has had an inadequate response or has contraindications to at least one non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide) **AND**
6. Patient is not receiving medication in combination with other biologic DMARDS **AND**
7. For non-preferred Adalimumab formulations, patient has had an adequate trial of ALL preferred Adalimumab formulations **AND**
8. Prescribed by or in consultation with a rheumatologist.

Diagnosis: for Psoriatic Arthritis (PsA) and Ankylosing Spondylitis (AS)

1. Patient has diagnosis of psoriatic arthritis OR ankylosing spondylitis **AND**
2. Patient is 18 years of age or older **AND**

3. Dosage and direction of use: 40 mg every other week, 40 mg every week or 80 mg every other week for patients that are not receiving methotrexate **AND**
4. Quantity requested does not exceed: 4 pens (40mg per pen)/28 days or 2 pens (80mg per pen)/28 days
5. Patient has had an inadequate response or has contraindications to:
    a. PsA: at least ONE non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide;
    b. AS: at least TWO scheduled/maintenance NSAIDs, each used for a duration of at least four weeks **AND**
6. Patient is not receiving medication in combination with other biologic DMARDS **AND**
7. For non-preferred Adalimumab formulations, patient has had an adequate trial of **ALL** preferred Adalimumab formulations **AND**
8. Prescribed by or in consultation with a rheumatologist.

Diagnosis: for Plaque Psoriasis (PP)

1. Patient has diagnosis of moderate to severe chronic plaque psoriasis
2. PP is affecting more than 3% of body surface area (BSA) or affecting crucial body areas (e.g., hands, feet, face, or genitals) **AND**
3. Patient is 18 years of age or older **AND**
4. Dosage and direction of use: Initial 80 mg as a single dose; maintenance: 40 mg every other week beginning 1 week after initial dose **AND**
5. Quantity requested does not exceed: initial dose: 3 pens/21 days (may vary depending on product package) maintenance: 2 pens (40mg per pen)/28 days **AND**
6. Patient has had an adequate trial and failure of UV or systemic therapy (methotrexate, acitretin, cyclosporine) AND
7. Patient has had an adequate trial and failure of topical therapy (corticosteroids, calcipotriene, calcitriol, tazarotene, tacrolimus) **AND**
8. Patient is not receiving medication in combination with other biologic DMARDS **AND**
9. For non-preferred Adalimumab formulations, patient has had an adequate trial of **ALL** preferred Adalimumab formulations **AND**
10. Prescribed by or in consultation with a rheumatologist or dermatologist.

Diagnosis: for Ulcerative Colitis (UC)

1. Patient has diagnosis of moderately to severely active ulcerative colitis (UC) **AND**
2. Patient is 5 years of age or older **AND**
3. Dosage and direction of use:
    a. Adults: Initial 160 mg (given on day 1 or split and given over 2 consecutive days), then 80 mg 2 weeks later (day 15); Maintenance: 40 mg every other week beginning day 29;
    b. Pediatric Patients 5 years of age and older:

Pediatric Weight	Recommended Dosage	
	Days 1 through 15	Starting on Day 29*
20 kg (44 lbs) to less than 40 kg (88 lbs)	Day 1: 80 mg Day 8: 40 mg Day 15: 40 mg	40 mg every other week or 20 mg every week
40 kg (88 lbs) and greater	Day 1: 160 mg (single dose or split over two consecutive days) Day 8: 80 mg Day 15: 80 mg	80 mg every other week or 40 mg every week

*Continue the recommended pediatric dosage in patients who turn 18 years of age and who are well-controlled on their HUMIRA regimen **AND**

4. Quantity requested does not exceed: Initial: 3 pens (80mg/pen)/28 days (may vary depending on product package); Maintenance: 4 pens (20mg or 40mg per pen)/28 days or 2 pens (80mg per pen)/28 days **AND**
5. Patient has the patient had an adequate trial and failure of at least ONE oral systemic agent (e.g., 6-mercaptopurine, azathioprine, methotrexate, cyclosporine, tacrolimus, corticosteroid (e.g., prednisone). A trial of a mesalamine

product does not count as a systemic therapy for ulcerative colitis **AND**

6. Patient is not receiving medication in combination with other biologic DMARDs **AND**
7. For non-preferred Adalimumab formulations, patient has had an adequate trial of ALL preferred Adalimumab formulations **AND**
8. Prescribed by or in consultation with a gastroenterologist.

Diagnosis: for Crohn's Disease (CD)

1. Patient has diagnosis of moderate to severe Crohn's disease **AND**
2. Patient is 6 years of age or older **AND**
3. Dosage and direction of use:
    a. Adults: Initial 160 mg (given on day 1 or split and given over 2 consecutive days), then 80 mg 2 weeks later (day 15); Maintenance: 40 mg every other week beginning day 29;
    b. Pediatric Patients 6 years and older:

Pediatric Weight	Recommended Dosage	
	Days 1 and 15	Starting on Day 29
17 kg (37 lbs) to less than 40 kg (88 lbs)	Day 1: 80 mg Day 15: 40 mg	20 mg every other week
40 kg (88 lbs) and greater	Day 1: 160 mg (single dose or split over two consecutive days) Day 15: 80 mg	40 mg every other week

AND

4. Quantity requested does not exceed: Initial: 3 pens (80mg/pen)/28 days (may vary depending on product package); Maintenance: 2 pens (40mg per pen)/28 days **AND**
5. Patient has the patient had an adequate trial and failure of at least one of the following: azathioprine, 6-mercaptopurine, methotrexate, glucocorticoids. A trial of a mesalamine product does not count as a systemic therapy for Crohn's disease **AND**
6. Patient is not receiving medication in combination with other biologic DMARDs **AND**
7. For non-preferred Adalimumab formulations, patient has had an adequate trial of ALL preferred Adalimumab formulations **AND**
8. Prescribed by or in consultation with a gastroenterologist.

Diagnosis: for Hidradenitis Suppurativa (HS)

1. Patient has diagnosis of Hidradenitis Suppurativa (Hurley stage II or stage III) **AND**
2. Patient is 12 years of age and older
3. Dosage and direction of use:
    a. Adults: Initial 160 mg (given on day 1 or split and given over 2 consecutive days), then 80 mg 2 weeks later (day 15); Maintenance: 40 mg every week or 80 mg every other week beginning day 29;
    b. Adolescents 12 years of age and older:

Adolescent Weight	Recommended Dosage
30 kg (66 lbs) to less than 60 kg (132 lbs)	Day 1: 80 mg Day 8 and subsequent doses: 40 mg every other week
60 kg (132 lbs) and greater	Day 1: 160 mg (given in one day or split over two consecutive days) Day 15: 80 mg Day 29 and subsequent doses: 40 mg every week or 80 mg every other week

AND

4. Quantity requested does not exceed: Initial: 3 pens (80mg/pen)/28 days (may vary depending on product package); Maintenance: 4 pens (40mg per pen)/28 days or 2 pens (80mg per pen)/28 days **AND**
5. Patient has had an adequate trial and failure of at least ONE conventional therapy (e.g. 12-week course of oral antibiotic, oral retinoid, anti-androgenic therapy (cyproterone acetate, oral contraceptive pills, spironolactone)) **AND**
6. Patient is not receiving medication in combination with other biologic DMARDs **AND**

7. For non-preferred Adalimumab formulations, patient has had an adequate trial of ALL preferred Adalimumab formulations **AND**
8. Prescribed by or in consultation with a dermatologist, rheumatologist, or gastroenterologist.

Diagnosis: for Uveitis

1. Patient has diagnosis of non-infectious intermediate, posterior, or panuveitis **AND**
2. Patient is 2 years of age and older **AND**
3. Dosage and direction of use:

Pediatric Weight 2 Years of Age and Older	Recommended Dosage
10 kg (22 lbs) to less than 15 kg (33 lbs)	10 mg every other week
15 kg (33 lbs) to less than 30 kg (66 lbs)	20 mg every other week
30 kg (66 lbs) and greater	40 mg every other week

AND

4. Quantity requested does not exceed: 2 pens (10, 20, or 40mg per pen)/28 days **AND**
5. Patient had an adequate trial of topical or oral corticosteroids (e.g., prednisolone acetate, prednisone) **AND**
6. Patient had an adequate trial of a non-biologic immunosuppressant therapy (e.g., azathioprine, methotrexate, cyclosporine, tacrolimus) **AND**
7. For non-preferred Adalimumab formulations, patient has had an adequate trial of ALL preferred Adalimumab formulations **AND**
8. Prescribed by or in consultation with an ophthalmologist

INITIAL APPROVALS

- ✓ Please review formulary for current preferred adalimumab formulations. All non-formulary adalimumab formulations must first try and fail ALL preferred formulary formulations products.
- ✓ Prescriber attestation that labs/notes indicate patient has the disease or requires the medication **AND**
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided (e.g., baseline decrease in number of plaques, improvement in skin appearance, etc.) **AND**
- ✓ Patient is not receiving medication in combination with other biologic DMARDs or phosphodiesterase 4 (PDE4) inhibitors **AND**
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	2.2013
Revised	Formatted to new template	8.2019
Updated	Added default denial message	12.2019
Reviewed	Under Jan 2020 CAB meeting, no change.	1.2020
Updated	Specified extended course duration for HS (at least 12 weeks) and added examples of systemic antibiotics	7.2020
Updated	Updated criteria for JIA, removed NSAIDs to ensure patient t/f non-biologic DMARDs	12.2020
Updated	Updated quantity and dose to include weekly dosing	4.2021
Updated	Updated criteria for UV	9.2021
Annual Review	Updated age for UC to 5 years of age or older.	2.2022
Updated	Updated denial statement for AS	3.2023
Updated	Removed non-DMARDS for AS	4.2023
Annual Review	Updated t/f verbiage for RA, JIA, PsA; PP: updated BSA requirement to 3%; AS: updated t/f requirement to at least TWO scheduled/maintenance NSAIDs for at least four weeks; UC/CD: updated	6.2023

	t/f requirement to at least one of the following: topical or oral 5-ASA agents, glucocorticoids, azathioprine, 6-mercaptopurine; Uveitis: updated dosage and t/f requirement: trial of topical or oral corticosteroids AND a non-biologic immunosuppressant therapy; Updated initial approval verbiage to include: Prescriber attestation that labs/notes indicate patient has the disease or requires the medication; Removed negative TB test requirement.	
Updated	Updated criteria to include preferred and non-preferred adalimumab verbiage, updated initial approval message, removed "completed by" column, and updated denial message.	8.2023
Annual Review	Updated format of plaque psoriasis criteria; Updated trial and failure for ulcerative colitis; updated HS criteria to require one conventional therapy	7.2024

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Prior Authorization Criteria for HYCAMTIN (topotecan capsule)

FDA-Approved Indications

- Treatment of relapsed small cell lung cancer (SCLC) in patients with a prior complete or partial response and who are at least 45 days from the end of first-line chemotherapy

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual review	Updated duration of approval; added FDA approved dx and age	5.2024

REFERENCE:

1. Hycamtin (topotecan capsule).[Prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. September 2018.

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Prior Authorization Criteria for HYFTOR™ (sirolimus topical gel)

1. Patient has a diagnosis of tuberous sclerosis complex (TSC) **AND**
2. Patient is 6 years of age or older **AND**
3. Dosage and Direction for Use: Apply to the skin on the face affected with angiofibroma twice daily. Apply 600 mg (2 cm) for patients 6 to 11 years of age and 800 mg (2.5 cm) for patients 12 years of age and older **AND**
4. Quantity requested does not exceed: 600 mg (2 cm) for patients 6 to 11 years of age and 800 mg (2.5 cm) for patients 12 years of age and older **AND**
5. Patient has 3 or more papules of angiofibroma (≥2 mm in diameter with redness in each) on the face at screening **AND**
6. Patient is not a candidate for laser therapy or surgery **AND**
7. Prescribed by or in consultation with a specialist such as a dermatologist.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 3 months.

RENEWALS

✓ Patient must indicate symptom improvement with therapy (composite improvement from baseline in size and redness of facial angiofibroma)
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 8.11.2022	8.2022
Annual Review	No Changes; Update format	8.2023
Annual Review	No Changes	3.2024

REFERENCE:

1. Hyftor (sirolimus topical) [prescribing information]. Bethesda, MD: Nobelpharma America LLC; March 2022.
2. Wataya-Kaneda M, Ohno Y, Fujita Y, et al. Sirolimus gel treatment vs placebo for facial angiofibromas in patients with tuberous sclerosis complex: a randomized clinical trial. JAMA Dermatol. 2018;154(7):781-788. doi:10.1001/jamadermatol.2018.1408[PubMed 29800026]
3. Krakowski AC, et al. Inhibition of angiofibromas in a tuberous sclerosis patient using topical timolol 0.5% gel. *Pediatrics*. 2015;136(3):e709‘13. doi: 10.1542/peds.2015-0025
4. Macri A, et al. Cutaneous angiofibroma. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022. Accessed August 4, 2022. https://www.ncbi.nlm.nih.gov/books/NBK482470/
5. Wataya-Kaneda M, et al. Clinical and histologic analysis of the efficacy of topical rapamycin therapy against hypomelanotic macules in tuberous sclerosis complex. *JAMA Dermatol*. 2015;151(7):722‘730. doi:10.1001/jamadermatol.2014.4298

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Prior Authorization Criteria for HYRIMOZ® (adalimumab-adaz) & Adalimumab-adaz (Sandoz), high-concentration formulation

FDA-APPROVED INDICATIONS

- Rheumatoid arthritis (RA): Adult patients with moderately to severely active rheumatoid arthritis
- Juvenile idiopathic arthritis (JIA): Polyarticular Juvenile Idiopathic Arthritis: Pediatric patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis
- Psoriatic arthritis (PsA): Adult patients with active psoriatic arthritis
- Ankylosing spondylitis (AS): Adult patients with active ankylosing spondylitis
- Plaque Psoriasis (PP): Adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate
- Crohn's disease (CD): Pediatric patients 6 years of age and older with moderately to severely active Crohn's disease
- Ulcerative colitis (UC): Adult patients 18 years of age and older with moderately to severely active ulcerative colitis
- Hidradenitis suppurativa (HS): Moderate to severe hidradenitis suppurativa in patients 18 years of age and older
- Uveitis (UV): Adults patients 18 years of age and older with non-infectious intermediate, posterior, and panuveitis

Diagnosis: for Rheumatoid Arthritis (RA)

1. Patient has diagnosis of moderate to severe rheumatoid arthritis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 40 mg every other week, 40 mg every week or 80 mg every other week for patients that are not receiving methotrexate **AND**
4. Quantity requested does not exceed: 4 pens (40mg per pen)/28 days or 2 pens (80mg per pen)/28 days **AND**
5. Patient has had an inadequate response or has contraindications to at least one non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide) **AND**
6. Patient is not receiving medication in combination with other biologic DMARDS **AND**
7. For non-preferred Adalimumab formulations, patient has had an adequate trial of **ALL** preferred Adalimumab formulations **AND**
8. Prescribed by or in consultation with a rheumatologist.

Diagnosis: for Polyarticular Juvenile Idiopathic Arthritis (JIA)

1. Patient has diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis **AND**
2. Patient is 2 years of age or older **AND**
3. Dosage and direction of use:

Pediatric Weight 2 Years of Age and Older	Recommended Dosage
10 kg (22 lbs) to less than 15 kg (33 lbs)	10 mg every other week
15 kg (33 lbs) to less than 30 kg (66 lbs)	20 mg every other week
30 kg (66 lbs) and greater	40 mg every other week

AND

4. Quantity requested does not exceed: 2 pens (10, 20, or 40mg per pen)/28 days **AND**
5. Patient has had an inadequate response or has contraindications to at least one non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide) **AND**
9. Patient is not receiving medication in combination with other biologic DMARDS **AND**
10. For non-preferred Adalimumab formulations, patient has had an adequate trial of **ALL** preferred Adalimumab formulations **AND**
11. Prescribed by or in consultation with a rheumatologist.

Diagnosis: for Psoriatic Arthritis (PsA) and Ankylosing Spondylitis (AS)

1. Patient has diagnosis of psoriatic arthritis OR ankylosing spondylitis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 40 mg every other week, 40 mg every week or 80 mg every other week for patients that are not receiving methotrexate **AND**
4. Quantity requested does not exceed: 4 pens (40mg per pen)/28 days or 2 pens (80mg per pen)/28 days
5. Patient has had an inadequate response or has contraindications to:
    a. PsA: at least ONE non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide;
    b. AS: at least TWO scheduled/maintenance NSAIDs, each used for a duration of at least four weeks; **AND**
6. Patient is not receiving medication in combination with other biologic DMARDS **AND**
7. For non-preferred Adalimumab formulations, patient has had an adequate trial of **ALL** preferred Adalimumab formulations **AND**
8. Prescribed by or in consultation with a rheumatologist.

Diagnosis: for Plaque Psoriasis (PP)

1. Patient has diagnosis of moderate to severe chronic plaque psoriasis
2. PP is affecting more than 3% of body surface area (BSA) or affecting crucial body areas (e.g., hands, feet, face, or genitals) **AND**
3. Patient is 18 years of age or older **AND**
4. Dosage and direction of use: Initial 80 mg as a single dose; maintenance: 40 mg every other week beginning 1 week after initial dose **AND**
5. Quantity requested does not exceed: initial dose: 3 pens/21 days (may vary depending on product package) maintenance: 2 pens (40mg per pen)/28 days **AND**
6. Patient has had an adequate trial and failure of both UV or systemic therapy (methotrexate, acitretin, cyclosporine) **AND**
7. Patient has had an adequate trial and failure of topical therapy (corticosteroids, calcipotriene, calcitriol, tazarotene, tacrolimus) **AND**
8. Patient is not receiving medication in combination with other biologic DMARDS **AND**
9. For non-preferred Adalimumab formulations, patient has had an adequate trial of **ALL** preferred Adalimumab formulations **AND**
10. Prescribed by or in consultation with a rheumatologist or dermatologist.

Diagnosis: for Ulcerative Colitis (UC)

1. Patient has diagnosis of moderately to severely active ulcerative colitis (UC) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: Initial 160 mg (given on day 1 or split and given over 2 consecutive days), then 80 mg 2 weeks later (day 15); Maintenance: 40 mg every other week beginning day 29 **AND**
4. Quantity requested does not exceed: Initial: 3 pens (80mg/pen)/28 days (may vary depending on product package); Maintenance: 4 pens (20mg or 40mg per pen)/28 days or 2 pens (80mg per pen)/28 days **AND**
5. Patient has the patient had an adequate trial and failure of at least ONE oral systemic agent (e.g., 6-mercaptopurine, azathioprine, methotrexate, cyclosporine, tacrolimus, corticosteroid (e.g., prednisone). A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis **AND**
6. Patient is not receiving medication in combination with other biologic DMARDs **AND**
7. For non-preferred Adalimumab formulations, patient has had an adequate trial of **ALL** preferred Adalimumab formulations **AND**
8. Prescribed by or in consultation with a gastroenterologist.

Diagnosis: for Crohn's Disease (CD)

1. Patient has diagnosis of moderate to severe Crohn's disease **AND**
2. Patient is 6 years of age or older **AND**
3. Dosage and direction of use:
    a. Adults: Initial 160 mg (given on day 1 or split and given over 2 consecutive days), then 80 mg 2 weeks later (day 15); Maintenance: 40 mg every other week beginning day 29;
    b. Pediatric Patients 6 years and older:

Pediatric Weight	Recommended Dosage	
	Days 1 and 15	Starting on Day 29
17 kg (37 lbs) to less than 40 kg (88 lbs)	Day 1: 80 mg Day 15: 40 mg	20 mg every other week
40 kg (88 lbs) and greater	Day 1: 160 mg (single dose or split over two consecutive days) Day 15: 80 mg	40 mg every other week

AND

4. Quantity requested does not exceed: Initial: 3 pens (80mg/pen)/28 days (may vary depending on product package); Maintenance: 2 pens (40mg per pen)/28 days **AND**
5. Patient has the patient had an adequate trial and failure of at least one of the following: azathioprine, 6-mercaptopurine, methotrexate, glucocorticoids. A trial of a mesalamine product does not count as a systemic therapy for Crohn's disease **AND**
6. Patient is not receiving medication in combination with other biologic DMARDs **AND**
7. For non-preferred Adalimumab formulations, patient has had an adequate trial of ALL preferred Adalimumab formulations **AND**
8. Prescribed by or in consultation with a gastroenterologist.

Diagnosis: for Hidradenitis Suppurativa (HS)

1. Patient has diagnosis of moderate to severe Hidradenitis Suppurativa (Hurley stage II or stage III) **AND**
2. Patient is 18 years of age and older **AND**
3. Dosage and direction of use: Initial 160 mg (given on day 1 or split and given over 2 consecutive days), then 80 mg 2 weeks later (day 15); Maintenance: 40 mg every week or 80 mg every other week beginning day 29 **AND**
4. Quantity requested does not exceed: Initial: 3 pens (80mg/pen)/28 days (may vary depending on product package); Maintenance: 4 pens (40mg per pen)/28 days or 2 pens (80mg per pen)/28 days **AND**
5. Patient has had an adequate trial and failure of at least ONE conventional therapy (e.g. 12-week course of oral antibiotic, oral retinoid, anti-androgenic therapy (cyproterone acetate, oral contraceptive pills, spironolactone)) **AND**
6. Patient is not receiving medication in combination with other biologic DMARDs **AND**
7. For non-preferred Adalimumab formulations, patient has had an adequate trial of ALL preferred Adalimumab formulations **AND**
8. Prescribed by or in consultation with a dermatologist, rheumatologist, or gastroenterologist

Diagnosis: for Uveitis

1. Patient has diagnosis of non-infectious intermediate, posterior, or panuveitis **AND**
2. Patient is 18 years of age and older **AND**
   Dosage and direction of use: Initial 80 mg as a single dose; maintenance: 40 mg every other week beginning 1 week after initial dose **AND**
3. Quantity requested does not exceed: 2 pens (10, 20, or 40mg per pen)/28 days **AND**
4. Patient had an adequate trial of topical or oral corticosteroids (e.g., prednisolone acetate, prednisone) **AND**
5. Patient had an adequate trial of a non-biologic immunosuppressant therapy (e.g., azathioprine, methotrexate, cyclosporine, tacrolimus) **AND**
6. Patient is not receiving medication in combination with other biologic DMARDs **AND**
7. For non-preferred Adalimumab formulations, patient has had an adequate trial of ALL preferred Adalimumab formulations **AND**
8. Prescribed by or in consultation with an ophthalmologist

INITIAL APPROVALS

- ✓ Please review formulary for current preferred adalimumab formulations. All non-formulary adalimumab products must first try and fail ALL preferred formulary adalimumab formulations.
- ✓ Prescriber attestation that labs/notes indicate patient has the disease or requires the medication **AND**
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided (e.g., baseline decrease in number of plaques, improvement in skin appearance, etc.) **AND**
- ✓ Patient is not receiving medication in combination with other biologic DMARDs or phosphodiesterase 4 (PDE4) inhibitors **AND**
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created criteria for new adalimumab formulations	8.2023
Annual Review	Updated format of plaque psoriasis criteria; Updated trial and failure for ulcerative colitis; updated HS criteria to require one conventional therapy	7.2024

REFERENCE:

1. Adalimumab injection [product monograph]. Kirkland, Quebec, Canada: Pfizer Canada ULC; January 2021.
2. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations: Part II: Topical, intralesional, and systemic medical management. J Am Acad Dermatol. 2019 Jul;81(1):91-101. doi: 10.1016/j.jaad.2019.02.068. Epub 2019 Mar 11. PMID: 30872149; PMCID: PMC9131892.
3. Amjevita (adalimumab) [prescribing information]. Thousand Oaks, CA: Amgen Inc; April 2023
4. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. Arthritis Care Res. 2011; 63(4):465-482.
5. Braun J, van den berg R, et al. 2010 Update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. Am Rheu Dis. 2011; 70:896-904
6. Cyltezo (adalimumab) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; May 2023.
7. Feuerstein JD, Ho EY, Shmidt E, et al; American Gastroenterological Association Institute Clinical Guidelines Committee. AGA clinical practice guidelines on the medical management of moderate to severe luminal and perianal fistulizing Crohn's disease. Gastroenterology 2021;160:2496-2508. (https://doi.org/10.1053/j.gastro.2021.04.022)
8. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology. 2020 Apr;158(5):1450-1461. doi: 10.1053/j.gastro.2020.01.006. Epub 2020 Jan 13. PMID: 31945371; PMCID: PMC7175923.
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10. Hadlima and Hadlima PushTouch (adalimumab) [product monograph]. Kirkland, Quebec, Canada: Organon Canada Inc; December 2022.
11. Hulio (adalimumab) [product monograph]. Etobicoke, Ontario, Canada: BGP Pharma ULC; May 2023.
12. Humira Prescribing Information. North Chicago, IL: AbbVie, Inc.; January 2019. Available at: http://www.rxabbvie.com/pdf/humira.pdf. Accessed February 26, 2019.
13. Hyrimoz (adalimumab) [product monograph]. Boucherville, Québec, Canada: Sandoz Canada Inc; September 2021.
14. Idacio (adalimumab) [product monograph]. Toronto, Ontario, Canada: Fresenius Kabi Canada Ltd; October 2020.
15. Kolasinski SL, Neogi T, Hochberg MC, etc. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee. Arthritis Care Res (Hoboken). 2020 Feb;72(2):149-162. doi: 10.1002/acr.24131. Epub 2020 Jan 6. Erratum in: Arthritis Care Res (Hoboken). 2021 May;73(5):764. PMID: 31908149.
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17. Lichtenstein GR, Loftus Jr. EV, Isaacs KI, Regueiro MD, Gerson LB, and Sands BE. ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2018; 113:481-517.
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20. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011; 65(1):137-174.
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22. Singh JA, Furst DE, Bharat A, et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. Arthritis Care Res. 2012; 64(5):625-639
23. Smolen JS, Landewé R, Breedveld FC, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2013 update. Ann Rheum Dis. 2014; 73:492-509.
24. Ward MM, Deodhar A, Aki EA, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2015. DOI 10.1002/ART.39298.
25. Yuflyma (adalimumab) [prescribing information]. Jersey City, NJ: Celltrion USA Inc; May 2023.
26. Yuflyma (adalimumab) [product monograph]. Toronto, Ontario, Canada: Celltrion Healthcare Canada Limited; December 2021.

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Prior Authorization Criteria for ICLUSIG (ponatinib hcl)

FDA Indications

- Chronic Myeloid Leukemia (CML)
  - Chronic phase (CP) chronic myeloid leukemia (CML) with resistance or intolerance to at least two prior kinase inhibitors
  - Accelerated phase (AP) or blast phase (BP) CML or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) for whom no other kinase inhibitors are indicated
  - T315I-positive CML (chronic phase, accelerated phase, or blast phase) or T315I-positive Ph+ ALL.
- Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ ALL)
  - Newly diagnosed Ph+ ALL in combination with chemotherapy
  - As monotherapy in Ph+ ALL for whom no other kinase inhibitors are indicated or T315I-positive Ph+ ALL

1. Patient has an FDA approved diagnosis **AND**
2. Patient is 18 years of age or older **AND**
3. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated indication to include PH+ALL; updated duration to 1 year	5.2024

REFERENCE:

1. ICLUSIG [Prescribing Information]. Lexington, MA. Takeda Pharmaceuticals America, Inc: March 2023.

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Prior Authorization Criteria for IDHIFA (enasidenib)

FDA-Approved Indications

- Treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated duration of approval; added FDA approved dx and age	5.2024

REFERENCE:

1. IDHIFA. [Prescribing Information]. Princeton, NJ. Celgene Corporation: December 2023.

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Prior Authorization Criteria for IGALMI ™ (dexmedetomidine)

1. Patient has a diagnosis of schizophrenia or bipolar I or II disorder **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use:

Patient Population	Agitation Severity	Initial Dose*	Maximum Recommended Total Daily Dosage
Adults	Mild or Moderate	120 mcg	240 mcg
	Severe	180 mcg	360 mcg
Patients with Mild or Moderate Hepatic Impairment*	Mild or Moderate	90 mcg	210 mcg
	Severe	120 mcg	240 mcg
Patients with Severe Hepatic Impairment*	Mild or Moderate	60 mcg	180 mcg
	Severe	90 mcg	210 mcg
Geriatric Patients (≥ 65 years old)	Mild, Moderate, or Severe	120 mcg	240 mcg

*Hepatic Impairment: **Mild** (Child-Pugh Class A); **Moderate** (Child-Pugh Class B); **Severe** (Child-Pugh Class C)
Note: If agitation persists, up to two additional doses may be administered at least 2 hours apart.

4. Quantity should not exceed: See table above. Maximum of 3 doses per agitation episode.
5. Requested medication is being used for acute treatment of agitation associated with schizophrenia or bipolar I or II disorder **AND**
6. Patient has had an adequate trial of at least two antipsychotics for acute agitation (e.g., olanzapine, ziprasidone) unless contraindicated **AND**
7. Prescribed by or in consultation with a psychiatrist.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ May renew in up to 12 month intervals when patient does not show evidence of disease progression and criteria above continue to be met.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 6.2.2022	6.2022
Annual Review	Updated criteria to include t/f of two antipsychotics for acute agitation and removed benzodiazepine requirement; Updated denial message.	6.2023
Annual Review	Removed contraindications	5.2024

REFERENCE:

1. Igalmi (dexmedetomidine) [prescribing information]. New Haven, CT: BioXcel Therapeutics Inc; April 2022.
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Prior Authorization Criteria for IMBRUVICA® (ibrutinib)

FDA-APPROVED INDICATIONS

- Adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)
- Adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) with 17p deletion
- Adult patients with Waldenström's macroglobulinemia (WM)
- Adult and pediatric patients age 1 year and older with chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy

Diagnosis: Chronic Lymphocytic Leukemia/Small Lymphocytic lymphoma/Waldenstrom's Macroglobulinemia

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

Diagnosis: for Chronic Graft-Versus-Host Disease

1. Patient has diagnosis of cGVHD **AND**
2. Patient is 1 year of age or older **AND**
3. Dosage and direction of use:
    - Patients 12 years and older: 420 mg orally once daily
    - Patients 1 to less than 12 years of age: 240 mg/m^2 orally once daily. BSA >1.6: 420mg/6 mL oral suspension once daily. Please refer to package insert for full dose recommendation chart based on BSA **AND**
4. Quantity requested does not exceed:
    - Patients 12 years and older: 28 tablets/28 days or 90 capsules/30 (1 tablet or 3 capsules/day) **AND**
    - Patients 1 to less than 12 years of age: 420 mg (6 ml)/dose 180 ml/30 days for patients with a BSA range >1.6 **AND**
5. Patient has a history of bone marrow/stem cell transplant **AND**
6. Patient has had trial and failure of at least one prior line of systemic therapy for GVHD (ex: corticosteroids, mycophenolate mofetil, cyclosporine, tacrolimus, sirolimus) **AND**
7. Prescribed by or in consultation with is an oncologist, hematologist, or bone marrow transplant specialist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	9.2019
Update	Update Format / Renewals	6.2020
Update	Annual Review: No Change	6.2021
Reviewed	Annual Review: No Change	6.2022

Update	Added pediatric expansion for cGVHD and new oral suspension formulation; Updated denial message for cGVHD	10.2022
Annual Review	Removed MZL and MCL from FDA approved indications; updated formatting; removed requirement to step through tablets; updated references	10.2023
Update	Updated duration of approval; added FDA approved age language for oncology indications	5.2024
Annual Review	Updated criteria from t/f of corticosteroid to t/f of 1 line of systemic therapy based on clinical studies	9.2024

REFERENCE:

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3. Lampson BL, Yu L, Glynn RJ, et al. Ventricular arrhythmias and sudden death in patients taking ibrutinib. Blood. 2017;129(18):2581-2584.[PubMed 28223277]
4. Mato AR, Islam P, Daniel C, et al. Ibrutinib-induced pneumonitis in patients with chronic lymphocytic leukemia. Blood. 2016;127(8):1064-1067.[PubMed 26702066]
5. Miklos D, Cutler CS, Arora M, et al. Ibrutinib for chronic graft-versus-host disease after failure of prior therapy. Blood. 2017;130(21):2243-2250. doi: 10.1182/blood-2017-07-793786.[PubMed 28924018]
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7. National Comprehensive Cancer Network. B-Cell Lymphoma (Version 5.2022). https://www.nccn.org/professionals/physician_gls/pdf/b-cell_blocks.pdf. Accessed Oct 13, 2022.
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Prior Authorization Criteria for IMPAVIDO® (miltefosine)

1. Patient has diagnosis of leishmaniasis **AND**
2. Patient is 12 years of age or older **AND**
3. Dosage and direction of use:
    a. 30 kg-44 kg: 50 mg capsule twice daily for 28 days
    b. 45 kg or greater: 50 mg three times daily for 28 days **AND**
4. Quantity requested does not exceed: 84 capsules/28 days **AND**
5. Disease is one of the following:
    a. Visceral leishmaniasis caused by *Leishmania donovani* **OR**
    b. Cutaneous leishmaniasis caused by *Leishmania braziliensis*, *Leishmania guyanensis*, and *Leishmania panamensis* **OR**
    c. Mucosal leishmaniasis caused by *Leishmania braziliensis* **AND**
6. Confirm patient is not pregnant **AND**
7. Prescribed by or in consultation with a specialist such as an infectious disease physician

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 1 month

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated reference and format; Added confirmation patient is not pregnant	7.2024

REFERENCE

1. Impavido (miltefosine). [Prescribing information]. Orlando, FL. Profounda, Inc. May 2021.

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Prior Authorization Criteria for INBRIJA™ (levodopa)

1. Patient has confirmed diagnosis of Parkinson's disease **AND**
2. Patient is at least 18 years of age **AND**
3. Dosage and Directions for use:
    - Inhale the contents of two capsules (84 mg) as needed for OFF symptoms, up to 5 times daily.
    - The maximum dose per OFF period is 84 mg, and the maximum recommended daily dosage is 420 mg **AND**
4. Quantity requested does not exceed: 300 capsules/30 days **AND**
5. Patient is experiencing intermittent OFF episodes related to Parkinson's disease **AND**
6. Confirm patient is currently on and will continue to receive treatment with oral carbidopa/levodopa **AND**
7. Documentation that attempts have been made to adjust dosage or formulation of carbidopa/levodopa to manage OFF symptoms **AND**
8. Patient had an inadequate trial or has been intolerant to at least one of the following different classes of medications for the management of OFF symptoms related to Parkinson's disease:
    a. Dopamine agonists (i.e., pramipexole, ropinirole) **OR**
    b. Catechol-O-methyl transferase (COMT) inhibitors (i.e., entacapone) **OR**
    c. Monoamine oxidase (MAO) B inhibitors (i.e., selegiline) **AND**
9. Patient does not have asthma, COPD, or other chronic underlying lung disease **AND**
10. Patient has not taken a non-selective MAO inhibitor in the previous two weeks **AND**
11. Prescribed by or in consultation with a specialist such as neurologist or specialist in the treatment of Parkinson's disease

INITIAL APPROVALS

✓ Initial approval will be for a period of 12 months.

RENEWALS

✓ May renew in up to 12 month intervals when the current chart notes, and other pertinent information demonstrate patient has experienced a positive response, stabilization of disease or in absence of disease progression AND absence of unacceptable toxicity from the drug.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	5.2019
Update	Add Denial Message	6.2020
Update	Annual Review. Update criteria to include adequate trial of alternatives and a specialist; added default denial message	6.2021
Annual Review	No Change	6.2022
Annual Review	Added requirement for dose/formulation adjustments of carbidopa/levodopa to manage OFF episodes; Removed psychiatric condition exclusion; changed diagnosis language	6.2023
Annual Review	Updated references	5.2024

REFERENCE:

1. Inbrija (levodopa) [prescribing information]. Ardsley, NY: Acorda Therapeutics, Inc; August 2020.
2. Lloyd KG, Davidson L, Hornykiewicz O. The neurochemistry of Parkinson's disease: effect of L-dopa therapy. J Pharmacol Exp Ther. 1975;195(3):453-464.[PubMed 489]
3. Connolly BS, Lang AE. Pharmacological treatment of Parkinson disease: a review. JAMA 2014; 311:1670.
4. Seier M, Hiller A. Parkinson's disease and pregnancy: An updated review. Parkinsonism Relat Disord. 2017;40:11-17. doi:10.1016/j.parkreldis.2017.05.007.[PubMed 28506531]
5. Miyasaki JM, Martin W, Suchowersky O, Weiner WJ, Lang AE. Practice parameter: initiation of treatment for Parkinson's disease: an evidence-based review: report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2002 Jan 8;58(1):11-7.

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Prior Authorization Criteria for INGREZZA® (valbenazine)

FDA Approved Indications

- Chorea associated with Huntington's disease
- Tardive dyskinesia

Chorea associated with Huntington's disease

1. Patient has a diagnosis of chorea associated with Huntington disease confirmed by genetic testing **AND**
2. Patient is 18 years and older **AND**
3. Dosage and direction of use: Initial: 40 mg once daily; titrate up to maintenance dose of 80 mg once daily **AND**
4. Quantity requested does not exceed: 30 capsules/30 days **AND**
5. Patient is not on concomitant therapy with other vesicular monoamine transporter 2 (VMAT2) inhibitors such as Xenazine (tetrabenazine) or Ingrezza (valbenazine) **AND**
6. Prescribed by or in consultation with a neurologist

Tardive dyskinesia

1. Patient has a diagnosis of moderate to severe tardive dyskinesia **OR**
2. Patient is 18 years and older **AND**
3. Dosage and direction of use: Initial: 40 mg once daily; titrate up to maintenance dose of 80 mg once daily **AND**
4. Quantity requested does not exceed: 30 capsules/30 days **AND**
5. One of the following:
    a. Patient has symptoms despite a trial dose reduction or discontinuation of medication known to cause tardive dyskinesia **OR**
    b. Patient is not a candidate for a trial dose reduction or discontinuation of medications known to cause tardive dyskinesia **AND**
6. Patient is not on concomitant therapy with other vesicular monoamine transporter 2 (VMAT2) inhibitors such as Xenazine (tetrabenazine) or Ingrezza (valbenazine) **AND**
7. Prescribed by or in consultation with a neurologist or psychiatrist

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 1 year.

RENEWALS

✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	11.2019
Update	Add Denial Message	9.2020
Annual Review	No Changes	9.2021
Updated	Updated diagnosis	5.2022
Annual Review	No Changes	5.2023
Updated	Added expanded indication for chorea associated with Huntington disease	11.2023
Annual Review	Split indications into separate criteria pathways	5.2024

REFERENCE:

1. Ingrezza (valbenazine) [prescribing information]. San Diego, CA: Neurocrine Biosciences Inc; August 2023.
2. Factor SA, Remington G, Comella CL, et al. The effects of valbenazine in participants with tardive dyskinesia: Results of the 1-year KINECT 3 extension study. J Clin Psych. 2017;78(9):1344-1350. doi: 10.4088/JCP.17m11777.[PubMed 29141124]
3. Factor S, Comella C, Correll C, et al. Efficacy of valbenazine (NBI-98854) in subjects with tardive dyskinesia: Results of a long-term study (KINECT 3 extension) (S56.005). Neurology. April 18, 2017; 88(16): S56.005.
4. Bhidayasiri R, Fahn S, Weiner WJ, et al. Evidence-based guideline: Treatment of tardive syndromes. Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2013; 31: 463-469.
5. Ricciardi L, Pringsheim T, Barnes TRE, Martino D, Gardner D, Remington G, Addington D, Morgante F, Poole N, Carson A, Edwards M. Treatment Recommendations for Tardive Dyskinesia. Can J Psychiatry. 2019 Jun;64(6):388-399. doi: 10.1177/0706743719828968. Epub 2019 Feb 21. PMID: 30791698; PMCID: PMC6591749.

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Prior Authorization Criteria for AIMOVIG® (erenumab-aooe)

Diagnosis: preventive treatment of episodic and chronic migraine

1. Patient has diagnosis of:
    a. Episodic migraine (4-14 headache days per month or headaches that last longer than 12 hours) **OR**
    b. Chronic migraine (15 or more headache days per month for more than 3 months) **AND**
2. Patient is 18 years of age and older **AND**
3. Dosage and direction of use: Administer 70 mg subcutaneously once monthly; some patients may benefit from a dosage of 140 mg once monthly **AND**
4. Quantity requested does not exceed: 70 mg or 140 mg given subcutaneously (SC) once per month (1 injection/month) **AND**
5. Patient has a trial and failure of **TWO** prophylactic medications from at least two different therapeutic classes, each consisting of an 8-week trial unless clinically significant adverse effects are experienced, or all are contraindicated:
    a. antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate)
    b. beta-blockers (e.g., metoprolol, propranolol, timolol)
    c. antidepressants (e.g., amitriptyline, venlafaxine) **AND**
6. Medication is not prescribed concurrently with another CGRP inhibitor when used for migraine prevention

INITIAL APPROVALS

✓ For chronic/episodic migraine: Initial approval will be granted for a period of 1 year

RENEWALS

✓ Patient has experienced a positive response with a reduction in headache frequency, duration, or intensity
✓ For chronic/episodic migraine: 1 year

HISTORY

ACTION	SUMMARY OF CHANGES	DATE
Reviewed	Reviewed based on existing criteria – created group Injectable CGRP criteria	3.2019
Updated	Added default denial message and added to new template	1.2020
Annual Review	Removed Requirement of "prescribed by a neurologist or pain specialist"	3.2020
Updated	Included additional off-label alternatives based on guideline recommendations	10.2020
Annual Review	No Changes	10.2021
Updated/ Annual Review	Removed Botox from criteria.	9.2022/ 10.2022
Reviewed	Created separate criteria for CGRP drug Aimovig and updated default denial message.	8.2023
Updated	Added 8-week trial of preventative therapy	10.2023
Annual Review	No changes	8.2024

REFERENCE:

1. Aimovig (erenumab-aooe) [prescribing information]. Thousand Oaks, CA: Amgen Inc; May 2023.
2. Ailani J, Lipton RB, Goadsby PJ, et al; ADVANCE Study Group. Atogepant for the preventive treatment of migraine. N Engl J Med. 2021;385(8):695-706. doi:10.1056/NEJMoa2035908[PubMed 34407343]
3. American Family Physician. Treatment of Acute Migraine Headache. Gilmore and Michael. Am Fam Physician. 2011; 83:271-280. Accessed August 30, 2022.
4. American Headache Society. Information for Clinicians: Practice Parameters, Guidelines and Classification. Accessed August 30, 2022.
5. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. Headache. 2019;59:1-18.

6. American College of Obstetricians and Gynecologists (ACOG). ACOG Committee on Clinical Practice Guidelines–Obstetrics. Headaches in pregnancy and postpartum: ACOG clinical practice guideline no. 3. Obstet Gynecol. 2022;139(5):944-972. doi:10.1097/AOG.0000000000004766[PubMed 35576364]
7. Pellesi L, Do TP, Ashina H, Ashina M, Burstein R. Dual therapy with anti-CGRP monoclonal antibodies and botulinum toxin for migraine prevention: is there a rationale? Headache. 2020;60:1056-1065.
8. Boinpally R, Jakate A, Butler M, Borbridge L, Periclou A. Single-dose pharmacokinetics and safety of atogepant in adults with hepatic impairment: results from an open-label, phase 1 trial. Clin Pharmacol Drug Dev. 2021;10(7):726-733. doi:10.1002/cpdd.916[PubMed 33501783]
9. Burch R, et al. The prevalence and burden of migraine and severe headache in the United States: updated statistics from government health surveillance studies. Headache. 2015;55(1):21-34. doi:10.1111/head.12482 Migraine.com. How common is migraine? Published April 19, 2021. Accessed August 30, 2022. https://migraine.com/migraine-statistics
10. Reuter U, Goadsby PJ, Lanteri-Minet M, et al. Efficacy and tolerability of erenumab in patients with episodic migraine in whom two-to-four previous preventive treatments were unsuccessful: a randomised, double-blind, placebo-controlled, phase 3b study. Lancet. 2018;392(10161):2280-2287. doi:10.1016/S0140-6736(18)32534-0[PubMed 30360965]
11. Ailani J, Burch RC, Robbins MS; Board of Directors of the American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. 2021 Jul;61(7):1021-1039. doi: 10.1111/head.14153. Epub 2021 Jun 23. PMID: 34160823.

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Prior Authorization Criteria for AJOVY® (fremanezumab-vfrm)

Diagnosis: preventive treatment of episodic and chronic migraine

1. Patient has diagnosis of:
    a. Episodic migraine (4-14 headache days per month or headaches that last longer than 12 hours) **OR**
    b. Chronic migraine (15 or more headache days per month for more than 3 months) **AND**
2. Patient is 18 years of age and older **AND**
3. Dosage and direction of use: Administer225 mg subcutaneously monthly or 675 mg every 3 months (quarterly), administered as three consecutive subcutaneous injections of 225 mg each **AND**
4. Quantity requested does not exceed: 225 mg (1 injection) once monthly or 675 mg (3 injections) every 3 months **AND**
5. Patient has a trial and failure of **TWO** prophylactic medications from at least two different therapeutic classes, each consisting of an 8-week trial unless clinically significant adverse effects are experienced, or all are contraindicated:
    a. antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate)
    b. beta-blockers (e.g., metoprolol, propranolol, timolol)
    c. antidepressants (e.g., amitriptyline, venlafaxine) **AND**
6. Medication is not prescribed concurrently with another CGRP inhibitor when used for migraine prevention

INITIAL APPROVALS

✓ For chronic/episodic migraine: Initial approval will be granted for a period of 1 year

RENEWALS

✓ Patient has experienced a positive response with a reduction in headache frequency, duration, or intensity
✓ For chronic/episodic migraine: 1 year

HISTORY

ACTION	SUMMARY OF CHANGES	DATE
Reviewed	Reviewed based on existing criteria – created group Injectable CGRP criteria	3.2019
Updated	Added default denial message and added to new template	1.2020
Annual Review	Removed Requirement of "prescribed by a neurologist or pain specialist"	3.2020
Updated	Included additional off-label alternatives based on guideline recommendations	10.2020
Annual Review	No Changes	10.2021
Updated/ Annual Review	Removed Botox from criteria.	9.2022/10.2022
Reviewed	Created separate criteria for CGRP drug Ajovy and updated default denial message.	8.2023
Updated	Added 8-week trial of preventative therapy	10.2023
Annual Review	Updated references	8.2024

REFERENCE:

1. Ajovy (fremanezumab-vfrm) [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc; October 2022.
2. Ailani J, Lipton RB, Goadsby PJ, et al; ADVANCE Study Group. Atogepant for the preventive treatment of migraine. N Engl J Med. 2021;385(8):695-706. doi:10.1056/NEJMoa2035908[PubMed 34407343]
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Prior Authorization Criteria for EMGALITY® (galcanezumab-gnlm)

FDA-Approved Indications

- Preventive treatment of migraine in adults
- Treatment of episodic cluster headache in adults

Diagnosis: preventive treatment of episodic and chronic migraine

1. Patient has diagnosis of:
    a. Episodic migraine (4-14 headache days per month or headaches that last longer than 12 hours) **OR**
    b. Chronic migraine (15 or more headache days per month for more than 3 months) **AND**
2. Patient is 18 years of age and over **AND**
3. Dosage and directions for use: 240 mg (two-consecutive subcutaneous injections of 120 mg each) once as a loading dose, followed by monthly doses of 120 mg **AND**
4. Quantity requested does not exceed: 2 injections/loading dose or 1 injection/month (maintenance dose)
5. Patient has a trial and failure of **TWO** prophylactic medications from at least two different therapeutic classes, each consisting of an 8-week trial unless clinically significant adverse effects are experienced, or all are contraindicated:
    a. antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate)
    b. beta-blockers (e.g., metoprolol, propranolol, timolol)
    c. antidepressants (e.g., amitriptyline, venlafaxine) **AND**
6. Medication is not prescribed concurrently with another CGRP inhibitor when used for migraine prevention

Diagnosis: treatment of episodic cluster headache

1. Patient has diagnosis of episodic cluster headache (8 attacks per day, a minimum of 1 attack every other day, and at least 4 attacks during the previous 7-day period) **AND**
2. Patient is 18 years of age and over **AND**
3. Dosage and directions for use: 300 mg subcutaneously at the onset of the cluster period and once monthly until the end of the cluster period (administered as three consecutive subcutaneous injections of 100 mg each) **AND**
4. Quantity requested does not exceed: 3 injections/onset or 3 injections/month **AND**
5. Patient has an adequate trial of at least two generic triptans, unless contraindicated as follows:
    a. History of coronary artery disease or cardiac accessory conduction pathway disorders
    b. History of stroke, transient ischemic attack, or peripheral vascular disease
    c. Ischemic bowel disease, uncontrolled hypertension, or severe hepatic impairment
    d. Diagnosis of complicated headaches, hemiplegic, or basilar migraine
6. Medication is not prescribed concurrently with another CGRP inhibitor when used for migraine prevention

INITIAL APPROVALS

- ✓ For chronic/episodic migraine: Initial approval will be granted for a period of 1 year
- ✓ For episodic cluster headache: 3 months or estimated duration of the cluster period (whichever is shorter)

RENEWALS

- ✓ Patient has experienced a positive response with a reduction in headache frequency, duration or intensity
- ✓ For chronic/episodic migraine: 1 year
- ✓ For episodic cluster headache: 3 months or estimated duration of the cluster period (whichever is shorter)

HISTORY

ACTION	SUMMARY OF CHANGES	DATE
Reviewed	Reviewed based on existing criteria – created group Injectable CGRP criteria	3.2019
Updated	Added default denial message and added to new template	1.2020
Annual Review	Removed Requirement of "prescribed by a neurologist or pain specialist"	3.2020
Updated	Add additional dosing and criteria for Emgality's new indication- cluster headache	5.2020
Updated	Included additional off-label alternatives based on guideline recommendations	10.2020
Annual Review	No Changes	10.2021
Updated/ Annual Review	Removed Botox from criteria.	9.2022/10.2022
Reviewed	Created separate criteria for CGRP drug Emgality and updated default denial message	8.2023
Updated	Added contraindications to triptans	10.2023
Annual Review	Updated format; updated references	8.2024

REFERENCE:

1. Emgality (galcanezumab-gnlm) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; March 2021.
2. American Family Physician. Treatment of Acute Migraine Headache. Gilmore and Michael. Am Fam Physician. 2011; 83:271-280. Accessed August 30, 2022.
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Prior Authorization Criteria for INLYTA (axitinib)

FDA-Approved Indications

- First-line Advanced Renal Cell Carcinoma
  - First-line treatment of patients with advanced renal cell carcinoma (RCC), in combination with avelumab
  - First-line treatment of patients with advanced renal cell carcinoma (RCC), in combination with pembrolizumab
- Second-Line Advanced Renal Cell Carcinoma
  - Treatment of advanced RCC after failure of one prior systemic therapy, as a single agent

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
✓ Initial authorization will be granted for a period of 1 year

RENEWALS

✓ Documentation or claim data supports continuation of treatment
✓ Patient is responding positively to therapy and still requires the medication for induction of remission
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Annual Review	Updated duration of approval; added FDA approved dx and age wording; added indication section	5.2024

REFERENCE:

1. INLYTA [Prescribing Information]. New York, NY. Pfizer Labs: September 2022.

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Prior Authorization Criteria for Insulin Pump Supplies

	Brand/Model	Indication	FDA approved age	Maintenance Supplies
Tr a	**Medtronic** MiniMed 630G	Type 1 & 2 Diabetes	> 14 years old	Minimed Reservoirs: should be replaced when the reservoir is empty. Minimed Infusion Sets: should be replaced every 48 to 72 hours. Devices should not exceed one per covered period.
Disposable	**Insulet** OmniPod/OmniPod Dash	Type 1 & Type 2 Diabetes	≥ 2 years old	Omnipod 5 Pack/Omnipod Dash 5 Pack/PODS (15/30 days): Pods should be replaced every 48 to 72 hours or after delivering 200 units of insulin (U-100 rapid-acting insulin analogs). Number of Pods does not exceed 15 per month. OMNIPOD DASH INTRO KIT & OMNIPOD 5 G6 INTRO KIT: 1 time fill
		Type 2 Diabetes	≥ 18 years old	Omnipod GO (10/30 days): Pods should be replaced every 72 hours. Number of Pods does not exceed 10 per month.
	Valeritas VGO 20, 30, and 40 Kit	Type 2 Diabetes	≥ 21 years old	V-GO 20/30/40 devices (30/30 days): the V-Go is filled with insulin using the EZ Fill. Each EZ Fill is only intended to fill a 30-day supply of V-Go devices (1 V-Go per day). Number of V-Go devices does not exceed 30 per month.

Please note:

- The listed insulin pump products are not all-inclusive. Due to advanced technology, a new generation of the same brand product(s) may have different approved age limit. Some products may be covered under medical benefits. Reviewers are encouraged to check product label for updates.
- For continuation of insulin pumps, Maxor adjudication system has "COT (continuation of therapy) Grandfather" in place to allow claims to be processed without PA rejection upon initial PA approval.

Any insulin pump supplies shall require a prior authorization to help insure that these supplies meet the following criteria:

1. Confirm patient has diagnosis of diabetes mellitus **AND**
2. Patient meets FDA-approved age requirement **AND**
3. Patient has been using a blood glucose monitor (BGM) and performing frequent testing FOUR or more times per day or is using CGM **AND**
4. Patient is insulin dependent with three or more daily injections **AND**
5. Patient's insulin regimen requires frequent adjustment due to unstable A1c or frequent hypoglycemic episodes **AND**
6. Patient meets **one** or more of the following criteria while on the multiple daily injection regimen:
    a. Glycosylated hemoglobin level (HbAlc) > 7.0% **OR**
    b. History of recurring hypoglycemia **OR**
    c. Wide fluctuations in blood glucose before mealtime **OR**
    d. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl **OR**
    e. History of severe glycemic excursions.
7. The patient is capable of using an insulin pump, and the severity of the Diabetes Mellitus warrants the use of an insulin pump versus traditional methods of insulin delivery **AND**
8. The quantity of insulin pump supplies needed, are deemed reasonable for standard insulin pump therapy.

INITIAL APPROVALS

✓ Initial review may be granted for up to 1 year.

RENEWALS

✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	3.2017; 3.2018; 3.2019
Update	Update Format/Add Denial Message	3.2020
Update	Update PA criteria per CAB 12.16.21	12.2021
Update	Update QL for Omnipod to 15/30	3.2022
Update	Update QL for Omnipod Intro Kits to 1 time fill.	5.2022
Annual Review	Updated format and references	3.2023
Update	Added Omnipod Go based on CAB 5.18.23	5.2023
Updated	Separated out formulary products for APC	8.2023
Annual Review	Updated format	3.2024

References

1. Diabetes Technology: Standards of Medical Care in Diabetes—2021 American Diabetes Association Diabetes Care Jan 2021, 44 (Supplement 1) S85-S99; DOI: 10.2337/dc21-S007
2. Omnipod Insulin Management System and Omnipod DASH Insulin Management System 510(k) summary, No. K182630. Acton, MA: Insulet Corporation; January 2019. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf18/K182630.pdf. Accessed November 12, 2021.
3. Omnipod Insulin Management System User Guide PDM Model UST400. Rev B September 2017. Available at: https://www.myomnipod.com/podder-support. Accessed November 12, 2021.
4. VGO Wearable Insulin Delivery Prescribing and Dosing. Valeritas Inc. https://www.go-vgo.com/hcp/prescribing- dosing/overview/ Accessed Nov 2021.
5. Medtronic. Minimed 630G System User Guide. 2017. Available at: https://www.medtronicdiabetes.com/sites/default/files/library/download-library/user-guides/MiniMed%20630G%20System%20User%20Guide%20-%2020-Mar-2018.pdf
6. American Diabetes Association. Standards of medical care in diabetes - 2021. Available at: http://professional.diabetes.org/ResourcesForProfessionals.aspx?cid=84160. Accessed November 12, 2021.
7. Blevins T, Shwartz SL, Bode B et al. A study assessing an injection port for administration of insulin. Diabetes Spectrum. 2008;21(3):197–202.
8. LeRoith D, Biessels GJ, Braithwaite SS, et al. Treatment of diabetes in older adults: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2019 May 1;104(5):1520-1574.
9. Layne JE, Parkin CG, Zisser H, et al. Efficacy of a tubeless patch pump in patients with type 2 diabetes previously treated with multiple daily injections. J Diabetes Sci Technol. 2017;11(1):178-179.

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Prior Authorization Criteria for IRESSA (gefitinib)

FDA-Approved Indications

- First-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist.

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Updated	Updated duration to 1 year; update to oncology template	5.2024

REFERENCE:

1. Iressa (gefitinib). [Prescsribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals. February 2023.

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Prior Authorization Criteria for IWILFIN™ (eflornithine)

1. Patient has an FDA approved diagnosis **AND**
2. Dosage and direction of use:

Body Surface Area (m^2)	Dosage
>1.5	768 mg (four tablets) orally twice a day
0.75-1.5	576 mg (three tablets) orally twice a day
0.5 to <0.75	384 mg (two tablets) orally twice a day
0.25 to <0.5	192 mg (one tablet) orally twice a day

AND

3. Quantity requested does not exceed: 120 tablets/30 days **AND**
4. Patient has demonstrated partial response to prior multiagen, multimodality therapy, including anti-GD2 immunotherapy **AND**
5. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
6. Prescribed by or in consultation with an oncologist.

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created from CAB 1.11.2024	1.2024

REFERENCE:

1. Iwilfin (eflornithine) [prescribing information]. Louisville, KY: USWM, LLC; December 2023.

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Prior Authorization Criteria for JAKAFI® (ruxolitinib)

FDA-APPROVED INDICATIONS

- Intermediate or high-risk myelofibrosis (MF): in adults, including:
  - Primary MF
  - Post-polycythemia vera (post-PV MF)
  - Post-essential thrombocythemia (post-ET MF)
- Polycythemia vera (PCV): in adults who have had an inadequate response to or are intolerant to hydroxyurea
- Steroid-refractory acute graft-versus-host disease (GVHD): in adults and pediatric patients 12 years and older
- Chronic graft-versus-host disease: after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older

Diagnosis: for Myelofibrosis, Polycythemia vera (PCV)

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with a hematologist or oncologist

Diagnosis: for Acute Graft-Versus-Host Disease

1. Patient has diagnosis of steroid-refractory acute GVHD **OR**
2. Patient is 12 years of age or older **AND**
3. Dosage and direction of use: starting dose of 5 mg given orally twice daily. May be increased to 10 mg if the ANC and platelet counts are not decreased by 50% or more relative to the first day of dosing with Jakafi.
4. Quantity requested does not exceed: max dose 20 mg/day **AND**
5. Patient has had an adequate trial of systemic corticosteroids **AND**
6. Prescribed by or in consultation with an oncologist, hematologist, or bone marrow transplant specialist

Diagnosis: for Chronic Graft-Versus-Host Disease

1. Patient has diagnosis of chronic graft-versus-host disease (cGVHD) **AND**
2. Patient is 12 years of age or older **AND**
3. Dosage and direction of use: starting dose of 10 mg given orally twice daily **AND**
4. Quantity requested does not exceed: max dose 20 mg/day **AND**
5. Patient has had trial and failure of one or two prior lines of systemic therapy for GVHD (ex: corticosteroids, mycophenolate mofetil, cyclosporine, tacrolimus, sirolimus, Imbruvica) **AND**
6. Prescribed by or in consultation with an oncologist, hematologist, or bone marrow transplant specialist

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 12 months

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	11.2021
Update	Update dosage	2.2022
Annual Review	Added criteria for Myelofibrosis to require that patient is not eligible for allogeneic HCT or not a transplant candidate	11.2022
Annual Review	Updated format; MF: Removed requirement for transplant; MF/PCV: Removed lab values and added follows appropriate sequence of therapy	11.2023
Annual Review	Combined oncology indications; added FDA approved diagnosis and age language for oncology indications; separated acute vs chronic GVHD; updated renewal section	9.2024

REFERENCE:

1. Jakafi Prescribing Information. Wilmington, DE: Incyte Corporation; January 2023.
2. National Comprehensive Cancer Network. Myeloproliferative Neoplasms (Version 3.2022). https://www.nccn.org/professionals/physician_gls/pdf/mpn_blocks.pdf. Accessed November 12th, 2022.
3. Hydroxyurea. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; Hydroxyurea. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.;
4. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed January 13, 2021.
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7. Zeiser R, Burchert A, Lengerke C, et al. Ruxolitinib in corticosteroid-refractory graft versus host disease after allogeneic stem cell transplantation: a multicenter survey. Leukemia. 2015; 29(10):2062-8.
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Prior Authorization Criteria for JATENZO® (testosterone undecanoate)

1. Patient has diagnosis of a condition associated with a deficiency or absence of endogenous testosterone (e.g., primary or secondary hypogonadism) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: Initial dose of 237 mg orally once in the morning and once in the evening. Adjust the dose to a maximum dose of 396 mg twice daily **AND**
4. Quantity requested does not exceed: 120/30 days or 396 mg (two-198mg capsules) twice daily **AND**
5. Documentation of serum testosterone level < 300 ng/dL on at least 2 separate days or less than the reference range for labs within the last 6 months **AND**
6. Patient had an adequate trial of at least one generic testosterone product (e.g., testosterone cypionate injection, topical testosterone, testosterone transdermal patches).

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Approval duration for renewal 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA Criteria created based on CAB 1.16.2020	1.2020
Annual Review	No Changes	1.2021
Update	Added Tlando from CAB 4.21.22	4.2022
Annual Review	Updated diagnosis to include: Patient has diagnosis of a condition associated with a deficiency or absence of endogenous testosterone such primary or secondary hypogonadism; Update references; Remove specialist requirement	4.2023
Updated	Created separate criteria for Jatenzo and updated format	8.2023
Annual Review	No Change; Updated format	2.2024

REFERENCES:

1. 2019 American Geriatrics Society Beers Criteria Update Expert Panel. American Geriatrics Society 2019 updated AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc. 2019;67(4):674-694. doi: 10.1111/jgs.15767.[PubMed 30693946]
2. Jatenzo (testosterone) oral [prescribing information]. Northbrook, IL: Clarus Therapeutics Inc; June 2019.
3. Testosterone enanthate injection [prescribing information]. Eatontown, NJ: West-Ward Pharmaceutical; November 2016.
4. Testosterone Gel [prescribing information]. Baudette, MN: ANI Pharmaceuticals, Inc; October 2016.
5. Tlando (testosterone capsules) [prescribing information]. Ewing, NJ: Antares Pharma Inc; March 2022.
6. Jayasena CN, Anderson RA, Llahana S, et al. Society for Endocrinology guidelines for testosterone replacement therapy in male hypogonadism. Clinical Endocrinology. 2022 February; 96(2): 200-219.
7. Mulhall JP, Trost LW, Brannigan RE, et al. Evaluation and management of testosterone deficiency AUA guideline. American Urological Association. Published 2018. Available at: https://www.auajournals.org/doi/10.1016/j.juro.2018.03.115
8. Basin S, Brito JP, Cunningham GR, et al. Testosterone therapy in men with hypogonadism: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2018; 103(5): 1715-1744. Available at: https://academic.oup.com/jcem/article/103/5/1715/4939465.

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Prior Authorization Criteria for JELMYTO® (mitomycin)

FDA-Approved Indications

- Treatment of adult patients with low-grade Upper Tract Urothelial Cancer (LG-UTUC)

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist or urologist.

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 3 months (6 instillations per kidney)

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient has achieved complete response after 3 months of Jelmyto therapy
- ✓ Approval duration for renewal: 1 year (up to 11 additional instillations per kidney)

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 6.4.2020	6.2020
Annual Review	No Changes	6.2021
Annual Review	No Changes	6.2022
Annual Review	Revised/updated dosage and direction for use; added "urologist" specialist requirement; updated denial message	5.2023
Annual Review	Updated initial approval to 3 months and renewal to 1 year; added requested medication follows appropriate therapy language; added patient has achieved complete response to renewal criteria; added FDA approved dx and age	5.2024

REFERENCE:

1. Jelmyto (mitomycin) [prescribing information]. Princeton, NJ: UroGen Pharma Inc; September 2022.
2. Perry MC, ed. Chemotherapeutic agents: mitomycin. The Chemotherapy Source Book. 5th ed. Philadelphia, PA: 2012.
3. US Department of Health and Human Services; Centers for Disease Control and Prevention; National Institute for Occupational Safety and Health. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings 2016. http://www.cdc.gov/niosh/topics/antineoplastic/pdf/hazardous-drugs-list_2016-161.pdf. Updated September 2016. Accessed May 5, 2020.
4. National Comprehensive Cancer Network. Bladder Cancer (Version 2.2023). https://www.nccn.org/professionals/physician_gls/pdf/bladder_blocks.pdf. Accessed May 10, 2023.

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Prior Authorization Criteria for JOENJA® (leniolisib phosphate)

1. Patient has a diagnosis of activated phosphoinositide 3-kinase delta syndrome (APDS) **AND**
2. Patient is 12 years of age and older **AND**
3. Dosage and direction for use: 70 mg orally twice daily in patients weighing 45 kg or greater **AND**
4. Quantity requested does not exceed: 60 tabs/30 days **AND**
5. Patient has documented genetic test confirming APDS/PASLI-associated genetic PI3K delta mutation (e.g., *PIK3CD* and/or *PIK3R1)* **AND**
6. Patient has at least one clinical finding or manifestation consistent with APDS/PASLI (e.g., nodal and/or extranodal lymphoproliferation, recurrent sinopulmonary infections, hepatomegaly, splenomegaly, organ dysfunction) **AND**
7. Prescribed by or in consultation with a specialist specializing in APDS such as an immunologist.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Patient has positive clinical response in signs and manifestations of APDS
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 4.20.2023	4.2023
Annual Review	Updated criteria requirement to include patient has at least one clinical finding or manifestation consistent with APDS/PASLI.	4.2024

REFERENCE:

1. Joenja (leniolisib) [prescribing information]. Fallavier, France: Skyepharma Production; March 2023.
2. Rao VK, Webster S, Šedivá A, et al. A randomized, placebo-controlled phase 3 trial of the PI3Kδ inhibitor leniolisib for activated PI3Kδ syndrome. Blood. 2023;141(9):971-983. doi:10.1182/blood.2022018546[PubMed 36399712]
3. Costagliola G, et al. Autoimmunity in primary immunodeficiency disorders: an updated review on pathogenic and clinical implications. J Clin Med. 2021;10(20):4729. doi:10.3390/jcm10204729
4. Craig M, et al. Activated phosphoinositide 3-kinase δ syndrome associated with nephromegaly, growth hormone deficiency, bronchiectasis: a case report. Allergy Asthma Clin Immunol. 2022;18(1):15. doi:10.1186/s13223-022-00655-5
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6. Ewertowska, M., Grześk, E., Urbańczyk, A. et al. Activated phosphoinositide 3-kinase delta syndrome 1 and 2 (APDS 1 and APDS 2): similarities and differences based on clinical presentation in two boys. Allergy Asthma Clin Immunol 16, 22 (2020). https://doi.org/10.1186/s13223-020-00420-6
7. Coulter TI and Cant AJ (2018) The Treatment of Activated PI3Kδ Syndrome. Front. Immunol. 9:2043. doi: 10.3389/fimmu.2018.02043

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Prior Authorization Criteria for JUXTAPID® (lomitapide)

1. Patient has a confirmed diagnosis of homozygous familial hypercholesterolemia (HoFH) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 5 mg once daily. Increase dose based on response to treatment up to a maximum of 60 mg daily **AND**
4. Quantity requested does not exceed: 60 mg/day **AND**
5. The diagnosis is confirmed by one of the following (clinical documentation and lab results required):
    a. The diagnosis is supported by genetic testing showing TWO generic mutations for LDLR, APOB, PCSK9 or ARH adaptor protein 1/LDLRAP1 gene locus **OR**
    b. Patient has an untreated low-density lipoprotein cholesterol (LDL-C) level > 500 mg/dL or a treated LDL-C ≥ 300 mg/dL AND one of the following:
        i. Both parents have documented elevated LDL-C before lipid-lowering treatment (pre-treatment) consistent with a diagnosis of heterozygous familial hypercholesterolemia [e.g. untreated LDL-C >190 mg/dL] **OR**
        ii. Presence of cutaneous or tendon xanthoma before 10 years of age **AND**
6. One of the following:
    a. Patient has been compliant (at least 12 weeks) with the maximum tolerated dose of a statin and will continue the statin while taking requested medication **OR**
    b. If patient has statin intolerant, confirm one of the following (documentation required)
        i. The patient has had two retrials with lower dose statins, alternative statins or less frequent dosing **OR**
        ii. The patient has had experienced rhabdomyolysis or muscle symptoms with CK elevation > 10 times ULN **AND**
7. Patient has tried and failed therapy with ezetimibe in combination with statin therapy (or alone if statin intolerant) for at least 12 weeks **AND**
8. Patient has a current LDL-C level of > 100 mg/dL (without ASCVD) or >70 mg/dL (with ASCVD) or >55mg/dl (with extreme risk designation) after at least three months treatment with maximally tolerated statin dose, unless statin intolerant, and ezetimibe **AND**
9. This agent is not being taken with another PCSK9 inhibitor or Kynamro **AND**
10. Prescribed by or in consultation with a specialist such as a cardiologist, an endocrinologist, or a physician who focuses in the treatment of cardiovascular (CV) risk management and/or lipid disorders

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 12 months.

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided
- ✓ Approval duration for renewal: 12 months.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Added Requested medication is not being taken with a PCSK9 inhibitor or Kynamro; updated approval duration	9.2024

REFERENCE:

1. Juxtapid (lomitapide mesylate). [Prescribing information]. Dublin, Ireland: Amryt Pharmaceuticals. September 2020.
2. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA guideline on the management of blood cholesterol [published online November 10, 2018]. Circulation. 2018. doi: 10.1161/CIR.0000000000000625.[PubMed 30586774]
3. Jacobson TA, Ito MK, Maki KC, et al. National lipid association recommendations for patient-centered management of dyslipidemia: part 1--full report. J Clin Lipidol. 2015;9(2):129-169. doi: 10.1016/j.jacl.2015.02.003.[PubMed 25911072]

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Prior Authorization Criteria for JYNARQUE® (tolvaptan)

1) Patient has diagnosis of autosomal dominant polycystic kidney disease (ADPKD) and at high risk of rapidly progressive kidney disease **AND**
2) Patient is 18 years of age or older **AND**
3) Dosage and Direction for Use:
    - **Initial dosage**: total of 60 mg daily; given as 45 mg upon wakening and 15 mg 8 hours later; titrate per response and tolerability at intervals of at least 7 days
    - **Titration step:** total of 90 mg daily; given as 60 mg upon wakening and 30 mg 8 hours later
    - **Target dosage:** total of 120 mg daily; given as 90 mg and 30 mg 8 hours later **AND**
4) Quantity requested does not exceed:
    - Jynarque 15 & 30 mg tablets: 30/30 days
    - Jynarque therapy pack: 120 mg/day (56 tablets/28 days) **AND**
5) Chart notes and documentation that patient has rapidly progressing ADPKD and must meet one of the following:
    a. Confirmed GFR decline of at least 5 mL/min/1.73 m^2 per year over 1 year and/or 2.5 mL/min/1.73 m^2 per year over a period of 5 years **OR**
    b. Total kidney volume increase of at least 5% per year confirmed by at least 3 repeated ultrasound or MRI measurements taken at least 6 months apart **AND**
6) Patient is on a strict plan for blood pressure control, dietary protein restriction, low salt diet, and statins **AND**
7) Prescriber agrees to obtain ALT, AST and bilirubin prior to initiation, at weeks 2, 4, and then monthly during the first 18 months of therapy **AND**
8) Patient does not have liver impairment, hyponatremia, eGFR of less than 25 mL/min, or breast-feeding **AND**
9) Prescribed by a nephrologist.

INITIAL APPROVALS

✓ Initial approval will be for a period of 1 year

RENEWALS

✓ Documentation and chart notes of the patient's progression with ALT, AST, liver function test
✓ Approval for 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2019
Update	Add Denial Message	1.2020
Update	Add tolvaptan pack based on CAB 6.4.2020	6.2020
Annual Review	No Changes	7.2021
Annual Review	No Changes	7.2022
Annual Review	No Changes	7.2023
Annual Review	Updated approval duration to 1 year	1.2024

REFERENCE:

1. Jynarque (tolvaptan) [prescribing information]. Rockville, MD: Otsuka America Pharmaceutical, Inc; October 2020.
2. Devuyst O, Chapman AB, Gansevoort RT, et al. Urine osmolality, response to tolvaptan, and outcome in autosomal dominant polycystic kidney disease: results from the TEMPO 3:4 trial. *J Am Soc Nephrol*. 2017;28(5):1592-1602. doi: 10.1681/ASN.2016040448.
3. Torres V, Chapman A, et al. Tolvaptan in Patients with autosomal dominant polycystic kidney disease. N Engl J Med 2012; 367:2407-18.
4. Torres V, Chapman A, et al. Tolvaptan in later-stage autosomal dominant polycystic kidney disease. N Engl J Med. DOI: 10.1056/NEJMoa1710030.
5. Muller RU, Haas CS, Sayer JA. Practical approaches to the management of autosomal dominant polycystic kidney disease patients in the era of tolvaptan. Clin Kidney J, 2018 Feb; 11(1):62-69.

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Prior Authorization Criteria for KERYDIN® (tavaborole)

1. Patient has diagnosis of onychomycosis of the toenail(s) **AND**
2. Patient is 6 years of age and older **AND**
3. Dosage and Direction for Use: apply once daily to affected toenail(s) for 48 weeks **AND**
4. Quantity requested does not exceed: one tube/month (may vary depending on affected area) **AND**
5. Cultures confirms the infection is caused by *Trichophyton rubrum* or *Trichophyton mentagrophytes* (documentation required) **AND**
6. Patient has had at least a 3-month treatment course with oral terbinafine or itraconazole **AND**
7. Patient has had at least a 48 weeks treatment course with topical ciclopirox **AND**
8. The treatment is not for cosmetic use

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 48 weeks (12 months)

RENEWALS

✓ Medical necessity for longer duration provided
✓ Patient is responding positively to therapy
✓ Approval duration: 48 weeks (12 months) or requested duration, whichever is shorter.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA Criteria created based on existing criteria; added default denial message	2.2020
Updated	Updated PA criteria	7.2021
Annual Review	Updated treatment age to 6 years of age and older and separated criteria for Kerydin and Jublia into separate documents	8.2022
Annual Review	Updated denial message to include all criteria	7.2023
Annual Review	Updated references	2.2024

REFERENCE:

1. Jublia (efinaconazole) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America; August 2018.
2. Kerydin (tavaborole) [prescribing information]. Palo Alto, CA: Anacor Pharmaceuticals Inc; August 2018.
3. Westerberg, DP, Voyack MJ. Onychomycosis: Current Trends in Diagnosis and Treatment. American Family Physician 2013;88(11):762-70.
4. Ciclopirox Prescribing Information. South Plainfield, NJ: G&W Laboratories, Inc.; March 2015. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=3ef301b7- c40a-0635-4a76-185141473dba. Accessed October 15, 2019.
5. Gupta AK, Daigle D, and Foley KA. Network meta-analysis of onychomycosis treatments. Skin Appendage Disorder. 2015; 1: 74-81.
6. Gupta AK, Foley KA, Mays RR, Shear NH, and Piguet V. Monotherapy for toenail onychomycosis: a systematic review and network meta-analysis. British Journal of Dermatology. 2019. DOI 10.1111/bjd.18155
7. Ameen M, Lear JT, Madan V, Mustapa MF, and Richardson M. British Association of Dermatologists' guidelines for management of onychomycosis 2014. British Journal of Dermatology. 2014; 171: 937-958.

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Prior Authorization Criteria for KEVEYIS® (dichlorphenamide)

1. Patient has diagnosis of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis or related variants **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 50 mg once or twice daily up to a maximum of 200 mg daily **AND**
4. Quantity requested does not exceed: 200 mg/day **AND**
5. Patient has had and adequate trial and failure of acetazolamide **AND**
6. Prescribed by or in consultation with a neurologist

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 3 months.
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided
- ✓ Approval duration for renewal: 12 months.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	No change	3.2024

REFERENCE:

1. Keveyis (dichlorphenamide). [Prescribing Information]. Trevose, PA: Strongbridge US, Inc. November 2019.

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Prior Authorization Criteria for KISQALI (ribociclib)

FDA-Approved Indications

- In combination with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence
- Treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with:
    - an aromatase inhibitor as initial endocrine-based therapy; or
    - fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy.

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist.

INITIAL APPROVALS

✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
✓ Initial authorization will be granted for a period of 1 year

RENEWALS

✓ Documentation or claim data supports continuation of treatment
✓ Patient is responding positively to therapy and still requires the medication for induction of remission
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Annual Review	Updated to oncology template; update duration to 1 year	5.2024
Annual Review	Updated indication to remove requirement to be used only in postmenopausal women or men	7.2024
Update	Updated criteria to include expanded indication in combination with an aromatase inhibitor for the adjuvant treatment of adults with early breast cancer at high risk of recurrence	9.2024

REFERENCE:

1. Kisqali (ribociclib) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; July 2024.

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Prior Authorization Criteria for
KISQALI FEMARA (letrozole and ribociclib kit)

FDA-Approved Indications

- Initial endocrine-based therapy for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated duration to 1 year; updated to oncology template	5.2024

REFERENCE:

1. KISQALI FEMARA. [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2023.

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Prior Authorization Criteria for KORLYM® (mifepristone)

1. Patient has diagnosis of hyperglycemia secondary to endogenous Cushing's Syndrome **AND**
2. Patient is 18 years of age and older **AND**
3. Dosage and direction of use: 300mg once daily with a meal **AND**
4. Quantity requested does not exceed: 1,200mg daily or 20 mg/kg per day whichever is less (four 300mg tablets) **AND**
5. Patient has type 2 diabetes mellitus or glucose intolerance confirmed (2-hr glucose tolerance test glucose value of 140-199 mg/dL) **AND**
6. Patient is not a candidate for surgery or has failed surgery **AND**
7. For female patients, patient must have a baseline negative pregnancy test prior to initiation of therapy **AND**
8. Prescribed by or in consultation with an endocrinologist.

INITIAL APPROVALS

- ✓ Initial approval will be granted for a period of 1 year
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation of positive response to therapy as evidenced by improved glycemic control by fasting plasma glucose, an oral glucose tolerance test, or hemoglobin A1c.
- ✓ Initial approval will be granted for a period of 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2017
Annual Review	No Change	8.2018
Annual Review	No Change	8.2019
Updated	Formatted PA criteria	2.2020
Annual Review	No Change	8.2021
Annual Review	Updated format and verbiage	8.2022
Annual Review	Added max dose requirement of 20 mg/kg per day whichever is less; added contraindications.	8.2023
Annual Review	Removed trial and failure of diabetic medications and medications for the treatment of Cushing's disease based on guidelines; removed contraindications	3.2024

REFERENCE:

1. Korlym (mifepristone) [prescribing information]. Menlo Park, CA: Corcept Therapeutics; November 2019.
2. Mifeprex (mifepristone) [prescribing information]. New York, NY: Danco Laboratories, LLC; received April 2019.
3. Nieman LK, Biller BMK, Findling JW et al. Treatment of Cushing's syndrome: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2015; 100(8): 2807-2831.
4. Standards of medical care in diabetes – 2013: position statement. American Diabetes Association. Diabetes Care 2013; 36 (Suppl 1): S11-S66.
5. Fleseriu M, Molitch ME, Gross C, et al. A new therapeutic approach in the medical treatment of Cushing's syndrome: glucorticoid receptor blockade with mifepristone. Endocr Pract. March/April 2013; 19(2): 313-326.

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Prior Authorization Criteria for KOSELUGO™ (selumetinib sulfate)

1. Patient has diagnosis of neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN) **AND**
2. Patient is between 2 to 18 years of age **AND**
3. Dosage and Direction for Use: The recommended dose of Koselugo based on body surface area (BSA) is shown below:

Body Surface Area*	Recommended Dosage
0.55 – 0.69 m^2	20 mg AM and 10 mg PM
0.70 – 0.89 m^2	20 mg twice daily
0.90 – 1.09 m^2	25 mg twice daily
1.10 – 1.29 m^2	30 mg twice daily
1.30 – 1.49 m^2	35 mg twice daily
1.50 – 1.69 m^2	40 mg twice daily
1.70 – 1.89 m^2	45 mg twice daily
≥ 1.90 m^2	50 mg twice daily

4. Quantity requested does not exceed: 112/28 days (four-25mg capsules) **AND**
5. Patient has significant morbidity related to the target PN (e.g., disfigurement, motor dysfunction, pain, airway dysfunction, visual impairment, and bladder/bowel dysfunction) **AND**
6. Patient has at least one inoperable and measurable PN, defined as a lesion ≥ 3 cm measured in one dimension **AND**
7. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
8. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
- ✓ Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA Criteria created based on CAB 4.23.20	5.2020
Annual Review	No Changes	5.2021
Annual Review	No Changes	5.2022
Annual review	No Changes	5.2023
Annual review	Added renewal criteria; updated initial approval to 1 year; added requested medication to follow appropriate sequence of therapy language	5.2024

REFERENCE:

1. Dombi E, Baldwin A, Marcus LJ, et al. Activity of selumetinib in neurofibromatosis type 1-related plexiform neurofibromas. N Engl J Med. 2016;375(26):2550-2560.[PubMed 28029918]
2. Gross AM, Wolters PL, Dombi E, et al. Selumetinib in children with inoperable plexiform neurofibromas. N Engl J Med. 2020;382(15):1430-1442. doi:10.1056/NEJMoa1912735[PubMed 32187457]
3. Koselugo (selumetinib) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; January 2024.
4. Zar T, Graeber C, Perazella MA. Recognition, treatment, and prevention of propylene glycol toxicity. Semin Dial. 2007;20(3):217-219.[PubMed 17555487]
5. National Comprehensive Cancer Network. Central Nervous System Cancers (Version 1.2023). https://www.nccn.org/professionals/physician_gls/pdf/cns_blocks.pdf. Accessed May 10, 2023.

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Prior Authorization Criteria for KUVAN®, JAVYGTOR™ (sapropterin dihydrochloride)

1. Patient has a diagnosis of hyperphenylalaninemia due to tetrahydrobiopterin-responsive phenylketonuria (PKU) **AND**
2. Patient is at least 1 month of age or older **AND**
3. Dosage and direction of use:
    a. *Starting Dose Pediatric Patients 1 month to 6 years: 10 mg/kg once daily*
    b. *Starting Dose Patients 7 years and older: 10 to 20 mg/kg once daily*
4. Quantity requested does not exceed: based on body weight (please optimize approved quantity) **AND**
5. Documentation of elevated phenylalanine blood levels (PHe) persistently above 120 umol/L (2mg/dL) and altered ratio of phenylalanine to tyrosine in the untreated state with BH4 cofactor metabolism **AND**
6. Patient has been and will continue to adhere to a strict PKU diet, managed by a dietician **AND**
7. Patient is not taking requested medication in combination with Palynziq; **AND**
8. Prescribed by or in consultation with a specialist in metabolic disorders.

INITIAL APPROVALS

- ✓ Initial authorization may be granted for up to 1 year
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Responder status is determined by PHe level at four or eight weeks:
    - Patients taking at least 20mg/kg/day, are responders when PHe levels have decreased to within 2-6 mg/dL OR
    - There is a greater than 30% decrease in PHe levels from baseline
- ✓ For patients not meeting the above PHe levels by week four, AND, were dosed less than 20mg/kg/day, should have their dose increased to 20mg/kg/day
    - PHe levels at four weeks of 20mg/kg/day therapy will meet the above guidelines for responders
- ✓ May renew in up to 12 month intervals when the current chart notes, labs and other pertinent information demonstrates the patient's PHe levels remain within 2-6 mg/dL and they remain adherent to their PKU diet.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	3.2017; 2018; 2019
Update	Update Format/Add Denial Message	3.2020
Annual Review	No Change	3.2021
Annual Review	No Change	3.2022
Annual Review	Updated dosage and directions	3.2023
Update	Added Javygtor to criteria; added brand name may be subject to formulary exclusions language	9.2023
Annual Review	No changes	3.2024

REFERENCE:

1. Kuvan (sapropterin) [product monograph]. Toronto, Ontario, Canada: BioMarin Pharmaceutical (Canada) Inc; July 2022.
2. Feillet F, Muntau AC, Debray FG, et al. Use of sapropterin dihydrochloride in maternal phenylketonuria. A European experience of eight cases. J Inherit Metab Dis. 2014;37(5):753-762. doi: 10.1007/s10545-014-9716-5.[PubMed 24789341]

3. Vockly J, Andersson HC, Antshel KM, et al. ACMG practice guidelines: phenylalanine hydroxylase deficiency: diagnosis and management guideline. Genet Med. 2014; 16(2): 188-200.
4. Camp KM, Parisi MA, Acosta PB, et al. Phenylketonuria scientific review conference: state of the science and future research needs. Mol Genet Metab. June 2014; 112(2): 87- 122.
5. Sakamoto O, Arai-Ichinoi N, Murayama K, et al. Successful control of maternal phenylketonuria by tetrahydrobiopterin. Pediatr Int. 2018;60(10):985-986. doi: 10.1111/ped.13678.[PubMed 30345699]
6. van Wegberg AMJ, MacDonald A, Ahring K, et al. The complete European guidelines on phenylketonuria: diagnosis and treatment. Orphanet J Rare Dis. 2017;12(1):162. doi: 10.1186/s13023-017-0685-2.[PubMed 29025426]

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Prior Authorization Criteria for LACRISERT®
(hydroxypropyl cellulose ophthalmic insert)

1. Patient has diagnosis of moderate to severe dry eye syndromes, including keratoconjunctivitis sicca **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: insert one ophthalmic insert in each eye once daily **AND**
4. Quantity requested does not exceed: 60/30 days **AND**
5. Patient has tried other alternative therapies such as artificial tears, wetting ophthalmic gels, and a preferred alternative (e.g., generic Restasis, Xiidra) **AND**
6. Prescribed by or in consultation with an ophthalmologist or optometrist

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Initial approval will be granted for a period of 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	No change	3.2024

REFERENCE:

1. Lacrisert® ophthalmic insert [prescribing information]. Bridgewater, NJ: Bausch & Lomb; October 2019.
2. Akpek EK, Amescua G, Farid M, et al. Dry Eye Syndrome Preferred Practice Pattern®. Ophthalmology. 2019 Jan;126(1):P286-P334.
3. Vichyanond P, Kosrirukvongs P. Use of cyclosporine A and tacrolimus in treatment of vernal keratoconjunctivitis. Curr Allergy Asthma Rep. 2013;13(3):308-314.
4. Dunn JD, et al. Evolving knowledge of the unmet needs in dry eye disease. Am J Manag Care. 2021;27(2 Suppl):S23–S32. doi:10.37765/ajmc.2021.88625
5. Farrand KF, et al. Prevalence of diagnosed dry eye disease in the United States among adults aged 18 years and older. Am J Ophthalmology. 2017; 182:P90–98. doi:10.1016/j.ajo.2017.06.033

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Prior Authorization Criteria for LENVIMA (lenvatinib kit)

FDA Indications

- Differentiated Thyroid Cancer
  - Treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer (DTC).
- Renal Cell Carcinoma
  - In combination with pembrolizumab, for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC)
  - In combination with everolimus, for the treatment of adult patients with advanced RCC following one prior anti-angiogenic therapy
- Hepatocellular Carcinoma
  - First-line treatment of patients with unresectable hepatocellular carcinoma
- Endometrial Carcinoma
  - In combination with pembrolizumab, for the treatment of patients with advanced endometrial carcinoma (EC) that is mismatch repair proficient (pMMR), as determined by an FDA-approved test, or not microsatellite instability-high (MSI-H), who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated duration to 1 year; added FDA approved age	5.2024

REFERENCE:

1. Lenvima [Prescribing Information]. Nutley, NJ. Eisai, Inc: August 2023.

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Prior Authorization Criteria for LEUKERAN (chlorambucil)

FDA-Approved Indications

- Treatment of chronic lymphatic (lymphocytic) leukemia, malignant lymphomas including lymphosarcoma, giant follicular lymphoma, and Hodgkin's disease

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated duration of approval; added FDA approved dx and age	5.2024

REFERENCE:

1. Leukeran (chlorambucil). [Prescribing Information]. Mason, OH: Prasco Laboratories. August 2022.

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Prior Authorization Criteria for LEUKINE® (sargramostim)

1. Patient has an FDA-Approved diagnosis:
   - To shorten time to neutrophil recovery and to reduce the incidence of severe and life-threatening infections and infections resulting in death following induction chemotherapy in adult patients 55 years and older with acute myeloid leukemia (AML).
   - For the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis and autologous transplantation in adult patients.
   - For the acceleration of myeloid reconstitution following autologous bone marrow or peripheral blood progenitor cell transplantation in adult and pediatric patients 2 years of age and older.
   - For the acceleration of myeloid reconstitution following allogeneic bone marrow transplantation in adult and pediatric patients 2 years of age and older.
   - For treatment of delayed neutrophil recovery or graft failure after autologous or allogeneic bone marrow transplantation in adult and pediatric patients 2 years of age and older.
   - To increase survival in adult and pediatric patients from birth to 17 years of age acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]).
2. Dosage and directions of use: the dosage is within FDA recommended dosing or dose is supported by compendia or medical literature **AND**
3. Quantity requested does not exceed: Weight based dosage and direction

INITIAL APPROVALS

✓ Initial approval duration will be 1 year

RENEWALS

✓ Patient responded positively to therapy
✓ Medical justification for continuation of therapy
✓ Renewal approval may be granted for 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Revised	Created	3.2017; 3.2018; 3.2019
Update	Update Format/Add Denial Message	3.2020
Annual Review	No Changes	3.2021
Annual Review	No Changes	3.2022
Annual Review	Updated indication to include “patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS])”; update format and update denial message.	3.2023
Annual Review	Updated criteria based on FDA-approved indications per package insert and updated initial and renewal approval duration.	3.2024

REFERENCE:

1. Leukine (sargramostim) [prescribing information]. Lexington, MA: Partner Therapeutics; August 2023

2. National Comprehensive Cancer Network: Hematopoietic Growth Factors Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf. Accessed: February 24, 2023.
3. Carr R, Modi N, Dore CJ, et al, “A Randomized, Controlled Trial of Prophylactic Granulocyte-Macrophage Colony-Stimulating Factor in Human Newborns Less Than 32 Weeks Gestation,” Pediatrics, 1999, 103(4 Pt 1):796-802.[PubMed 10103305]
4. Gilman AL, Ozkaynak MF, Matthay KK, et al. Phase I study of ch14.18 with granulocyte-macrophage colony-stimulating factor and interleukin-2 in children with neuroblastoma after autologous bone marrow transplantation or stem-cell rescue: a report from the Children's Oncology Group. J Clin Oncol. 2009;27(1):85-91.[PubMed 19047298]
5. Lieschke GJ and Burgess AW, “Granulocyte Colony-Stimulating Factor and Granulocyte-Macrophage Colony-Stimulating Factor,” (2) N Engl J Med, 1992, 327(2):99-106.[PubMed 1376442]
6. Smith TJ, Bohlke K, Lyman GH, et al; American Society of Clinical Oncology. Recommendations for the Use of WBC Growth Factors: American Society of Clinical Oncology Clinical Practice Guideline Update. J Clin Oncol. 2015;33(28):3199-3212.[PubMed 26169616]

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Prior Authorization Criteria for
LEVULAN KERASTICK (aminolevulinic acid hcl)

1. Patient has diagnosis of minimally to moderately thick actinic keratosis **AND**
2. Patient is 18 years of age or older **AND**
3. Lesions are located on the face, scalp, or upper extremities **AND**
4. Requested medication will be used in combination with blue light illumination **AND**
5. Patient has had a trial and failure of topical fluorouracil or imiquimod **AND**
6. Patient is not on dual therapy with another aminolevulinic acid agent **AND**
7. Prescribed by or in consultation with a dermatologist

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 3 months.

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided
- ✓ Approval duration for renewal: 3 months.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Annual review	Added requirement for no dual therapy with aminolevulinic acid agent; clarified type of actinic keratosis	2.2024

REFERENCE:

1. LEVULAN KERASTICK. [Prescribing Information]. Billerica, MA. Sun Pharmaceuticals Industries, Inc: February 2020.
2. Berman, Brian. Treatment of actinic keratosis. UpToDate. https://www-uptodate-com.ezproxy.cnsu.edu/contents/treatment-of-actinic-keratosis. February 23, 2023.

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Prior Authorization Criteria for LITFULO™ (ritlecitinib)

1. Patient has a diagnosis of severe alopecia areata **AND**
2. Patient is 12 years of age or older **AND**
3. Dosage and Direction for Use: 50 mg capsule orally once daily **AND**
4. Quantity requested does not exceed: 30 capsules/30 days **AND**
5. Confirm patient has a current episode of alopecia areata lasting for 6 months or more with at least 50% scalp hair loss **AND**
6. Confirm patient does not have hair loss due to androgenetic alopecia, chemotherapy-induced hair loss, or other causes of hair loss other than alopecia areata **AND**
7. Confirm patient has had adequate trials of all of the following:
    a. Topical corticosteroids **AND**
    b. Additional topical therapies (Elidel, minoxidil) **AND**
    c. Systemic therapy (glucocorticoids, methotrexate, cyclosporine, azathioprine, sulfasalazine) **AND**
8. Confirm patient is not receiving Litfulo in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants **AND**
9. Prescribed by or in consultation with a dermatologist

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 7.28.2023	7.2023
Annual Review	Updated references	2.2024

REFERENCE:

1. Litfulotm (ritlecitinib) [prescribing information]. New York, NY: Pfizer Labs; June 2023.

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Prior Authorization Criteria for LIVMARLI™ (maralixibat chloride)

FDA Approved Indications

- Treatment of cholestatic pruritus in patients 12 months of age and older with progressive familial intrahepatic cholestasis (PFIC).
- Treatment of cholestatic pruritus in patients 3 months of age and older with Alagille syndrome (ALGS)

Diagnosis: Progressive Familial Intrahepatic Cholestasis (PFIC)

1. Patient has diagnosis of progressive familial intrahepatic cholestasis (PFIC) with molecular genetic testing **AND**
2. Patient is 12 months of age and older **AND**
3. Dosage and Direction for Use: Use 19 mg/mL solution. Initial dose is 285 mcg/kg once daily in the morning, titrated to a recommended dosage of 570 mcg/kg twice daily. Not to exceed a maximum daily dose of 38 mg.
4. Quantity requested does not exceed: 570 mcg/kg or 38 mg **AND**
5. Patient does not have PFIC type 2 with ABCB11 variants resulting in nonfunctional or complete absence of bile salt export pump (BSEP) protein **AND**
6. Patient has moderate to severe pruritus **AND**
7. Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory **AND**
8. Patient does not have prior or active hepatic decompensation events **AND**
9. Patient has had an adequate trial of at least **two** of the following medications used to treat pruritus: ursodiol, bile acid sequestrants (i.e., cholestyramine, colesevelam), rifampin, naltrexone, or sertraline **AND**
10. Prescribed by or in consultation with a gastroenterologist or hepatologist.

Diagnosis: Alagille syndrome (ALGS)

1. Patient has a diagnosis of alagille syndrome (ALGS) confirmed by genetic testing demonstrating a JAG1 or NOTCH2 deletion or mutation **AND**
2. Patient is 3 months of age or older **AND**
3. Dosage and Direction for Use: Use 9.5 mg/mL solution. Initial dose: 190 mcg/kg administered orally once daily; after one week, increase to 380 mcg/kg once daily, as tolerated up to a maximum dose of 28.5 mg **AND**
4. Quantity requested does not exceed: 380mcg/kg or the recommended volume per package insert. The maximum volume is 3 mL for patients above 70kg or 28.5 mg per day **AND**
5. Patient has symptoms of moderate to severe pruritus associated with Alagille syndrome **AND**
6. Patient has cholestasis **AND**
7. Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory **AND**
8. Patient does not have prior or active hepatic decompensation events **AND**
9. Patient has had an adequate trial of at least **two** of the following medications used to treat pruritus: ursodiol, bile acid sequestrants (i.e., cholestyramine, colesevelam), rifampin, naltrexone, or sertraline **AND**
10. Prescribed by or in consultation with a specialist such as a gastroenterologist or hepatologist.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 6 months

RENEWALS

- ✓ Confirm patient is tolerating therapy and there has been improvement in pruritus (e.g., decrease in serum bile acids and pruritus). Documentation must be provided.
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 10.21.2021	10.2021
Annual Review	Format update	10.2022
Update	Updated criteria to include expanded indication for patients 3 months of age and older; Updated denial message	8.2023
Annual Review	Added new PFIC indication; updated AS criteria to include bile acid concentration and no hepatic decompensation events	3.2024
Update	Updated age for PFIC to 12 months and older	8.2024

REFERENCE:

1. American Academy of Pediatrics (AAP) Committee on Drugs. "Inactive" ingredients in pharmaceutical products: update (subject review). Pediatrics. 1997;99(2):268-278.[PubMed 9024461]
2. Livmarli (maralixibat) [prescribing information]. Foster City, CA: Mirum Pharmaceuticals Inc; March 2023.
3. Ayoub MD, et al. Alagille syndrome: diagnostic challenges and advances in management. Diagnostics (Basel). 2020;10(11):907. Published November 6, 2020. doi:10.3390/diagnostics10110907.
4. Jacquemin E, et al. Ursodeoxycholic acid therapy in pediatric patients with progressive familial intrahepatic cholestasis. Hepatology. 1997;25(3):519-523. doi:10.1002/hep.510250303.
5. Poupon R, Chopra S. Pruritus associated with cholestasis. Lindor KD, Grover S, eds. UpToDate. Waltham, MA: UpToDate Inc. Updated February 16, 2021. Accessed August 10, 2021. https://www.uptodate.com/contents/pruritus-associated-withcholestasis
6. National Organization for Rare Diseases (NORD). Primary Biliary Cholangitis. July 31, 2023. Available from: https://rarediseases.org/rare-diseases/primary-biliary-cholangitis/
7. National Organization for Rare Diseases (NORD). Primary Sclerosing Cholangitis July 31, 2023. Available from: https://rarediseases.org/rare-diseases/primary-sclerosing-cholangitis/
8. Kamath BM, et al. Outcomes of childhood cholestasis in Alagille syndrome: Results of a multicenter observational study. Hepatol Comm. 2020; 4:387-398. https://doi.org/10.1002/hep4.1468
9. National Organization of Rare Disorders (NORD). Alagille syndrome. Accessed July 31, 2023. https://rarediseases.org/rare-diseases/alagille-syndrome/
10. National Organization for Rare Diseases (NORD). Biliary Atresia. Accessed July 31, 2023. Available from: https://rarediseases.org/rare-diseases/extrahepatic-biliary-atresia/
11. Siddiqi I, Tadi P. Progressive Familial Intrahepatic Cholestasis. [Updated 2022 Jul 4]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan. Available from: https://www.ncbi.nlm.nih.gov/books/NBK559317/
12. Thompson R. J., Arnell H., Artan R., Baumann U., Calvo P. L., Czubkowski P., Dalgic B., D'Antiga L., Durmaz Ö., Fischler B., Gonzalès E., Grammatikopoulos T., Gupte G., Hardikar W., Houwen , (2022). Odevixibat treatment in progressive familial intrahepatic cholestasis: a randomised, placebo-controlled, phase 3 trial. Lancet Gastroenterol Hepatol, 7(9), 830–42. doi: 10.1016/S2468-1253(22)00093-0
13. Ganschow R, Maucksch C. Odevixibat Treatment of Alagille Syndrome: A Case Report. JPGN Rep. 2023 Mar 24;4(2):e301. doi: 10.1097/PG9.0000000000000301. PMID: 37200711; PMCID: PMC10187842.

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Prior Authorization Criteria for LIVTENCITY™ (maribavir)

1. Patient has a diagnosis of post-transplant CMV infection/disease **AND**
2. Patient is 12 years of age or older and weighing at least 35 kg **AND**
3. Dosage and direction for use: 400 mg (two 200 mg tablets) orally twice daily with or without food **AND**
4. Quantity requested does not exceed: 112/28 days **AND**
5. Patient has a history of a hematopoietic stem cell transplant (HSCT) or solid organ transplant (SOT) **AND**
6. Patient has had an adequate trial of a preferred alternative treatment (i.e., ganciclovir, valganciclovir, cidofovir or foscarnet) **AND**
7. Patient is not on any other CMV antivirals **AND**
8. Prescribed by or in consultation with a specialist such an infectious disease specialist

INITIAL APPROVALS

✓ Approval will be granted for a period of 2 months

RENEWALS

✓ Approval duration for renewal: 2 months
✓ Documented need for continued therapy

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 12.16.2021	12.2021
Annual Review	Updated dosage and directions	12.2022
Annual Review	Updated approval duration to 2 months	12.2023

REFERENCE:

1. A Faure Bardon V, Peytavin G, Lê MP, et al. Placental transfer of Letermovir & Maribavir in the ex vivo human cotyledon perfusion model. New perspectives for in utero treatment of congenital cytomegalovirus infection. *PLoS One*. 2020;15(4):e0232140. doi:10.1371/journal.pone.0232140[PubMed 32353010]
2. Livtencity (maribavir) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals; November 2021.
3. Maertens J, Cordonnier C, Jaksch P, et al. Maribavir for preemptive treatment of cytomegalovirus reactivation. *N Engl J Med*. 2019;381(12):1136-1147. doi:10.1056/NEJMoa1714656[PubMed 31532960]
4. Papanicolaou GA, Silveira FP, Langston AA, et al. Maribavir for refractory or resistant cytomegalovirus infections in hematopoietic-cell or solid-organ transplant recipients: a randomized, dose-ranging, double-blind, phase 2 study. *Clin Infect Dis*. 2019;68(8):1255-1264. doi:10.1093/cid/ciy706[PubMed 30329038]
5. Razonable RR, et al. Cytomegalovirus in solid organ transplant recipients—Guidelines of the American Society of Transplantation Infectious Diseases Community of Practice. Clin Transplant. 2019;33(9):e13512. doi:10.1111/ctr.13512
6. Winston DJ, et al. Efficacy and safety of maribavir dosed at 100 mg orally twice daily for the prevention of cytomegalovirus disease in liver transplant recipients: a randomized, double-blind, multicenter controlled trial. Am J Transplant. 2012;12(11):3021-3030. doi:10.1111/j.1600-6143.2012.04231.x

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Prior Authorization Criteria for LONSURF (trifluridine and tipiracil)

FDA Indications

- Metastatic colorectal cancer
  - Treatment of adult patients with metastatic colorectal cancer previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy
- Metastatic gastric cancer
  - Treatment of adult patients with metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy

1. Patient has an FDA approved diagnosis **AND**
2. Patient is 18 years of age or older **AND**
3. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Annual Review	Updated duration to 1 year	5.2024

REFERENCE:

1. LONSURF. [Prescribing Information] Princeton, NJ: Taiho Oncology, Inc: January 2022.

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Prior Authorization Criteria for LORBRENA® (lorlatinib)

FDA-Approved Indications

- Treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist.

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
- ✓ Initial authorization will be granted for 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2022
Annual Review	Updated format	8.2023
Annual Review	Updated duration of approval; added FDA approved dx and age; added indication section; added requested therapy follows appropriate therapy verbiage	5.2024

REFERENCE:

1. Lorbrena (lorlatinib) [product monograph]. Kirkland, Quebec, Canada: Pfizer Canada ULC; April 2023.
2. Shaw AT, Bauer TM, de Marinis F, et al; CROWN Trial Investigators. First-line lorlatinib or crizotinib in advanced ALK-positive lung cancer. N Engl J Med. 2020;383(21):2018-2029. doi:10.1056/NEJMoa2027187[PubMed 33207094]
3. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer (Version 3.2023). Available at: https://www.nccn.org/login?ReturnURL=https://www.nccn.org/professionals/physician_gls/pdf/nscl_blocks.pdf. Accessed July 18, 2023.

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Prior Authorization Criteria for LUMAKRAS™ (sotorasib)

1. Patient has a diagnosis of locally advanced or metastatic non–small cell lung cancer (NSCLC) with KRAS G12C-mutation as detected by an FDA-approved test **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: 960 mg orally once daily **AND**
4. Quantity requested does not exceed: 240 tablets/30 days (eight - 120 mg tablets/day) OR 90 tablets/30 days (three- 320 mg tablets/day) **AND**
5. Patient has had an adequate trial of at least one prior systemic therapy (i.e., cisplatin, carboplatin) **AND**
6. Prescribed by or in consultation with a specialist such as an oncologist.

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
- ✓ Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 6.17.2021	6.2021
Annual Review	No Change	6.2022
Updated	Updated maximum dose to include new 320 mg strength based on CAB 3.23.23	3.2023
Annual Review	Updated initial and renewal approval duration	3.2024

REFERENCE:

1. Hwang JP, Feld JJ, Hammond SP, et al. Hepatitis B virus screening and management for patients with cancer prior to therapy: ASCO provisional clinical opinion update. *J Clin Oncol*. 2020;38(31):3698-3715. doi:10.1200/JCO.20.01757[PubMed 32716741]
2. Lumakras (sotorasib) [prescribing information]. Thousand Oaks, CA: Amgen Inc; May 2021.
3. Skoulidis F, Li BT, G Ramaswamy, et al. Overall survival and exploratory subgroup analyses from the phase 2 CodeBreaK 100 trial evaluating sotorasib in pretreated KRAS p.G12C mutated non-small cell lung cancer. *J Clin Oncol.* 2021;39(suppl 15; abstr 9003). doi:10.1200/JCO.2021.39.15_suppl.9003
4. Hong DS, et al. KRASG12C inhibition with sotorasib in advanced solid tumors. N Engl J Med. 2020;383(13):1207-1217. doi:10.1056/NEJMoa1917239
5. National Comprehensive Cancer Network. Small Cell Lung Cancer (Version 2.2024). https://www.nccn.org/professionals/physician_gls/pdf/nscl_blocks.pdf. Accessed March 19, 2024.

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Prior Authorization Criteria for LUMRYZ™ (sodium oxybate) extended-release oral suspension

INDICATIONS

- Treatment of excessive daytime sleepiness (EDS) in narcolepsy
- Treatment of cataplexy in narcolepsy

Diagnosis: Narcolepsy with excessive daytime sleepiness (without cataplexy)

1. Patient has diagnosis of narcolepsy without cataplexy and has excessive daytime sleepiness **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 6 to 9 gram per night (maximum dose: 9 g per night) **AND**
4. Quantity requested does not exceed: 30 packets/30 days (9 g per night) **AND**
5. Patient has daily periods of irrepressible need to sleep or daytime lapses into drowsiness or sleep occurring for at least three months **AND**
6. Narcolepsy is confirmed by an overnight polysomnogram followed the next day by an MSLT that demonstrates a mean sleep latency ≤8 minutes and at least two sleep-onset REM periods (SOREMPs). A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT **AND**
7. Patient is not taking CNS depressants (e.g. ethanol, sedative hypnotics, anxiolytics, barbiturates, benzodiazepines) or using alcohol **AND**
8. Patient does not have succinic semialdehyde dehydrogenase deficiency **AND**
9. Patient has had an adequate trial and failure (at least 90 days) or contraindication to:
    a. Modafinil or armodafinil **OR**
    b. A central nervous system (CNS) stimulant [e.g., amphetamine, dextroamphetamine, methylphenidate]
10. Prescribed by or in consultation with a neurologist, psychiatrist, pulmonologist, or sleep medicine specialist

Diagnosis: Narcolepsy with cataplexy

1. Patient has diagnosis of cataplexy in narcolepsy **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: initiate dosage at 4.5 g once per night orally. The recommended dosage range is 6 to 9 gram per night (maximum dose: 9 g per night) **AND**
4. Quantity requested does not exceed: 30 packets/30 days (9 g per night) **AND**
5. Patient has daily periods of irrepressible need to sleep or daytime lapses into drowsiness or sleep occurring for at least three months **AND**
6. Diagnosis is confirmed by one of the following:
    a. Cataplexy and mean sleep latency of ≤8 minutes and at least two sleep-onset REM periods (SOREMPs) or a SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram **OR**
    b. CSF hypocretin-1 concentration, measured by radioimmunoassay, is ≤110 pg/mL (using a Stanford reference sample) or <1/3 of mean values obtained in normal subjects with the same standardized assay **AND**
7. Patient is not taking CNS depressants (e.g. ethanol, sedative hypnotics, anxiolytics, barbiturates, benzodiazepines) or using alcohol **AND**
8. Patient does not have succinic semialdehyde dehydrogenase deficiency **AND**
9. Patient has had an adequate trial and failure (at least 90 days) or contraindication to a central nervous system (CNS) stimulant [e.g., amphetamine, dextroamphetamine, methylphenidate], a tricyclic antidepressant (TCA) [e.g., amitriptyline, desipramine, imipramine], a selective serotonin reuptake inhibitor (SSRI) [e.g., fluoxetine, sertraline, paroxetine], or venlafaxine **AND**
10. Prescribed by or in consultation with a neurologist, psychiatrist, pulmonologist, or sleep medicine specialist

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 6 months

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided
- ✓ Patient has disease stabilization or improvement in disease
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 6.1.2023	6.2023
Updated	Updated ST edits: removed preferred brand ST edits and updated generic verbiage, and added requirement to confirm that medication is not taken in combination with Sunosi, Wakix, Xyrem, or Xywav, and updated denial messages.	10.2023
Annual Review	Removed antidepressants as trial option for EDS per guidelines; removed modafinil/armodafinil as trial option for cataplexy per guidelines; removed medication not used in combination per practice recommendations; updated diagnostic criteria	7.2024

REFERENCE:

1. Lumryz (sodium oxybate) [prescribing information]. Chesterfield, MO: Avadel CNS Pharmaceuticals, LLC; May 2023.
2. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2021;17(9):1881–1893.
3. Morgenthaler TI, Kapur VK, Brown T, et al. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. Sleep. 2007;30(12):1705-17711.[PubMed 18246980]

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Prior Authorization Criteria for LUPKYNIS™ (voclosporin)

1. Patient has diagnosis of lupus nephritis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 23.7 mg (three capsules) orally twice daily in combination with corticosteroids and mycophenolate **AND**
4. Quantity requested does not exceed: 180/30 days **AND**
5. Patient has Class III, IV, or V lupus nephritis (documentation provided) **AND**
6. Patient has an eGFR > 45 mL/min/1.73 m^2 **AND**
7. Patient does not have a baseline BP > 165/105 mmHg or hypertensive emergency **AND**
8. Patient does not have any of the labeled contraindications **AND**
9. Lupkynis is prescribed in combination with background immunosuppressive therapy (e.g., mycophenolate mofetil (MMF)) and corticosteroids (e.g., prednisone) **AND**
10. Patient is not receiving therapy in combination with cyclophosphamide or Benlysta **AND**
11. Prescribed by or in consultation with a specialist such as a nephrologist or rheumatologist

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 24 weeks

RENEWALS

✓ If the patient has not experienced therapeutic benefit by 24 weeks, Lupkynis should potentially be discontinued
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 2.11.21	2.2021
Updated	Updated punctuation	2.2021
Annual Review	Update format	2.2022
Annual Review	Updated criteria to include "Patient is not receiving Lupkynis in combination with cyclophosphamide or Benlysta"	2.2023
Annual Review	Updated criteria and format	2.2024

REFERENCE:

1. Lupkynis (voclosporin) [prescribing information]. Rockville, MD: Aurinia Pharmaceuticals Inc; January 2021.
2. Rovin BH, Solomons N, Pendergraft WF 3rd, et al; AURA-LV Study Group. A randomized, controlled double-blind study comparing the efficacy and safety of dose-ranging voclosporin with placebo in achieving remission in patients with active lupus nephritis. Kidney Int. 2019;95(1):219-231. doi:10.1016/j.kint.2018.08.025[PubMed 30420324]
3. Sammaritano LR, Bermas BL, Chakravarty EE, et al. 2020 American College of Rheumatology guideline for the management of reproductive health in rheumatic and musculoskeletal diseases. Arthritis Rheumatol. 2020;72(4):529-556. doi:10.1002/art.41191[PubMed 32090480]
4. Stojan G, et al. Epidemiology of systemic lupus erythematosus: an update. Curr Opin Rheumatol. 2018;30(2):144-150. doi:10.1097/
5. Gasparotto M, et al. Lupus nephritis: clinical presentations and outcomes in the 21st century. Rheumatology (Oxford). 2020;59(Suppl5):v39-v51.doi:10.1093/rheumatology/keaa381
6. Feldman CH, Hiraki LT, Liu J, et al. Epidemiology and sociodemographics of systemic lupus erythematosus and lupus nephritis among US adults with Medicaid coverage, 2000–2004. Arthritis Rheum. 2013;65(3):753-763.

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Prior Authorization Criteria for LUPRON® (leuprolide acetate)

FDA-APPROVED INDICATIONS

- Treatment of adult patients with advanced prostate cancer

Advanced Prostate Cancer

1. Patient has diagnosis of advanced prostate cancer **AND**
2. Dosage and Direction for Use: 1 mg/0.2mL solution SQ injection daily. The dosage is within FDA recommended dosing or dose is supported by compendia or medical literature **AND**
3. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Brand name may be subject to formulary exclusions
- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year.

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA Criteria created based on CAB 5.2020	5.2020
Update	Added Camcevi from CAB 4.21.22	4.2022
Update	Prostate Cancer: removed age range Endometriosis: Added add-back therapy requirements; removed aged CPP: Updated testing levels; Added reference Uterine fibroids: Removed aged, change dosing duration	4.2023
Update	Separated out criteria; updated indications for Lupron to prostate cancer	9.2023
Annual Review	Updated initial approval duration	4.2024

REFERENCE:

1. Lupron (leuprolide) [prescribing information]. North Chicago, IL: AbbVie Inc; March 2019.
2. National Comprehensive Cancer Network. Prostate Cancer (Version 3.2024). https://www.nccn.org/professionals/physician_gls/pdf/prostate_blocks.pdf. Accessed April 18, 2024.

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Prior Authorization Criteria for LYNPARZA® (olaparib)

FDA-APPROVED INDICATIONS

- Ovarian cancer:
  - For the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza
  - In combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either a deleterious or suspected deleterious BRCA mutation, and/or genomic instability
  - For the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy
- Breast Cancer:
  - For the adjuvant treatment of adult patients with deleterious or suspected deleterious gBRCAm human epidermal growth factor receptor 2 (HER2)-negative high risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza
  - For the treatment of adult patients with deleterious or suspected deleterious gBRCAm, HER2-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.
- Pancreatic Cancer:
  - For the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.
- Prostate Cancer:
  - For the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

1. Patient has an FDA approved diagnosis **AND**
2. Patient is 18 years of age or older **AND**
3. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Revised	Created	3.2017
Update	Update Format/Add Denial Message	3.2020
Update	Added criteria for expanded indication of prostate cancer	10.2020
Annual Review	No Change	3.2021
Reviewed	Update to include expanded indication: adjuvant treatment of adult patients with deleterious or suspected deleterious gBRCAm HER2-negative high-risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy.	3.2022/8.2022
Annual Review	Remove diagnosis: Deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer and have been treated with THREE of more prior lines of chemotherapy which was indicated for discontinued capsules.	3.2023
Update	Condensed the FDA-approved indications, added reference, delete completed by column, and update format	8.2023
Annual review	Updated initial and renewal approval duration	3.2024

REFERENCE:

1. Lynparza (olaparib) tablets [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2023.
2. Lynparza (olaparib) tablets [product monograph]. Mississauga, Ontario, Canada: AstraZeneca Canada Inc; July 2022.
3. Lynparza [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 9/2018. Disease specific therapies from Up To Date, accessed 9/2020.
4. The NCCN Drugs & Biologics Compendium. 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 4, 2024.
5. National Comprehensive Cancer Network. Breast Cancer (Version 1.2024). https://www.nccn.org/professionals/physician_gls/pdf/breast_blocks.pdf. Accessed March 1, 2024
6. National Comprehensive Cancer Network. Uterine Neoplams (Version 1.2024). https://www.nccn.org/professionals/physician_gls/pdf/uterine_blocks.pdf. March 1, 2024.
7. National Comprehensive Cancer Network. Ovarian Cancer (Version 1.2024). https://www.nccn.org/professionals/physician_gls/pdf/ovarian_blocks.pdf. March 1, 2024.
8. National Comprehensive Cancer Network. Pancreatic Cancer (Version 1.2024). https://www.nccn.org/professionals/physician_gls/pdf/pancreatic_blocks.pdf. March 1, 2024.
9. National Comprehensive Cancer Network. Prostate Cancer (Version 1.2024). https://www.nccn.org/professionals/physician_gls/pdf/prostate_blocks.pdf. March 1, 2024.

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Prior Authorization Criteria for LYSODREN (mitotane)

FDA-Approved Indications

- Treatment of patients with inoperable, functional or nonfunctional, adrenocortical carcinoma (ACC)

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated duration of approval; added FDA approved dx and age	5.2024

REFERENCE:

1. LYSODREN. [Prescribing Information]. Farmingdale, NJ. HRA Pharma Rare Diseases: January 2024.

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Prior Authorization Criteria for LYTGOBI® (futibatinib)

1. Patient has a diagnosis of unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring FGFR2 gene fusions or other rearrangements **AND**
2. Patient is 18 years of age and older **AND**
3. Dosage and directions of use: 20 mg orally (five 4 mg tablets) once daily until disease progression or unacceptable toxicity occurs **AND**
4. Quantity requested does not exceed: 140/28 days **AND**
5. Disease has presence of a FGFR2 gene fusion or other rearrangements **AND**
6. Patient has been previously treated with at least one prior systemic therapy (i.e., capecitabine, gemcitabine) **AND**
7. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling)
8. Prescribed by or in consultation with an oncologist.

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission.
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 12.1.22	12.2022
Annual Review	Updated duration to 1 year; updated wording based on product label; added oncology drug requirements/format	11.2023

REFERENCE:

1. Lytgobi (futibatinib) [prescribing information]. Princeton, NJ: Taiho Oncology Inc; February 2023.
2. Goyal L, Meric-Bernstam F, Hollebecque A, et al. Updated results of the FOENIX-CCA2 trial: efficacy and safety of futibatinib in intrahepatic cholangiocarcinoma (iCCA) harboring FGFR2 fusions/rearrangements. J Clin Oncol. 2022;40(16)(suppl):4009-4009. https://ascopubs.org/doi/pdf/10.1200/JCO.2022.40.16_suppl.4009.
3. Borad MJ, et al. Fibroblast growth factor receptor 2 fusions as a target for treating cholangiocarcinoma. Curr Opin Gastroenterol. 2015;31(3):264–268. doi:10.1097/MOG.0000000000000171
4. Javle M, et al. Phase II Study of BGJ398 in patients with FGFR-altered advanced cholangiocarcinoma. J Clin Oncol. 2018;36(3):276–282. doi:10.1200/JCO.2017.75.5009
5. National Comprehensive Cancer Network. Multiple Myeloma (Version 3.2022). Available at: https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary_blocks.pdf. Accessed November 22, 2022.

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Prior Authorization Criteria for MATULANE (procarbazine hcl)

FDA-Approved Indications

- In combination with other anticancer drugs for the treatment of Stage III and IV Hodgkin's disease. Matulane is used as part of the MOPP (nitrogen mustard, vincristine, procarbazine, prednisone) regimen.

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated duration of approval; added FDA approved dx and age; added indication section	5.2024

REFERENCE:

1. Matulane. [Prescribing Information]. Gaithersburg, MD. Leadiant Biosciences, Inc: November 2022.

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Prior Authorization Criteria for MEKINIST® (trametinib dimethyl sulfoxine)

FDA-APPROVED INDICATIONS

- As a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test
- In combination with trametinib, for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test
- In combination with trametinib, for the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection
- In combination with trametinib, for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test
- In combination with trametinib, for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options
- In combination with trametinib, for the treatment of adult and pediatric patients 1 year of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options
- In combination with trametinib, for the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy

1. Patient has an FDA approved diagnosis **AND**
2. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
3. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
✓ Initial approval duration will be 1 year. Note: for the indication of adjuvant treatment of melanoma, it is recommended to be given until disease recurrence or unacceptable toxicity for up to 1 year

RENEWALS

✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
✓ Approval duration for renewal: 1 year. Note: for the indication of adjuvant treatment of melanoma, it is recommended to be given until disease recurrence or unacceptable toxicity for up to 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Revised	Created	3.2017
Update	Update Format/Add Denial Message	3.2020
Update	Update Indications and FDA-approved companion test info	9.2020
Update	Combined denial to one default message	2.2021
Annual Review	Annual Review: No Change	3.2022
Update	Added solid tumor and glioma indications; added pediatric dosing chart	4.2023
Annual Review	Updated duration to 1 year; updated solid tumor age requirement to 1 year and older; updated format to oncology drug criteria	12.2023

REFERENCE:

1. Mekinist (trametinib) [product monograph]. Dorval, Quebec, Canada: Novartis Pharmaceuticals Canada Inc; August 2023.

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Prior Authorization Criteria for MESNEX (mesna tablet)

1. Patient is using requested medication as prophylaxis for ifosfamide-induced hemorrhagic cystitis **AND**
2. Patient is 18 years of age or older **AND**
3. Patient is receiving ifosfamide **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 12 months.

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided
- ✓ Approval duration for renewal: 12 months.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual review	No changes	2.2024

REFERENCE:

1. Mesnex (mesna). [Prescribing Information]. Deerfield, IL: Baxter Healthcare Corporation: December 2019.

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Prior Authorization Criteria for MOUNJARO™ (tirzepatide)

FDA Indication

- An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus

Diagnosis: Type 2 diabetes

1. Patient has diagnosis of Type 2 diabetes mellitus A1c of 6.5% or greater (in conjunction with diet and exercise) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Administration: 15 mg SQ once weekly (max dose) **AND**
4. Quantity should not exceed: 2 mL (4 pens)/month **AND**
   ****Please note**: QLs are in accordance with FDA approved max dose
5. Patient has an A1c of 7% or greater measured within the last 90 days (clinical documentation of A1C clinical documentation of A1C must be provided) **AND**
6. Patient has had an adequate trial of metformin and has not been able to obtain, or maintain adequate A1c control along with diet and exercise programs **AND**
7. Patient is not currently taking a DPP-4 inhibitor such as Januvia (sitagliptin), Onglyza (saxagliptin), Tradjenta (linagliptin), or Nesina (alogliptin)

INITIAL APPROVALS

✓ Type 2 diabetes: Initial approval will be granted for a period of 1 year

RENEWALS

✓ Patient has diagnosis of Type 2 diabetes with A1c of 6.5% or greater measured within the previous 365 days (clinical documentation of A1c must be provided) **OR**

✓ Clinical documentation of positive response to therapy (e.g., chart notes/labs are provided to confirm improvement in A1c levels and type 2 diabetes) **AND**

✓ Patient is not currently taking a DPP-4 inhibitor such as Januvia (sitagliptin), Onglyza (saxagliptin), Tradjenta (linagliptin), or Nesina (alogliptin) **AND**

✓ Approval will be granted for a period of 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created criteria	10.2023

REFERENCE:

1. Mounjaro (tirzepatide) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; May 2022.
2. ElSayed NA, Aleppo G, Aroda VR, et al., American Diabetes Association. 2. Classification and diagnosis of diabetes: *Standards of Care in Diabetes—2023*. Diabetes Care 2023;46 (Suppl. 1):S19–S40. Accessed March 30, 2023.
3. ElSayed NA, Aleppo G, Aroda VR, et al., American Diabetes Association. 9. Pharmacologic approaches to glycemic treatment: Standards of Care in Diabetes—2023. Diabetes Care 2023;46 (Suppl. 1):S140–S157. Accessed March 30, 2023.

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Prior Authorization Criteria for AUBAGIO (teriflunomide)

1. Patient has diagnosis of Relapsing forms of Multiple Sclerosis including Relapsing-remitting disease, Active Secondary progressive MS, or Clinically Isolated Syndrome **AND**
2. Patients age is 18 years of age or older **AND**
3. Dosage and Direction for Use: 7mg or 14mg once daily with or without food **AND**
4. Quantity requested does not exceed: 28 tablets/28 days **AND**
5. Prescriber attestation that patient does **not** have any of the following contraindications:
    a. Confirm patient does not have severe hepatic impairment **OR**
    b. Confirm patient is not currently pregnant **OR**
    c. Confirm patient is not taking Aubagio in combination with leflunomide **AND**
6. Patient will not be taking this medication with other disease modifying therapies for treatment of MS **AND**
7. Prescribed by or in consultation with a specialist such as a neurologist.

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 1 year.
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Confirm patient is not on other disease modifying therapies for MS.
- ✓ May renew up to 1 year when the current chart notes and other pertinent information demonstrate patient has experienced a positive response to therapy.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	12.2019
Updated	Update PA Criteria for MS	2.2020
Annual Review	Updated format	12.2021
Update	Update criteria trial of two formulary preferred drugs	12.2022
Update	Created separate criteria for MS drugs, removed ST edits per guidelines, added contraindications, and updated denial message.	8.2023
Annual Review	No changes	1.2024

REFERENCE:

1. Aubagio [package insert]. Cambridge, MA: Genzyme Corporation; 2012.
2. Chaudhry BZ, Cohen JA, Conway DS. Sphingosine 1-phosphate receptor modulators for the treatment of multiple sclerosis. Neurotherapeutics. 2017;14(4):859-873. doi:10.1007/s13311-017-0565-4[PubMed 28812220]
3. Cohen JA, Barkhof F, Comi G, et al. Oral Fingolimod or Intramuscular Interferon for Relapsing Multiple Sclerosis. N Engl J Med 2010;362:402 415.
4. Dobson R, Giovannoni G. Multiple Sclerosis – a review. European Journal of Neurology 2019;26:27-40.
5. Finkelsztejn A. Multiple Sclerosis: Overview of Disease-Modifying Agents. Perspectives in Medicinal Chemistry. 2014;6:65-72.
6. Fox RJ, Miller DH, Phillips T, et al. Placebo-Controlled Phase 3 Study of Oral BG-12 or Glatiramer in Multiple Sclerosis. N Engl J Med 2012;367:1087-1097.
7. Gholamzad M, Ebtekar M, Ardestani MS, et al. A comprehensive review on the treatment approaches of multiple sclerosis: currently and in the future. Inflammation Research 2019;68:25-38.
8. Giovannoni G, Comi G, Cook S, et al. A Placebo-Controlled Trial of Oral Cladribine for Relapsing Multiple Sclerosis. N Engl J Med 2010;362:416-426.
9. Goldenberg MM. Multiple Sclerosis Review. P&T 2012;37(3):175-184.
10. Hatcher SE, Waubant E, Nourbakhsh B, Crabtree-Hartman E, Graves JS. Rebound syndrome in patients with multiple sclerosis after cessation of fingolimod treatment. JAMA Neurol. 2016;73(7):790-794. doi:10.1001/jamaneurol.2016.0826[PubMed 27135594]
11. Jamilloux Y, Néel A, Lecouffe-Desprets M, et al. Progressive multifocal leukoencephalopathy in patients with sarcoidosis. Neurology. 2014;82(15):1307-1313. doi:10.1212/WNL.0000000000000318[PubMed 24610328]
12. Kappos, L, Bar-Or A, Cree BA, et al. Siponimod versus placebo in secondary progressive multiple sclerosis (EXPAND): a double-blind, randomised, phase 3 study. The Lancet 2018;391:1263-1273.

13. Manouchehri N, Mirmosayyeb O, Badihian S, Shaygannejad V. Cutaneous anaplastic large cell lymphoma in a multiple sclerosis patient receiving fingolimod. Mult Scler Relat Disord. 2018;19:121-123. doi: 0.1016/j.msard.2017.11.012[PubMed 29195114
14. Montalban X, Gold R, Thompson AJ, et al. ECTRIMS/EAN guideline on the pharmacological treatment of people with multiple sclerosis. Eur J Neurol. 2018;25(2):215-237. doi:10.1111/ene.13536[PubMed 29352526]
15. Olek MJ, Howard J. Evaluation and diagnosis of multiple sclerosis in adults. In: UpToDate. Post, TW (Ed), UpToDate, Waltham, MA, 2019.
16. Olek MJ, Mowry E. Disease-modifying treatment of relapsing-remitting multiple sclerosis in adults. In: UpToDate. Post, TW (Ed), UpToDate, Waltham, MA, 2019.
17. Rae-Grant A, Day GS, Marrie RA, et al. Comprehensive systematic review summary: disease-modifying therapies for adults with multiple sclerosis. Neurology. 2018;90:789-800.
18. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: disease-modifying therapies for adults with multiple sclerosis: report of the guideline development, dissemination, and implementation subcommittee of the American Academy of Neurology. Neurology. 2018;90(17):777-788. doi:10.1212/WNL.0000000000005347[PubMed 29686116]
19. Tan CS, Koralnik IJ. Progressive multifocal leukoencephalopathy and other disorders caused by JC virus: clinical features and pathogenesis. LancetNeurol. 2010;9(4):425-437. doi:10.1016/S1474-4422(10)70040-5[PubMed 20298966]
20. Tice JA, Chapman R, Kumar V, et al. Disease-Modifying Therapies for Relapse-Remitting and Primary-Progressive Multiple Sclerosis: Effectiveness and Value. Institute for Clinical and Economic Review, 2017.
21. Vermersch P, Czlonkowska A, Grimaldi LM, et al. Teriflunomide versus subcutaneous interferon beta-1a in patients with relapsing multiple sclerosis: a randomized, controlled phase 3 trial. Multiple Sclerosis Journal 2014;20(6):705-716.
22. Willis M, Pearson O, Illes Z, et al. An observational study of alemtuzumab following fingolimod for multiple sclerosis. Neurol Neuroimmunol Neuroinflamm. 2017;4(2):e320. doi:10.1212/NXI.0000000000000320[PubMed 28101520]
23. Wingerchuk DM, Weinshenker BG. Disease modifying therapies for relapsing multiple sclerosis. BMJ 2016;354

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Prior Authorization Criteria for AVONEX® (interferon beta-1a)

1. Patient has diagnosis of relapsing forms of multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND**
2. Patients age is 18 years of age and older **AND**
3. Dosage and Direction for Use:
    a. **Initial**: 7.5mcg IM once weekly x 3 weeks, increase by 7.5mcg each week until 30mcg weekly;
    b. **Maintenance**: 30mcg once weekly **AND**
4. Quantity requested does not exceed: 4 vials or syringes/28 days (four of 30mcg/0.5ml single-use vial, 30mcg/0.5ml prefilled syringe, or 30mcg/0.5ml autoinjector)/28-days **AND**
5. Patient will not be taking this medication with other disease modifying therapies for treatment of MS **AND**
6. Prescribed by or in consultation with a specialist such as a neurologist.

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 1 year.

RENEWALS

- ✓ Confirm patient is not on other disease modifying therapies for MS.
- ✓ May renew up to 1 year when the current chart notes and other pertinent information demonstrate patient has experienced a positive response to therapy.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	12.2019
Updated	Update PA Criteria for MS	2.2020
Annual review	Updated format	12.2021
Annual review	No Changes	12.2022
Update	Update criteria trial of at least two formulary preferred drugs	2.2023
Update	Created separate criteria for MS drugs, removed ST requirement based on guidelines, and updated denial message.	8.2023
Annual review	No Changes	1.2024

REFERENCE:

1. Avonex (interferon beta-1a) [prescribing information]. Cambridge, MA: Biogen Inc; November 2021.
2. Avonex (interferon beta-1a) [product monograph]. Toronto, Ontario, Canada: Biogen Canada Inc; August 2022.
3. Chaudhry BZ, Cohen JA, Conway DS. Sphingosine 1-phosphate receptor modulators for the treatment of multiple sclerosis. Neurotherapeutics. 2017;14(4):859-873. doi:10.1007/s13311-017-0565-4[PubMed 28812220]
4. Cohen JA, Barkhof F, Comi G, et al. Oral Fingolimod or Intramuscular Interferon for Relapsing Multiple Sclerosis. N Engl J Med 2010;362:402 415.
5. Dobson R, Giovannoni G. Multiple Sclerosis – a review. European Journal of Neurology 2019;26:27-40.
6. Gholamzad M, Ebtekar M, Ardestani MS, et al. A comprehensive review on the treatment approaches of multiple sclerosis: currently and in the future. Inflammation Research 2019;68:25-38.
7. Giovannoni G, Comi G, Cook S, et al. A Placebo-Controlled Trial of Oral Cladribine for Relapsing Multiple Sclerosis. N Engl J Med 2010;362:416-426.
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13. Montalban X, Gold R, Thompson AJ, et al. ECTRIMS/EAN guideline on the pharmacological treatment of people with multiple sclerosis. Eur J Neurol. 2018;25(2):215-237. doi:10.1111/ene.13536[PubMed 29352526]
14. Olek MJ, Howard J. Evaluation and diagnosis of multiple sclerosis in adults. In: UpToDate. Post, TW (Ed), UpToDate, Waltham, MA, 2019.
15. Olek MJ, Mowry E. Disease-modifying treatment of relapsing-remitting multiple sclerosis in adults. In: UpToDate. Post, TW (Ed), UpToDate, Waltham, MA, 2019.
16. Rae-Grant A, Day GS, Marrie RA, et al. Comprehensive systematic review summary: disease-modifying therapies for adults with multiple sclerosis. Neurology. 2018;90:789-800.
17. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: disease-modifying therapies for adults with multiple sclerosis: report of the guideline development, dissemination, and implementation subcommittee of the American Academy of Neurology. Neurology. 2018;90(17):777-788. doi:10.1212/WNL.0000000000005347[PubMed 29686116]
18. Tan CS, Koralnik IJ. Progressive multifocal leukoencephalopathy and other disorders caused by JC virus: clinical features and pathogenesis. LancetNeurol. 2010;9(4):425-437. doi:10.1016/S1474-4422(10)70040-5[PubMed 20298966]
19. Tice JA, Chapman R, Kumar V, et al. Disease-Modifying Therapies for Relapse-Remitting and Primary-Progressive Multiple Sclerosis: Effectiveness and Value. Institute for Clinical and Economic Review, 2017.
20. Vermersch P, Czlonkowska A, Grimaldi LM, et al. Teriflunomide versus subcutaneous interferon beta-1a in patients with relapsing multiple sclerosis: a randomized, controlled phase 3 trial. Multiple Sclerosis Journal 2014;20(6):705-716.
21. Willis M, Pearson O, Illes Z, et al. An observational study of alemtuzumab following fingolimod for multiple sclerosis. Neurol Neuroimmunol Neuroinflamm. 2017;4(2):e320. doi:10.1212/NXI.0000000000000320[PubMed 28101520]
22. Wingerchuk DM, Weinshenker BG. Disease modifying therapies for relapsing multiple sclerosis. BMJ 2016;354

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Prior Authorization Criteria for BAFIERTAM™ (monomethyl fumarate)

1. Patient has diagnosis of relapsing forms of multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use:
    a. Initial dose: 95 mg (one capsule) twice a day, orally, for 7 days
    b. Maintenance dose: after 7 days: 190 mg (two capsules of 95 mg) twice a day **AND**
4. Quantity requested does not exceed: 14 capsules (95 mg)/7 days (initial dose); 190 mg twice daily (4 capsules (380 mg)/day) (maintenance dose) **AND**
5. Confirm patient is not currently pregnant **AND**
6. Physician attestation that patient does **not** have any of the following contraindications:
    - Known hypersensitivity to monomethyl fumarate, dimethyl fumarate, diroximel fumarate, or to any of the excipients of Bafiertam. Reactions may include anaphylaxis or angioedema
    - Co-administration with dimethyl fumarate or diroximel fumarate **AND**
7. Bafiertam will not be used in combination with any other disease-modifying therapy for MS **AND**
8. Prescribed by or in consultation with a specialist such as a neurologist.

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 1 year.

RENEWALS

✓ Confirm patient is not on other disease modifying therapies for MS.

✓ May renew up to 1 year when the current chart notes and other pertinent information demonstrate patient has experienced a positive response to therapy.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2022
Update	Updated criteria, remove ST and lab parameter requirements, and updated denial message.	8.2023
Annual Review	No changes	1.2024

REFERENCE:

1. Bafiertam [package insert]. High Point (NC): Banner Life Sciences LLC; December 2023.
2. Chaudhry BZ, Cohen JA, Conway DS. Sphingosine 1-phosphate receptor modulators for the treatment of multiple sclerosis. Neurotherapeutics. 2017;14(4):859-873. doi:10.1007/s13311-017-0565-4[PubMed 28812220]
3. Cohen JA, Barkhof F, Comi G, et al. Oral Fingolimod or Intramuscular Interferon for Relapsing Multiple Sclerosis. N Engl J Med 2010;362:402 415.
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5. Finkelsztejn A. Multiple Sclerosis: Overview of Disease-Modifying Agents. Perspectives in Medicinal Chemistry. 2014;6:65-72.
6. Fox RJ, Miller DH, Phillips T, et al. Placebo-Controlled Phase 3 Study of Oral BG-12 or Glatiramer in Multiple Sclerosis. N Engl J Med 2012;367:1087-1097.
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10. Hatcher SE, Waubant E, Nourbakhsh B, Crabtree-Hartman E, Graves JS. Rebound syndrome in patients with multiple sclerosis after cessation of fingolimod treatment. JAMA Neurol. 2016;73(7):790-794. doi:10.1001/jamaneurol.2016.0826[PubMed 27135594]

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15. Olek MJ, Howard J. Evaluation and diagnosis of multiple sclerosis in adults. In: UpToDate. Post, TW (Ed), UpToDate, Waltham, MA, 2019.
16. Olek MJ, Mowry E. Disease-modifying treatment of relapsing-remitting multiple sclerosis in adults. In: UpToDate. Post, TW (Ed), UpToDate, Waltham, MA, 2019.
17. Rae-Grant A, Day GS, Marrie RA, et al. Comprehensive systematic review summary: disease-modifying therapies for adults with multiple sclerosis. Neurology. 2018;90:789-800.
18. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: disease-modifying therapies for adults with multiple sclerosis: report of the guideline development, dissemination, and implementation subcommittee of the American Academy of Neurology. Neurology. 2018;90(17):777-788. doi:10.1212/WNL.0000000000005347[PubMed 29686116]
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Prior Authorization Criteria for BETASERON® (interferon beta-1b)

1. Patient has diagnosis of relapsing forms of multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND**
2. Patients age is 18 years of age and older **AND**
3. Dosage and Direction for Use:
   a. **Initial**: 0.0625 mg SQ every other day, increase over a six-week period to 0.25mg (1 mL) every other day;
   b. **Maintenance**: 0.25mg every other day **AND**
4. Quantity requested does not exceed: 14 vials (14 vials of 0.3mg)/28 days **AND**
5. Patient will not be taking this medication with other disease modifying therapies for treatment of MS **AND**
6. Prescribed by or in consultation with a specialist such as a neurologist.

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 1 year.

RENEWALS

- ✓ Confirm patient is not on other disease modifying therapies for MS.
- ✓ May renew up to 1 year when the current chart notes and other pertinent information demonstrate patient has experienced a positive response to therapy.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	12.2019
Updated	Update PA Criteria for MS	2.2020
Annual review	Updated format	12.2021
Annual review	No Changes	12.2022
Update	Created separate criteria for MS drugs, removed ST requirement based on guidelines, and updated denial message	8.2023
Annual review	No Changes	1.2024

REFERENCE:

1. Betaseron (interferon beta-1b) [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc; July 2023.
2. Betaseron (interferon beta-1b) [product monograph]. Mississauga, Ontario, Canada: Bayer Inc; April 2023.
3. Hatcher SE, Waubant E, Nourbakhsh B, et al. Rebound syndrome in patients with multiple sclerosis after cessation of fingolimod treatment. JAMA Neurol. 2016;73(7): 790-794. doi:10.1001/jamaneurol.2016.0826.[PubMed 27135594]
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5. Hatcher SE, Waubant E, Nourbakhsh B, Crabtree-Hartman E, Graves JS. Rebound syndrome in patients with multiple sclerosis after cessation of fingolimod treatment. JAMA Neurol. 2016;73(7):790-794. doi:10.1001/jamaneurol.2016.0826[PubMed 27135594]
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18. Olek MJ, Howard J. Evaluation and diagnosis of multiple sclerosis in adults. In: UpToDate. Post, TW (Ed), UpToDate, Waltham, MA, 2019.
19. Olek MJ, Mowry E. Disease-modifying treatment of relapsing-remitting multiple sclerosis in adults. In: UpToDate. Post, TW (Ed), UpToDate, Waltham, MA, 2019.
20. Rae-Grant A, Day GS, Marrie RA, et al. Comprehensive systematic review summary: disease-modifying therapies for adults with multiple sclerosis. Neurology. 2018;90:789-800.
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Prior Authorization Criteria for COPAXONE® (glatiramer acetate) & GLATOPA™ (glatiramer acetate)

1. Patient has diagnosis of relapsing forms of multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND**
2. Patients age is 18 years of age and older **AND**
3. Dosage and Direction for Use: 20 mg/mL per day or 40 mg/mL three times per week **AND**
4. Quantity requested does not exceed: 20mg: 28 syringes of 20mg/ml/28 days; 40mg: 12 syringes of 40mg/ml/28 days **AND**
5. Patient will not be taking this medication with other disease modifying therapies for treatment of MS **AND**
6. Prescribed by or in consultation with a specialist such as a neurologist.

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 1 year.
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Confirm patient is not on other disease modifying therapies for MS
- ✓ May renew up to 1 year when the current chart notes and other pertinent information demonstrate patient has experienced a positive response to therapy.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	12.2019
Updated	Update PA Criteria for MS	2.2020
Annual review	Updated format	12.2021
Annual review	No Changes	12.2022
Update	Update criteria trial of at least two formulary preferred drugs	2.2023
Update	Created separate criteria for MS drugs, removed ST requirement based on guidelines, and updated denial message	8.2023
Annual review	No changes	1.2024

REFERENCE:

1. Copaxone (glatiramer acetate) [prescribing information]. Parsippany, NJ: Teva Neuroscience Inc; February 2023.
2. Glatopa (glatiramer acetate) [prescribing information]. Princeton, NJ: Sandoz Inc; March 2023.
3. Chaudhry BZ, Cohen JA, Conway DS. Sphingosine 1-phosphate receptor modulators for the treatment of multiple sclerosis. Neurotherapeutics. 2017;14(4):859-873. doi:10.1007/s13311-017-0565-4[PubMed 28812220]
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Prior Authorization Criteria for GILENYA (fingolimod)

1. Patient has diagnosis of Relapsing forms of Multiple Sclerosis including Relapsing-remitting disease, Active Secondary progressive MS, or Clinically Isolated Syndrome **AND**
2. Patients age is 10 years of age or older **AND**
3. Dosage and Direction for Use:
    a. Pediatric patients 10 years of age and older ≤ 40 kg: 0.25 mg (1 capsule) once daily
    b. Adults and pediatric patients 10 years of age and older ≥ 40 kg: 0.5 mg (1 capsule) once-daily **AND**
4. Quantity requested does not exceed: 28/28 (1 capsule/day) **AND**
5. Confirm patient is not currently pregnant **AND**
6. Physician attestation that patient does **not** have any of the following contraindications:
    a. Confirm that patient did not have recent MI, unstable angina, stroke, TIA, decompensated heart failure that required hospitalization, or Class III or IV heart failure **AND**
    b. Confirm patient does not have second-degree AV block (Mobitz type II), third degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker **AND**
    c. Confirm patient does not have QTc prolongation (QTc greater than or equal to 500 msec)
    d. Confirm patient currently is not receiving treatment with Class Ia or Class III anti-arrhythmic drugs **AND**
7. Confirm Gilenya will not be used in combination with any other disease-modifying therapy for MS **AND**
8. Prescribed by or in consultation with a specialist such as a neurologist.

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 1 year
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Confirm patient is not on other disease modifying therapies for MS.
- ✓ May renew up to 1 year when the current chart notes and other pertinent information demonstrate patient has experienced a positive response to therapy.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created separate criteria for MS drugs	8.2022
Updated	Updated contraindications, approval duration, and denial comment	3.2023
Updated	Updated format and criteria, removed lab parameter requirements, and updated denial message	8.2023
Annual review	No changes	1.2024

REFERENCE:

1. Gilenya (fingolimod) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2023.
2. Gilenya (fingolimod) [product monograph]. Dorval, Quebec, Canada: Novartis Pharmaceuticals Canada Inc; December 2020.
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Prior Authorization Criteria for KESIMPTA® (ofatumumab)

1. Patient has diagnosis of relapsing forms of multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND**
2. Patient is 18 years of age and older **AND**
3. Dosage and Direction for Use: Initial dosing: 20 mg administered at week 0, 1, and 2; Subsequent dosing: 20 mg administered monthly starting at week 4 **AND**
4. Quantity requested does not exceed: Initial: 1.2mL (3 doses); maintenance 0.4mL (1 injection)/28 days **AND**
5. Patient does not have Active Hepatitis Virus (HBV) infection **AND**
6. Patient will not be taking this medication with other disease modifying therapies for treatment of MS **AND**
7. Prescribed by or in consultation with a specialist such as a neurologist.

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 1 year.

RENEWALS

- ✓ Confirm patient is not on other disease modifying therapies for MS.
- ✓ May renew up to 1 year when the current chart notes and other pertinent information demonstrate patient has experienced a positive response to therapy.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	12.2019
Updated	Update PA Criteria for MS	2.2020
Annual review	Updated format	12.2021
Annual review	No Changes	12.2022
Update	Created separate criteria for MS drugs, removed ST requirement based on guidelines, and updated denial message	8.2023
Annual review	No changes	1.2024

REFERENCE:

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2. Kesimpta (ofatumumab) [product monograph]. Dorval, Quebec, Canada: Novartis Pharmaceuticals Canada Inc; January 2021.
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Prior Authorization Criteria for MAVENCLAD® (cladribine)

1. Patient has diagnosis of relapsing forms of multiple sclerosis (MS) to include relapsing-remitting disease and active secondary progressive disease **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: Cumulative dosage of 3.5 mg/kg administered orally and divided into 2 treatment courses (1.75 mg/kg per treatment course). Each treatment course is divided into 2 treatment cycles **AND**
4. Quantity requested does not exceed: 1.75 mg/kg per treatment course with cumulative dosage of 3.5 mg/kg administered orally and divided into 2 treatment courses **AND**
5. Patient is not taking this medication for clinically isolated syndrome (CIS) **AND**
6. Physician attestation that patient does **not** have any of the following contraindications:
    a. Current malignancies or cancer **AND**
    b. HIV, active chronic infections (e.g., hepatitis, tuberculosis) **AND**
    c. Pregnant or breastfeeding **AND**
7. Patient will not be taking this medication with other disease modifying therapies for treatment of MS **AND**
8. Prescribed by or in consultation with a specialist such as a neurologist.

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 1 year.

RENEWALS

- ✓ Confirm patient is not on other disease modifying therapies for MS.
- ✓ May renew up to 1 year when the current chart notes and other pertinent information demonstrate patient has experienced a positive response to therapy.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	12.2019
Updated	Update PA Criteria for MS	2.2020
Annual Review	Format update	12.2021
Update	Update criteria trial of at least two formulary preferred drugs	12.2022
Update	Created separate criteria for MS drugs, removed ST edits per guidelines, and updated denial message	8.2023
Annual Review	No changes	1.2024

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Prior Authorization Criteria for MAYZENT® (siponimod)

1. Patient has diagnosis of relapsing forms of multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Directions for use:
    a. *For patients with CYP2C9 Genotypes *1/*1, *1/*2, *2/*2* maintenance dose*:* 2 mg/day after 5 day titration period;
    b. *For patients with CYP2C9 Genotypes *1/*3, *2/*3* maintenance dose*:* 1 mg/day after 4 day titration period **AND**
4. Quantity requested does not exceed:
    a. For patients with CYP2C9 Genotypes *1/*1, *1/*2, *2/*2: 28 pills/28 days;
    b. For patients with CYP2C9 Genotypes *1/*3, *2/*3: 14 pills/28 days **AND**
5. Patient is currently not pregnant **AND**
6. Physician attestation that patient does **not** have any of the following contraindications:
    a. A CYP2CP*3/3 genotype **OR**
    b. Within the last 6 months, experienced MI, unstable angina, stroke, TIA, decompensated heart failure that required hospitalization, or Class III or IV heart failure **OR**
    c. Presence of a second-degree AV block (Mobitz type II), third degree AV block, or sick-sinus syndrome, unless patient has a functioning pacemaker **OR**
7. Patient will not be taking this medication with other disease modifying therapies for treatment of MS **AND**
8. Prescribed by or in consultation with a specialist such as a neurologist.

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 1 year.

RENEWALS

- ✓ Confirm patient is not on other disease modifying therapies for MS.
- ✓ May renew up to 1 year when the current chart notes and other pertinent information demonstrate patient has experienced a positive response to therapy.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	12.2019
Updated	Update PA Criteria for MS	2.2020
Annual Review	Format update	12.2021
Annual Review	Update criteria trial of at least two formulary preferred drugs	12.2022
Update	Created separate criteria for MS drugs, removed ST edits per guidelines, added contraindications, and updated denial message.	8.2023
Annual Review	No changes	1.2024

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Prior Authorization Criteria for PLEGRIDY™ (peginterferon beta-1a)

1. Patient has diagnosis of relapsing forms of multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND**
2. Patients age is 18 years of age and older **AND**
3. Dosage and Direction for Use:
    a. **Initial**: 63 mcg/day SQ on Day 1, 94 mcg on Day 15, 125 mcg on Day 29;
    b. **Maintenance**: 125mcg every 14 days **AND**
4. Quantity requested does not exceed: *Starter Pack*: 1 pack/28 days; *Maintenance pack*: 2 syringes/28 days (two of 125 mcg/0.5ml per single-dose syringe or pen)/ 28 days **AND**
5. Patient will not be taking this medication with other disease modifying therapies for treatment of MS **AND**
6. Prescribed by or in consultation with a specialist such as a neurologist.

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 1 year.

RENEWALS

- ✓ Confirm patient is not on other disease modifying therapies for MS.
- ✓ May renew up to 1 year when the current chart notes and other pertinent information demonstrate patient has experienced a positive response to therapy.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	12.2019
Updated	Update PA Criteria for MS	2.2020
Annual review	Updated format	12.2021
Annual review	No Changes	12.2022
Annual review	Update criteria trial of at least two formulary preferred drugs	2.2023
Update	Created separate criteria for MS drugs, removed ST requirement based on guidelines, and updated denial message.	8.2023
Annual review	No Changes	1.2024

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Prior Authorization Criteria for PONVORY™ (ponesimod)

1. Patient has diagnosis of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and directions for use:
   - **Treatment Initiation**: A starter pack must be used with a 14-day titration schedule below:

Titration Day	Daily Dose
Days 1 and 2	2 mg
Days 3 and 4	3 mg
Days 5 and 6	4 mg
Day 7	5 mg
Day 8	6 mg
Day 9	7 mg
Day 10	8 mg
Day 11	9 mg
Days 12, 13, and 14	10 mg

   - **Maintenance dose:** 20 mg once daily starting on Day 15.

4. Quantity requested does not exceed: 30 tablets/30 days (20 mg orally once daily) **AND**
5. Confirm patient is not currently pregnant **AND**
6. Physician attestation that patient does **not** have any of the following contraindications:
   - In the last six months, the patient has not had myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, or Class III/IV heart failure **or**
   - Presence of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker **AND**
7. Confirm medication will not be used in combination with any other disease-modifying therapy for MS **AND**
8. Prescribed by or in consultation with a specialist such as a neurologist

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 1 year.

RENEWALS

- ✓ Confirm patient is not on other disease modifying therapies for MS.
- ✓ May renew up to 1 year when the current chart notes and other pertinent information demonstrate patient has experienced a positive response to therapy.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	12.2019
Updated	Update PA Criteria for MS	2.2020
Annual review	Updated format	12.2021
Update	Update criteria trial of two formulary preferred drugs	12.2022

Update	Created separate criteria for MS drugs, removed ST edits per guidelines, and updated denial message	8.2023
Annual review	No changes	1.2024

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1. Chaudhry BZ, Cohen JA, Conway DS. Sphingosine 1-phosphate receptor modulators for the treatment of multiple sclerosis. Neurotherapeutics. 2017;14(4):859-873. doi:10.1007/s13311-017-0565-4[PubMed 28812220]
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Prior Authorization Criteria for REBIF® (interferon beta-1a)

1. Patient has diagnosis of relapsing forms of multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND**
2. Patients age is 18 years of age and older AND
3. Dosage and Direction for Use:
    a. **Initial**: 20% of prescribed dose three times weekly; increase over 4 week period to target dose of either 22 mcg or 44 mcg injected subcutaneously three times per week;
    b. **Maintenance**: 22mcg or 44mcg SQ three times weekly **AND**
4. Quantity requested does not exceed: 12 pens/28 days (twelve of 22mcg/0.5ml or 44mcg/0.5ml per single-dose syringe or autoinjector) **AND**
5. Patient will not be taking this medication with other disease modifying therapies for treatment of MS **AND**
6. Prescribed by or in consultation with a specialist such a neurologist.

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 1 year.

RENEWALS

- ✓ Confirm patient is not on other disease modifying therapies for MS.
- ✓ May renew up to 1 year when the current chart notes and other pertinent information demonstrate patient has experienced a positive response to therapy.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	12.2019
Updated	Update PA Criteria for MS	2.2020
Annual review	Updated format	12.2021
Annual review	No Changes	12.2022
Update	Update criteria trial of at least two formulary preferred drugs.	2.2023
Update	Created separate criteria for MS drugs, removed ST requirement based on guidelines, and updated denial message	8.2023
Annual review	No changes	1.2024

REFERENCE:

1. Rebif (interferon beta-1a) [prescribing information]. Rockland, MA: EMD Serono Inc; February 2023.
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Prior Authorization Criteria for TECFIDERA® (dimethyl fumarate)

1. Patient has diagnosis of relapsing forms of multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: initial dose: 120 mg (one capsule) twice a day, orally, for 7 days. Maintenance dose: after 7 days: 240 mg twice a day **AND**
4. Quantity requested does not exceed: Initial dose: 14 capsules/7 days; maintenance dose: 240 mg twice daily (60 capsules/ 30 days) **AND**
5. Confirm patient is not currently pregnant **AND**
6. Confirm that patient will not be taking this medication with other disease modifying therapies for treatment of MS **AND**
7. Prescribed by or in consultation with a specialist such as a neurologist.

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 1 year
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Confirm patient is not on other disease modifying therapies for MS.
- ✓ May renew up to 1 year when the current chart notes and other pertinent information demonstrate patient has experienced a positive response to therapy.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created separate criteria for MS drugs	8.2022
Updated	Updated format and criteria, removed ST edits and lab parameter requirements based on guidelines, and updated denial message.	8.2023
Annual review	No changes	1.2024

REFERENCE:

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Prior Authorization Criteria for VUMERITY® (diroximel fumarate)

1. Patient has diagnosis of Relapsing forms of Multiple Sclerosis including Relapsing-remitting disease, Active Secondary progressive MS, or Clinically Isolated Syndrome **AND**
2. Patient is 18 years of age and older **AND**
3. Dosage and direction of use:
    a. Starting dose: 231 mg twice a day, orally, for 7 days;
    b. Maintenance dose after 7 days: 462 mg (administered as two 231 mg capsules) twice a day, orally **AND**
4. Quantity requested does not exceed: 120 capsules/30-days **AND**
5. Patient will not be taking this medication with other disease modifying therapies used for treatment of MS **AND**
6. Prescribed by or in consultation with a specialist such as a neurologist.

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 1 year.

RENEWALS

- ✓ Patient is not on other disease modifying therapies for MS.
- ✓ May renew up to 1 year when the current chart notes and other pertinent information demonstrate patient has experienced a positive response to therapy.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Updated	Update PA Criteria for MS	2.2020
Updated	Added generic Tecfidera as part of the preferred alternatives.	9.2020
Annual review	Format update	2.2021
Annual review	No changes	2.2022
Update	Update criteria trial of at least two formulary preferred drugs	2.2023
Update	Created separate criteria for MS drugs, removed ST requirement due to guidelines, and updated denial message.	8.2023
Annual review	No changes	1.2024

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Prior Authorization Criteria for MYCAPSSA™ (octreotide acetate)

1. Patient has diagnosis of Acromegaly **AND**
2. Patients is 18 years of age or older **AND**
3. Dosage and Direction for Use: Initiate at 40 mg daily (administered as 20 mg twice daily). Titrate to achieve target IGF-1 levels. Maximum dose of 80mg daily **AND**
4. Quantity requested does not exceed: 80mg daily **AND**
5. Patient had an inadequate response to or cannot be treated with surgical resection, radiotherapy, or dopamine agonist (i.e., bromocriptine mesylate at maximally tolerated doses) **AND**
6. Patient has tried and failed the injectable formulation of octreotide or lanreotide first and physician has provided a medical justification for oral formulation **AND**
7. Prescribed by or in consultation with an oncologist or gastroenterologist.

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial approval will be granted for a period of 12 months

RENEWALS

- ✓ Patient has a positive response to therapy
- ✓ Approval duration for renewal: 12 months

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA Criteria created based on CAB 5.22.2020	5.2020
Update	Added Sandostatin, Sandostatin LAR, Bynfezia	6.2020
Update	Added Mycapssa based on CAB 7.30.2020	8.2020
Annual Review	No Change	8.2021
Annual Review	No Change	8.2022
Annual Review	Removed Bynfezia (d/c), created separate criteria for Sandostatin/Sandostatin LAR, and Mycapssa, updated dosage, updated denial messaged, and updated format	8.2023
Update	Updated initial approval duration from 6 months to 12 months	10.2023

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8. Sandostatin LAR Depot (octreotide injection suspension) [prescribing information]. East Hanover, NJ: Novartis; April 2019.
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Prior Authorization Criteria for MYFEMBREE®
(relugolix-estradiol-norethindrone acetate)

FDA-APPROVED INDICATIONS

- Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids)
- Moderate to severe pain associated with endometriosis

Diagnosis: Management of heavy menstrual bleeding associated with uterine fibroids

1. Patient has diagnosis of heavy menstrual bleeding associated with uterine fibroids **AND**
2. Patient is aged 18 years of age or older **AND**
3. Dosage and Direction for Use: take one tablet orally once daily. Treatment should be limited to 24 months due to risk of bone loss that may not be reversible **AND**
4. Quantity requested does not exceed: 28 tablets/28 days **AND**
5. Patient is premenopausal **AND**
6. Patient has tried and failed one of the following generic alternatives: hormonal contraceptives, progestins (i.e., norethindrone), or injectable gonadotropin-release hormone agonists (i.e., leuprolide) **AND**
7. Patient does **not** have any of the labeled contraindications:
    a. History of arterial, venous thrombotic, or thromboembolic disorder OR at high risk for these events (i.e., women over age of 35 years and smoke, uncontrolled hypertension) **AND**
    b. Pregnant **AND**
    c. Osteoporosis with documentation of a DEXA-scan **AND**
    d. Hepatic impairment or disease **AND**
    e. Undiagnosed abnormal uterine bleeding **AND**
    f. Current or history of breast cancer or other hormonally-sensitive malignancies such as those with mutations in BRCA genes **AND**
8. Patient has not previously received ≥24 months of therapy combined with Orilissa, Oriahn, or Myfembree **AND**
9. Prescribed by or in consultation with a gynecologist.

Diagnosis: Moderate to severe pain associated with endometriosis

1. Patient has a diagnosis of moderate to severe pain associated with endometriosis **AND**
2. Patient is aged 18 years of age or older **AND**
3. Dosage and Direction for Use: take one tablet orally once daily. Treatment should be limited to 24 months due to risk of bone loss that may not be reversible **AND**
4. Quantity requested does not exceed: 28 tablets/28 days **AND**
5. Patient has tried and failed at least one NSAID (i.e., ibuprofen, meloxicam) or opioids (i.e., tramadol) unless labeled contraindication or clinical significant adverse effects are experienced **AND**
6. Patient has tried and failed one of the following: hormonal contraceptives or progestins (i.e., norethindrone) **AND**
7. Patient does **not** have any of the labeled contraindications:
    a. History of arterial, venous thrombotic, or thromboembolic disorder OR at high risk for these events (i.e., women over age of 35 years and smoke, uncontrolled hypertension) **AND**
    b. Pregnant **AND**
    c. Osteoporosis with documentation of a DEXA-scan **AND**
    d. Hepatic impairment or disease **AND**
    e. Undiagnosed abnormal uterine bleeding **AND**

f. Current or history of breast cancer or other hormonally-sensitive malignancies such as those with mutations in BRCA genes **AND**

8. Patient has not previously received ≥24 months of therapy combined with Orilissa, Oriahn, or Myfembree **AND**
9. Prescribed by or in consultation with a gynecologist.

INITIAL APPROVALS

✓ Myfembree Initial authorization will be granted for a period of 6 months.

RENEWALS

✓ Documentation of positive clinical response
✓ Myfembree approval duration up to 24 months
✓ Patient has not previously received ≥24 months of therapy combined with Orilissa, Oriahn, or Myfembree

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	3.2019
Update	Update Format/Add Denial Message	3.2020
Add	Added Oriahnn based on CAB 6.18	6.2020
Updated	Updated PA criteria and added Myfembree	6.2021
Reviewed	Created a separate document for Myfembree. Updated criteria to include expanded indication of management of moderate to severe pain associated with endometriosis.	8.2022
Annual Review	Updated format and denial message.	3.2023
Annual Review	Updated criteria verbiage to include "patient does not have any of the labeled contraindications"	3.2024

REFERENCE:

1. American College of Obstetricians and Gynecologists. Practice bulletin: clinical management guidelines for obstetrician-gynecologist: management of endometriosis. Am J Obstet Gynecol 2010; 116(1):223-236.
2. De la Cruz MS, et al. 2017. Uterine fibroids: diagnosis and treatment. Am Fam Physician. 95(2):100-107.
3. Hartmann KE, et al. Management of uterine fibroids. Comparative Effectiveness Review No. 195. AHRQ. Publication No. 17(18)-EHC028-EF. Rockville, MD: Agency for Healthcare Research and Quality; December 2017.
4. Oriahnn (elagolix, estradiol, and norethindrone) [prescribing information]. North Chicago, IL: Abbvie Inc; May 2020.
5. Orilissa (elagolix) [prescribing information]. North Chicago, IL: AbbVie Inc; August 2019.
6. Simon JA, et al. 2020. Elagolix treatment for up to 12 months in women with heavy menstrual bleeding and uterine leiomyomas. Obstet Gynecol. 135:1313–26.
7. Stewart EA. Uterine fibroids (leiomyomas): Treatment overview. UpToDate website. UpToDate. Accessed June 17, 2020.
8. Struthers RS, Nicholls AJ, Grundy J, et al. Suppression of gonadotropins and estradiol in premenopausal women by oral administration of the nonpeptide gonadotropin-releasing hormone antagonist elagolix. J Clin Endocrinol Metab. 2009;94(2):545-551. doi:10.1210/jc.2008-1695.
9. Myfembree (relugolix, estradiol, and norethindrone) [prescribing information]. Brisbane, CA: Myovant Sciences Inc; May 2021.
10. Allen C., Hopewell S., Prentice A. (2005). Non-steroidal anti-inflammatory drugs for pain in women with endometriosis. Cochrane Database Syst. Rev. 1:CD004753.
11. Maddern J, Grundy L, Castro J, Brierley SM. Pain in Endometriosis. Front Cell Neurosci. 2020 Oct 6;14:590823. doi: 10.3389/fncel.2020.590823. PMID: 33132854; PMCID: PMC7573391.

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Prior Authorization Criteria for MYLERAN (busulfan tablet)

FDA-Approved Indications

- Palliative treatment of chronic myelogenous (myeloid, myelocytic, granulocytic) leukemia

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated duration of approval; added FDA approved dx and age; added indication section	5.2024

REFERENCE:

1. Myleran (busulfan). [Prescribing Information]. Wixom, MI: Waylis Therapeutics, LLC. February 2023.

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Prior Authorization Criteria for NEBUPENT® (pentamidine isethionate inhalant)

1. Patient has a diagnosis of high risk HIV needing prevention of *Pneumocystis jiroveci* pneumonia (PJP) **AND**
2. Patient is at least 17 years of age **AND**
3. Dosage and direction of use: 300 mg once every 4 weeks **AND**
4. Quantity requested does not exceed: 1 vial/28 days **AND**
5. Patient has a history of one or more episodes of *Pneumocystis jiroveci* pneumonia **AND**
6. Patient's peripheral CD4+ lymphocyte count is $\leq$ 200 mm^3 **AND**
7. Patient has had trial and failure, intolerance to, or contraindication to all of the following: trimethoprim-sulfamethoxazole (TMP-SMX), dapsone, and atovaquone
8. Prescribed by or in consultation with an infectious disease specialist or physician who specializes in treatment of HIV

INITIAL APPROVALS

- ✓ Initial authorization may be granted for up to 12 months.
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Authorization may be extended in 12 month intervals when patient does not show evidence of disease progression and criteria above continue to be met.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	No changes	2.2024

REFERENCE:

1. NebuPent(pentamidine isethionate). [Prescribing information]. Lake Zurich, IL: Fresenius Kabi. October 2016.
2. Thomas, Charles F. Treatment and prevention of Pneumocystis pneumonia in patients without HIV. UpToDate. May 2023.

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Prior Authorization Criteria for NERLYNX (neratinib)

FDA-Approved Indications

- As a single agent is indicated for the extended adjuvant treatment of adult patients with early-stage human epidermal growth factor receptor 2 (HER2)-positive breast cancer, to follow adjuvant trastuzumab based therapy
- In combination with capecitabine is indicated for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 based regimens in the metastatic setting

1. Patient has an FDA approved diagnosis **AND**
2. Patient is 18 years of age or older **AND**
3. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year.

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy.
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Annual Review	Updated initial and renewal approval duration	3.2024

REFERENCE:

1. NERLYNX. [Prescribing Information]. Los Angeles, CA. Puma Biotechnology: March 2022.
2. National Comprehensive Cancer Network. Breast Cancer (Version 2.2024). https://www.nccn.org/professionals/physician_gls/pdf/breast_blocks.pdf. Accessed March 14, 2024.

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Prior Authorization Criteria for NEXAVAR (sorafenib)

FDA Indications

- Treatment of patients with unresectable hepatocellular carcinoma (HCC)
- Treatment of patients with advanced renal cell carcinoma (RCC)
- Treatment of patients with locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Updated	Updated duration of approval; added FDA approved age	5.2024
Annual Review	No Changes	6.2024

REFERENCE:

1. NEXAVAR. [Prescribing Information]. Whippany, NJ. Bayer HealthCare Pharmaceuticals Inc: August 2023.

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Prior Authorization Criteria for NEXLETOL™, NEXLIZET™ (bempedoic acid, bempedoic acid/ezetimibe)

FDA-APPROVED INDICATIONS

- Reduction in CV Risk: To reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with established cardiovascular disease (CVD), or a high risk for a CVD event but without established CVD.
- Primary hyperlipidemia (including heterozygous familial hypercholesterolemia): As an adjunct to diet, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH)

Diagnosis: CVD Risk Reduction

1. Patient has diagnosis of clinical atherosclerotic cardiovascular disease or is at high risk for CVD **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: 1 tablet (Nexletol 180 mg or Nexlizet 180mg/10mg) orally once daily **AND**
4. Quantity requested does not exceed: 30 tabs/30 days **AND**
5. Patient has **one** of the following (a or b):
    a. Established CVD with documented history of one of the following:
        - Coronary artery disease (e.g., myocardial infarction, percutaneous coronary or surgical coronary revascularization) **OR**
        - Symptomatic peripheral arterial disease (e.g., intermittent claudication and critical limb ischemia) **OR**
        - Cerebrovascular atherosclerotic disease (e.g., A past history of stroke or transient ischemic attack) **OR**
    b. Patient is at high risk for a CVD event but without established CVD demonstrating one of the following categories:
        - Diabetes mellitus (type 1 or type 2) in females over 65 years of age or males over 60 years of age **OR**
        - A Reynolds Risk score > 30% or a SCORE Risk score > 7.5% over 10 years) or other risk stratification models identifying patients as high risk **OR**
        - A coronary artery calcium score >400 Agatston units at any time in the past **AND**
6. One of the following:
    a. Patient has been compliant (at least 12 weeks) with the maximum tolerated dose of a statin and will continue the statin while taking requested medication **OR**
    b. If patient has statin intolerance, confirm one of the following (documentation required):
        i. The patient has had one retrial with lower dose statins, alternative statins, or less frequent dosing **OR**
        ii. The patient has had experienced rhabdomyolysis or muscle symptoms with CK elevation > 10 times ULN **AND**
7. Prescribed by or in consultation with a specialist such as a cardiologist, an endocrinologist, or a physician who focuses in the treatment of cardiovascular (CV) risk management and/or lipid disorders.

Diagnosis: Primary hyperlipidemia

1. Patient has diagnosis of heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease (ASCVD) who require additional lowering of LDL cholesterol (LDL-C) **AND**
2. Patient is 18 years of age or older **AND**

3. Dosage and Direction for Use: 1 tablet (Nexletol 180 mg or Nexlizet 180mg/10mg) orally once daily **AND**
4. Quantity requested does not exceed: 30 tabs/30 days **AND**
5. Patient has been compliant with physician recommended diet **AND**
6. Patient has been compliant (at least 12 weeks) with the maximum tolerated dose of a statin and will continue the statin while taking Nexletol or Nexlizet **AND**
7. If patient is statin intolerant, confirm one of the following (documentation required):
    a. Patient had two retrials with lower dose statins, alternative statins, or less frequent dosing **OR**
    b. Patient has experienced rhabdomyolysis or muscle symptoms with CK elevation > 10 times ULN **AND**
8. Patient has been adherent to ezetimibe used concomitantly with a statin (or alone if statin intolerant) at the maximally tolerated dose for at least 4 months unless contraindicated **AND**
9. LDL level remains > 100 mg/dL (or > 70 mg/dL in the presence of hypertension, diabetes, or stage 3 or 4 chronic kidney disease) despite statin/ezetimibe therapy **AND**
10. Prescribed by or in consultation with a specialist such as a cardiologist, an endocrinologist, or a physician who focuses on the treatment of cardiovascular (CV) risk management and/or lipid disorders.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Patient has a positive response to therapy (e.g., decrease in LDL levels)
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA Criteria created based on CAB 3.26.2020	4.2020
Updated	Added Nexlizet based on CAB 6.4.2020	6.2020
Updated	Updated drug name	4.2021
Annual Review	No Changes	6.2022
Annual Review	Updated numbering	6.2023
Annual Review	Updated criteria to include expanded indication reduction in CV Risk based on package insert	4.2024
Updated	Updated denial message	9.2024

REFERENCE:

1. Nexletol (bempedoic acid) [prescribing information]. Ann Arbor, MI: Esperion Therapeutics Inc; December 2023.
2. Nexlizet (bempedoic acid and ezetimibe) [prescribing information]. Ann Arbor, MI: Esperion Therapeutics Inc; December 2023.
3. Ballantyne CM, et al. Bempedoic Acid Plus Ezetimibe Fixed-Dose Combination in Patients With Hypercholesterolemia and High CVD Risk Treated With Maximally Tolerated Statin Therapy. European Journal of Preventive Cardiology. July 2019. doi: doi.org/10.1177/2047487319864671.
4. Grundy SM, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol. Journal of the American College of Cardiology. 2019; 73(24):e285-e350. doi: doi.org/10.1016/j.jacc.2018.11.003.
5. France M, Rees A, Datta D, et al. HEART UK statement on the management of homozygous familial hypercholesterolaemia in the United Kingdom. Atherosclerosis. 2016;255:128-139. doi: 10.1016/j.atherosclerosis.2016.10.017.[PubMed 27839699]
6. Jacobson TA, Ito MK, Maki KC, et al. National lipid association recommendations for patient-centered management of dyslipidemia: part 1--full report. J Clin Lipidol. 2015;9(2):129-169. doi: 10.1016/j.jacl.2015.02.003.[PubMed 25911072]
7. Nissen SE, Lincoff AM, Brennan D, Ray KK, Mason D, Kastelein JJP, Thompson PD, Libby P, Cho L, Plutzky J, Bays HE, Moriarty PM, Menon V, Grobbee DE, Louie MJ, Chen CF, Li N, Bloedon L, Robinson P, Horner M, Sasiela WJ, McCluskey J, Davey D, Fajardo-Campos P, Petrovic P, Fedacko J, Zmuda W, Lukyanov Y, Nicholls SJ; CLEAR Outcomes Investigators. Bempedoic Acid and Cardiovascular Outcomes in Statin-Intolerant Patients. N Engl J Med. 2023 Apr 13;388(15):1353-1364. doi: 10.1056/NEJMoa2215024. Epub 2023 Mar 4. PMID: 36876740.
8. Kim KI. Risk Stratification of Cardiovascular Disease according to Age Groups in New Prevention Guidelines: A Review. J Lipid Atheroscler. 2023 May;12(2):96-105. doi: 10.12997/jla.2023.12.2.96. Epub 2023 Mar 20. PMID: 37265845; PMCID: PMC10232216.

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Prior Authorization Criteria for NEXOBRID® (anacaulase-bcdb)

1. Confirm patient has deep partial thickness (second-degree) and/or full thickness thermal burns (third-degree) **AND**
2. Patient is 18 years of age and older **AND**
3. Dosage and Direction for Use: Apply in up to two applications of 4 hours each administered by a healthcare provider
    a. A first application may be applied to an area of up to 15% body surface area (BSA) **AND**
    b. A second application may be applied 24 hours later **AND**
4. Quantity requested does not exceed: depends on the treated area (2 glass vials or 110 g/treatment) **AND**
5. Confirm that the total treated area for both applications does not exceed 20% BSA **AND**
6. Patient does not have uncontrolled coagulation disorders **AND**
7. Patient has underdone wound cleansing including antibacterial solutions (i.e., silver sulfadiazine).

INITIAL APPROVALS

✓ One-time approval

RENEWALS

✓ Approval duration for renewal: one-time approval based on clinical judgement

-

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 1.26.2023	1.2023
Annual Review	No changes	1.2024

REFERENCE:

1. Nexobrid (anacaulase) [prescribing information]. Cambridge, MA: Vericel Corporation; December 2022.
2. American Burn Association. Burn incidence and treatment in the United States: 2016—fact sheet. https://ameriburn.org/who-we-are/media/burn-incidence-fact-sheet/. Published May 28, 2017. Accessed January 24, 2023.
3. MediWound. NexoBrid. https://www.mediwound.com/nexobrid/.Accessed January 24, 2023.
4. American Society for Surgery of the Hand. How to treat a burn. https://www.assh.org/handcare/condition/how-to-treat-a-burn. Accessed January 24, 2023.
5. Walker NJ, King KC. Acute and Chronic Thermal Burn Evaluation and Management. [Updated 2022 Jul 1]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK430730/

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Prior Authorization Criteria for NILANDRON (nilutamide)

FDA-Approved Indications

- In combination with surgical castration for the treatment of metastatic prostate cancer (Stage D2)

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Update	Updated duration of approval; added FDA approved dx and age; added indication section	5.2024
Annual Review	No Changes	7.2024

REFERENCE:

1. Nilandron (nilutamide). [Prescribing information]. Dublin, Ireland: Concordia Pharmaceuticals, Inc. July 2022.

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Prior Authorization Criteria for NINLARO (ixazomib)

1. Patient has a diagnosis of multiple myeloma **AND**
2. Patient is 18 years of age or older **AND**
3. Patient has received at least one prior therapy **AND**
4. Requested medication will be used in combination with lenalidomide and dexamethasone **AND**
5. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
6. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year.

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Annual Review	Updated initial and renewal approval duration	5.2024

REFERENCE:

1. Ninlaro (ixazomib) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America Inc; March 2024.
2. National Comprehensive Cancer Network. Multiple Myeloma (Version 3.2024). https://www.nccn.org/professionals/physician_gls/pdf/myeloma_blocks.pdf. Accessed May 2, 2024.

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Prior Authorization Criteria for NITYR®, ORFADIN® (nitisinone)

1. Patient has a diagnosis of hereditary tyrosinemia type 1 (HT-1) **AND**
2. Dosage and direction of use: **AND**
    - *Adults & Pediatric*: initial dose of 0.5 mg/kg orally twice daily; increase to 0.75 mg/kg twice daily if succinylacetone is detectable 4 weeks after initiation up to a maximum total daily dosage is 2 mg/kg orally **AND**
3. Quantity requested does not exceed: 2 mg/kg/day. Dose is adjusted based on weight and response, please optimize approved dose accordingly **AND**
    - **NOTE:** with pediatrics, once biochemical response is satisfactory, further dosage adjustments should be only according to body weight gain
4. Patient is using in combination with dietary restriction of tyrosine and phenylalanine **AND**
5. If request is for brand Orfadin, patient has tried and failed generic nitisinone **AND**
6. Patient will not be taking the medication concurrently with other nitisinone products **AND**
7. Prescribed by or in consultation with an endocrinologist or a metabolic or genetic disease specialist

INITIAL APPROVALS

✓ Initial approval will be granted for a period of up to 1 year

RENEWALS

✓ Renewal will be granted for a period of 12 months with documentation of a positive response to therapy

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	3.2019
Update	Update Format/Add Denial Message	3.2020
Update	Combined Nityr and Orfadin criteria; added requirement for brand Orfadin.	11.2020
Reviewed	Removed adult age limit; adjusted dosage and direction of use and quantity limit	3.2021
Annual review	No Change	3.2022
Annual review	Updated references	3.2023
Annual review	Updated criteria and format	2.2024

REFERENCE:

1. Nityr (nitisinone) [prescribing information]. Cambridge, UK: Cycle Pharmaceuticals; June 2021.
2. Orfadin (nitisinone) [prescribing information]. Waltham, MA: Sobi Inc; November 2021.
3. Tyrosinemia type 1. Genetic and Rare Diseases Information Center; National Institutes of Health, US Department of Health and Human Services. Updated November 8, 2021. Available at: https://rarediseases.info.nih.gov/diseases/2658/tyrosinemia-type-1. Accessed on March 1, 2023
4. Chinsky JM, Singh R, Ficicioglu C, et al. Diagnosis and treatment of tyrosinemia type I: a US and Canadian consensus group review and recommendations. Genet Med. 2017;19(12). doi:10.1038/gim.2017.101[PubMed 28771246]

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Prior Authorization Criteria for Nivestym (filgrastim-AAFI)

1. Patient has an FDA approved diagnosis:
   - Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever **OR**
   - Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of adults with acute myeloid leukemia **OR**
   - Reduce the duration of neutropenia and neutopenia-related clinical sequelae in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by marrow transplantation **OR**
   - Mobilize of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis **OR**
   - Reduce the incidence and duration of sequelae of severe neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia. The WBC level or count meets the requirements associated with severe Neutropenia justifying the need for treatment **AND**
2. Dosage and direction of use: the dosage is within FDA recommended dosing or dose is supported by compendia or medical literature **AND**
3. Quantity requested does not exceed: Weight based dosage and direction.

INITIAL APPROVALS

✓ Initial approval will be granted for 1 year

RENEWALS

✓ Patient responded positively to therapy
✓ Medical justification for continuation of therapy (e.g. indication of bone marrow transplant likely only needs one time approval)
✓ Renewal approval may be granted for 1 year.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Revised	Created based on existing criteria	3.2017
Update	Updated Format / Add Denial Message	2.2020
Annual Review	No changes	3.2021
Updated	Added Releuko per CAB 3.24.22	3.2022
Annual Review	Updated references and format	3.2023
Updated	Created separate criteria for Nivestym, updated format, and denial message	8.2023
Annual Review	Updated criteria based on FDA-approved indication per package insert and updated initial and renewal approval duration	3.2024

REFERENCE:

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8. Singal AK, Bataller R, Ahn J, et al. ACG Clinical Guideline: alcoholic liver disease. *Am J Gastroenterol.* 2018;113(2):175-194. doi: 10.1038/ajg.2017.469.[PubMed 29336434]
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11. Update of recommendations for the use of hematopoietic colony-stimulating factors: evidence-based clinical practice guidelines. American Society of Clinical Oncology. *J Clin Oncol*. 1996;14(6):1957-1960.[PubMed 8656266]
12. Wagner LM, Furman WL. Haemopoietic growth factors in paediatric oncology: a review of the literature. *Paediatr Drugs*. 2001;3(3):195-217.[PubMed 11310717]
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14. Wolach B. Neonatal sepsis: pathogenesis and supportive therapy. *Semin Perinatol*. 1997;21(1):28-38.[PubMed 9190031]
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Prior Authorization Criteria for NORTHERA™ (droxidopa)

1. Patient has diagnosis of neurogenic orthostatic hypotension **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: Starting dose is 100 mg three times during the day and can be titrated by 100 mg three times daily. Max dose of 600 mg three times daily **AND**
4. Quantity requested does not exceed: 180/30 days (6 capsules/day) **AND**
5. Patient has consistent symptoms of neurogenic orthostatic hypotension caused by ONE of the following:
    a. Primary autonomic failure (Parkinson's Disease (PD), multiple system atrophy, or pure autonomic failures)
    b. Dopamine beta-hydroxylase (DBH) deficiency
    c. Non-diabetic autonomic neuropathy (NDAN)
6. Patient has a decrease of at least 20 mmHg in systolic blood pressure or 10 mmHg diastolic blood pressure within three minutes after standing from a sitting position **AND**
7. Patient has tried two non-pharmacological therapies (e.g. elevated head of bed to 10 to 20 degrees, stepwise raising from supine position to standing position, adequate fluid intake, compression stocking, or increase salt and water intake) **AND**
8. Patient had an adequate trial of fludrocortisone or midodrine **AND**
9. Prescribed by or in consultation with a specialist (e.g. cardiologist, neurologist)

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 2 weeks

RENEWALS

✓ Patient is responding positively to therapy
✓ Approval duration for renewal: 3 months

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	12.2019
Update	Add Denial Message	2.18.2020
Annual review	No Changes	2.2021
Annual review	No Changes	2.2022
Annual review	No Changes	2.2023
Annual review	No Changes	1.2024

REFERENCE:

1. Logan IC, Witham MD. Efficacy of treatments for orthostatic hypotension: a systematic review. Age Ageing 2012; 41:587.
2. Mills PB, Fung CK, Travlos A, Krassioukov A. Nonpharmacologic management of orthostatic hypotension: a systematic review. Arch Phys Med Rehabil 2015; 96:366.
3. Northera (droxidopa) [prescribing information]. Deerfield, IL: Lundbeck; July 2019.
4. Palma JA, Kaufmann H. Epidemiology, Diagnosis, and Management of Neurogenic Orthostatic Hypotension. Mov Disord Clin Pract 2017; 4:298.

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Prior Authorization Criteria for NOURIANZ® (istradefylline)

1. Patient has diagnosis of Parkinson's disease **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 20 mg once daily, up to a maximum of 40 mg/day **AND**
4. Quantity requested does not exceed: 30 tablets/30 days **AND**
5. Patient is experiencing "off" episodes **AND**
6. Patient has tried and failed at least two of the following medication classes in addition to carbidopa/levodopa to reduce number and frequency of OFF episodes:
    a. Dopamine agonist (i.e., ropinirole) **OR**
    b. COMT inhibitor (i.e., entacapone) **OR**
    c. MAO-B inhibitor (i.e., selegiline) **AND**
7. Patient is using Nourianz as adjunctive treatment with carbidopa/levodopa **AND**
8. Prescribed by or in consultation with a neurologist

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Annual Review	Updated approval duration to 1 year; updated references	7.2024

REFERENCE:

1. Nourianz (istradefylline) [prescribing information]. Princeton, NJ. Kyowa Kirin, Inc; March 2023.
2. Fox, SH, et al. International Parkinson and Movement Disorder Society Evidence-Based Medicine Review: Update on Treatments for the Motor Symptoms of Parkinson's Disease. Movement Disorders 2018; 00:1-16.

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Prior Authorization Criteria for NOXAFIL™ (posaconazole)

1. Noxafil is indicated for the one of the following (please see formulation):
    a. Injection and delayed release tablets: treatment of invasive *Aspergillosis*
    b. Injection, delay-released tablets, oral suspension, PowderMix oral suspension: Prophylaxis of invasive *Aspergillus* and *Candida* infections in patients who are at high risk of developing these infections due to being severely immunocompromised
    c. Oral suspension: treatment of oropharyngeal candidiasis including OPC refractory (rOPC) to itraconazole and/or fluconazole **AND**
2. Patient's age meets one of the following:
    a. Treatment of invasive *Aspergillosis*:
        i. Injection & delayed release tablets: 13 years of aged an older **AND**
    b. Prophylaxis of invasive *Aspergillosis*
        i. Injection: 2 years of aged an older **AND**
        ii. Delay-released tablets: 2 years of age and older who weigh >40 kg
        iii. Oral Suspension: 13 years of age and older
        iv. Noxafil PowderMix for delayed-release oral suspension: 2 years of age and older who weigh < 40 kg
    c. Oropharyngeal candidiasis:
        i. Oral Suspension: 13 years of age and older

3. Dosage and direction of use: medication follows appropriate dosage recommendations per FDA/Labeling
    a. Dosing Regimens in Adult Patients

Indication	Dosage Form, Dose, and Duration of Therapy	Duration of therapy
Treatment of invasive Aspergillosis	**Noxafil Injection:** Loading dose: 300 mg (1 vial of 300mg/16.7ml) intravenously twice a day on the first day. Maintenance dose: 300 mg (1 vial of 300mg/16.7ml) intravenously once a day thereafter.	Loading dose: 1 day Maintenance dose: Recommended total duration of therapy is 6 to 12 weeks.
	Noxafil Delayed-Release Tablets: Loading dose: 300 mg (three 100 mg delayed-release tablets) twice a day on the first day. Maintenance dose: 300 mg (three 100 mg delayed-release tablets) once a day thereafter. Recommended total duration of therapy is 6 to 12 weeks. Switching between the intravenous and delayed-release tablets is acceptable. A loading dose is not required when switching between formulations.	
Prophylaxis of invasive Aspergillus and Candida infections	**Noxafil Injection:** Loading dose: 300 mg (1 vial of 300mg/16.7ml) intravenously twice a day on the first day. Maintenance dose: 300 mg (1 vial of 300mg/16.7ml) intravenously once a day thereafter.	Loading dose: 1 day Maintenance dose: Duration of therapy is based on recovery from neutropenia or immunosuppression.
	Noxafil Delayed-Release Tablets: Loading dose: 300 mg (three 100 mg delayed-release tablets) twice a day on the first day. Maintenance dose: 300 mg (three 100 mg delayed-release tablets) once a day, starting on the second day.	
	Noxafil Oral Suspension: 200 mg (5 mL) three times a day.	

Oropharyngeal Candidiasis (OPC)	**Noxafil Oral Suspension:** Loading dose: 100 mg (2.5 mL) twice a day on the first day. Maintenance dose: 100 mg (2.5 mL) once a day for 13 days.	Loading dose: 1 day Maintenance dose: 13 days
OPC Refractory (rOPC) to Itraconazole and/or Fluconazole	Noxafil Oral Suspension: 400 mg (10 mL) twice a day.	Duration of therapy is based on the severity of the patient's underlying disease and clinical response

b. Dosing Regimen for Noxafil Delayed-Release Tablet and Noxafil Injection for Pediatric Patients (ages 2 to < 18 years of age)

Indication	Weight (kg)/Age	Delayed-Release Tablet	Injection	Duration of therapy
Prophylaxis of Invasive *Aspergillus* and *Candida* infections	≤40 kg (2 to < 18 years of age)	N/A	Loading dose: 6 mg/kg up to a max of 300 mg twice daily on the first day Maintenance dose: 6 mg/kg up to a maximum of 300 mg once daily	Duration of therapy is based on recovery from neutropenia or immunosuppression.
	> 40 kg (2 to < 18 years of age)	Loading dose: 300 mg twice daily on the first day Maintenance dose: 300 mg once daily		
Treatment of invasive Aspergillosis	13 to < 18 years of age regardless of weight	Loading dose: 300 mg (three 100 mg delayed-release tablets) twice a day on the first day. Maintenance dose: 300 mg (three 100 mg delayed-release tablets) once a day, starting on the second day. Switching between the intravenous and delayed release tablets is acceptable. A loading dose is not required when switching between formulations.	Loading dose: 300 mg injection intravenously twice a day on the first day. Maintenance dose: 300 mg injection intravenously once a day, starting on the second day. Switching between the intravenous and delayed-release tablets is acceptable. A loading dose is not required when switching between formulations.	Loading dose: 1 day Maintenance dose: Recommended total duration of therapy is 6 to 12 weeks.

c. Noxafil Oral Suspension Dosing Regimens for Pediatric Patients (ages 13 to <18 years of age)

Indication	Loading Dose (volume) and frequency	Maintenance Dose (volume) and frequency	Duration of therapy
Prophylaxis of invasive *Aspergillus* and *Candida* infections	200 mg (5 mL) three times a day	200 mg (5 mL) three times a day	Duration of therapy is based on recovery from neutropenia or immunosuppression
Oropharyngeal Candidiasis (OPC)	100 mg (2.5 mL) twice daily on the first day	100 mg (2.5 mL) once daily	13 days
OPC Refractory (rOPC) to Itraconazole and/or fluconazole	400 mg (10 mL) twice daily	400 mg (10 mL) twice daily	Duration of therapy is based on the severity of the patient's underlying disease and clinical response

d. Noxafil PowderMix for delayed-release oral suspension (2 to <18 years of age; weight is 10 to 40kg):

Indication	Weight (kg)	Loading Dose (volume)	Maintenance Dose (volume)
Prophylaxis of *Invasive Aspergillus* and *Candida* infections	10 to less than 12	90 mg (3 mL) twice daily on the first day	90 mg (3 mL) once daily
	12 to less than 17	120 mg (4 mL) twice daily on the first day	120 mg (4 mL) once daily
	17 to less than 21	150 mg (5 mL) twice daily on the first day	150 mg (5 mL) once daily
	21 to less than 26	180 mg (6 mL) twice daily on the first day	180 mg (6 mL) once daily
	26 to less than 36	210 mg (7 mL) twice daily on the first day	210 mg (7 mL) once daily
	36 to 40	240 mg (8 mL) twice daily on the first day	240 (8 mL) once daily

4. Quantity requested does not exceed:
    a. Delayed-release tablet: 93 tablets/30 days depending on the duration and indication
    b. Suspension: 600ml/30 days depending on the duration and indication
    c. Injections: 518ml/30 days or 31 vials of 300mg/16.7ml depending on the duration and indication

INITIAL APPROVALS

✓ Initial authorization will be granted for up to a period of 1 year

RENEWALS

✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created from CAB 11.19.2020	11.2020
Annual Review	No Changes	11.2021
Updated	Update: include expanded indications, coverage age, patient population, and dose.	3.2022; 11.2022
Annual Review	Added "medication follows appropriate dosage recommendations per FDA/Labeling" to dosage recommendations	10.2023

REFERENCE:

1. Noxafil (posaconazole) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme; September 2020.
2. Döring M, Eikemeier M, Cabanillas Stanchi KM, et al. Antifungal prophylaxis with posaconazole vs. fluconazole or itraconazole in pediatric patients with neutropenia. Eur J Clin Microbiol Infect Dis. 2015;34(6):1189-1200.[PubMed 25680318]
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4. Pappas PG, Kauffman CA, Andes DR, et al. Clinical practice guidelines for the management of candidiasis: 2016 update by the Infectious Diseases Society of America. Clin Infect Dis. 2016;62(4):e1-50.
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Prior Authorization Criteria for NUBEQA® (darolutamide)

FDA Approved Indications

- Non-metastatic castration-resistant prostate cancer (nmCRPC)
- Metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist.

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2019
Update	Add Denial Message	2.2020
Annual Review	No Changes	2.2021
Annual Review	No Changes	2.2022
Updat	Updated criteria to include expanded indication of Metastatic hormone-sensitive prostate cancer (mHSPC)	9.2022
Annual Review	Updated format	9.2023
Update	Updated duration of approval; updated to oncology drug format	5.2024
Annual Review	No changes	8.2024

REFERENCE:

1. Nubeqa® (darolutamide) tablets [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, October 2023.
2. Bayer internal calculation based on Tesselon data (February 2018).
3. Luo, Jia, Beer, Tomasz, Graff, Julie. Treatment of nonmetastatic castration- resistant prostate cancer. Oncology 2016;30(4):336-44.
4. Mayo Clinic. Prostate cancer screening: Should you get a PSA test? https://www.mayoclinic.org/tests-procedures/psa-test/in-depth/prostate-cancer/art-20048087. Accessed July 2019
5. GLOBOCAN 2018: Estimated Cancer Incidence, Mortality and Prevalence Worldwide in 2018. Prostate Cancer. https://onlinelibrary.wiley.com/doi/epdf/10.3322/caac.21492. Accessed July 2019.
6. National Cancer Institute. Hormone Therapy for Prostate Cancer. https://www.cancer.gov/types/prostate/prostate-hormone-therapy-fact-sheet. Accessed July 2019.
7. National Comprehensive Cancer Network. Prostate Cancer (Version 3.2023). https://www.nccn.org/professionals/physician_gls/pdf/nscl_blocks.pdf. Accessed August 22, 2023.

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Prior Authorization Criteria for NUCALA® (mepolizumab)

FDA-APPROVED INDICATIONS

- Add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype.
- Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).
- Treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for ≥6 months without an identifiable non-hematologic secondary cause.
- Add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.

Diagnosis: for Severe Asthma

1. Patient has diagnosis of severe asthma with eosinophilic phenotype **AND**
2. Patient is 6 years of age or older **AND**
3. Dosage and direction of use:
    - Recommended dose for 6 to 11 years: administered 40 mg subcutaneously once every 4 weeks;
    - Recommended dose for 12 years and older: administered 100 mg subcutaneously once every 4 weeks **AND**
4. Quantity requested does not exceed: 1/28 days **AND**
5. Patient has an absolute blood eosinophil count ≥150 cells/mcL within 6 weeks or ≥ 300 cells/mcL in the past 12 months **AND**
6. Patient has been adherent to the use of controller therapy (i.e., medium- to high-dose inhaled corticosteroid (e.g. Flovent, Pulmicort, Qvar) plus either a long-acting beta2 agonist (e.g. Serevent) or leukotriene modifier (e.g. Singulair, Accolate) **AND**
7. Patient has uncontrolled asthma despite adherent use of optimized doses of therapy requiring any of the following:
    - Two or more exacerbations requiring oral/systemic corticosteroid treatment (or increase in dose if already on oral corticosteroid) in the past 12 months
    - Urgent care visit or hospital admission in the past 12 months
    - Use of maintenance oral corticosteroids for asthma control
    - Poor symptoms control (frequent symptoms or reliever use, activity limited by asthmas, night waking due to asthma)
8. Nucala is not prescribed concurrently with Cinqair®, Fasenra®, Dupixent®, Tezspire, or Xolair® **AND**
9. Patient will continue to use maintenance asthma treatments **AND**
10. Prescribed by or in consultation with a pulmonologist, immunologist, or allergist.

Diagnosis: for Eosinophilic Granulomatosis with Polyangiitis

1. Patient has a diagnosis of Eosinophilic Granulomatosis with Polyangiitis (EGPA) or Churg-Strauss syndrome **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: administered 300 mg (3 separate 100-mg injections) subcutaneously once every 4 weeks **AND**
4. Quantity requested does not exceed: 3/28 days **AND**
5. Patient has a blood eosinophil level of 10% of leucocyte or an absolute count > 1000 cells/mm^3 with EGPA clinical features (e.g., asthma, chronic rhinosinusitis with polyps, eosinophilia, neuropathy, lung infiltrates, eosinophilic cardiomyopathy or gastroenteritis, glomerulonephritis) **AND**

6. Patient has had trial and failure of a 3-month trial of a glucocorticoid (e.g. prednisone, methylprednisolone) or an immunosuppressant (e.g. methotrexate, azathioprine), unless contraindicated or clinically significant adverse events are experienced **AND**
7. Patient has a history of relapsing or refractory disease while being on standard of care therapy (e.g., oral corticosteroid with or without immunosuppressant therapy) **AND**
8. Nucala is not prescribed concurrently with Cinqair, Fasenra, Dupixent, Tezspire, or Xolair **AND**
9. Prescribed by or in consultation with a pulmonologist, allergist, rheumatologist, or immunologist

Diagnosis: for Hypereosinophilic syndrome (HES)

1. Patient has a diagnosis of Hypereosinophilic syndrome (HES) **AND**
2. Patient is 12 years of age or older **AND**
3. Dosage and direction of use: administered 300 mg (3 separate 100-mg injections) subcutaneously once every 4 weeks **AND**
4. Quantity requested does not exceed: 3/28 days **AND**
5. Patient has had HES for at least 6 months **AND**
6. Patient has had HES flares while on stable HES therapy (i.e., high-dose oral corticosteroids, immunosuppressents, or cytotoxic therapy) **AND**
7. Patient has had at least two HES flares within the past 12 months **AND**
8. Patient does not have an identifiable non-hematologic secondary HES (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy) **AND**
9. Patient is FIP1L1-PDGFRα kinase- negative **AND**
10. Patient has a blood eosinophil count greater than or equal to 1000 cells/mcL within the past 3 months **AND**
11. Patient had an adequate trial of at least one other treatment for hypereosinophilic syndrome (i.e., systemic corticosteroids, hydroxyurea, cyclosporine, imatinib, methotrexate, tacrolimus, and azathioprine) **AND**
12. Nucala is not prescribed concurrently with Cinqair, Fasenra, Dupixent, Tezspire, or Xolair **AND**
13. Prescribed by or in consultation with a pulmonologist, allergist, hematologist, rheumatologist, or immunologist

Diagnosis: for Chronic rhinosinusitis with nasal polyps (CRSwNP)

1. Patient has a diagnosis of Chronic rhinosinusitis with nasal polyps (CRSwNP)**AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 100 mg administered subcutaneously once every 4 weeks **AND**
4. Quantity requested does not exceed: 1/28 days **AND**
5. Patient has two or more of the following symptoms for 12 weeks or more:
    a. Nasal blockage/congestion
    b. Nasal discharge
    c. Facial pain/pressure
    d. Reduction of smell **AND**
6. Patient had an inadequate treatment response, intolerance, or contraindication to a two- month trial of a saline nasal irrigation and TWO nasal corticosteroid sprays (i.e., mometasone, fluticasone, budesonide, or triamcinolone) **AND**
7. Patient has one of the following:
    a. An inadequate treatment response, intolerance, or contraindication to a 5 day or more treatment course of oral corticosteroids in the past 2 years **OR**
    b. Patient has had a prior surgery for nasal polyps **AND**
8. Patient is currently on and will continue current maintenance therapy with intranasal corticosteroids, unless contraindicated
9. Nucala is not prescribed concurrently with Cinqair®, Fasenra®, Dupixent®, Tezspire, or Xolair® **AND**
10. Prescribed by or in consultation with an otolaryngologist, allergist, or immunologist

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 12 months.

RENEWALS

- ✓ Patient responds positively to treatment.
- ✓ Approval duration for renewal: 1 year.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Revised	Created	9.2019
Update	Update Format	6.2020
Annual review	Added new diagnosis requirement for HES to the criteria sections and updated default denial message	7.2021
Update	Added expanded indication, new diagnosis requirement to the criteria sections: chronic rhinosinusitis with nasal polyps and updated default denial message	9.2021
Annual Review	No change	7.2022
Annual Review	Updated references Asthma: updated severe asthma dx requirements, added Tezspire to excluded concomitant meds; added requirement to continue maintenance treatment CRSwNP: updated symptom wording, added Tezspire to excluded concomitant meds; updated t/f duration per guidelines; added requirement for OCS or surgery; updated prescriber requirements HES/EGPA: updated prescriber requirements; added Tezspire to excluded concomitant meds	6.2023
Annual Review	Updated references Asthma: updated uncontrolled asthma requirements	5.2024
Update	Updated diagnosis criteria for Eosinophilic granulomatosis with polyangiitis (EGPA)	9.2024

REFERENCE:

1. Nucala (mepolizumab) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; March 2023.
2. Nucala (mepolizumab) [product monograph]. Mississauga, Ontario, Canada: GlaxoSmithKline Inc; July 2018.
3. Palmeira P, Quinello C, Silveira-Lessa AL, Zago CA, Carneiro-Sampaio M. IgG placental transfer in healthy and pathological pregnancies. Clin Dev Immunol. 2012;2012:985646.[PubMed 22235228]
4. National Asthma Education and Prevention Program: Expert panel report III: Guidelines for the diagnosis and management of asthma. Bethesda, MD: National Heart, Lung, and Blood Institute, 2007. (NIH publication no. 08-4051). Available at http://www.nhlbi.nih.gov/healthpro/guidelines/current/asthma-guidelines.
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Prior Authorization Criteria for NUCALA® (mepolizumab)

FDA-APPROVED INDICATIONS

- Add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype.
- Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).
- Treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for ≥6 months without an identifiable non-hematologic secondary cause.
- Add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.

Diagnosis: for Severe Asthma

1. Patient has diagnosis of severe asthma with eosinophilic phenotype **AND**
2. Patient is 6 years of age or older **AND**
3. Dosage and direction of use:
    - Recommended dose for 6 to 11 years: administered 40 mg subcutaneously once every 4 weeks;
    - Recommended dose for 12 years and older: administered 100 mg subcutaneously once every 4 weeks **AND**
4. Quantity requested does not exceed: 1/28 days **AND**
5. Patient has an absolute blood eosinophil count ≥150 cells/mcL within 6 weeks or ≥ 300 cells/mcL in the past 12 months **AND**
6. Patient has been adherent to the use of controller therapy (i.e., medium- to high-dose inhaled corticosteroid (e.g. Flovent, Pulmicort, Qvar) plus either a long-acting beta2 agonist (e.g. Serevent) or leukotriene modifier (e.g. Singulair, Accolate) **AND**
7. Patient has uncontrolled asthma despite adherent use of optimized doses of therapy requiring any of the following:
    - Two or more exacerbations requiring oral/systemic corticosteroid treatment (or increase in dose if already on oral corticosteroid) in the past 12 months
    - Urgent care visit or hospital admission in the past 12 months
    - Use of maintenance oral corticosteroids for asthma control
    - Poor symptoms control (frequent symptoms or reliever use, activity limited by asthmas, night waking due to asthma)
8. Nucala is not prescribed concurrently with Cinqair®, Fasenra®, Dupixent®, Tezspire, or Xolair® **AND**
9. Patient will continue to use maintenance asthma treatments **AND**
10. Prescribed by or in consultation with a pulmonologist, immunologist, or allergist.

Diagnosis: for Eosinophilic Granulomatosis with Polyangiitis

1. Patient has a diagnosis of Eosinophilic Granulomatosis with Polyangiitis (EGPA) or Churg-Strauss syndrome **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: administered 300 mg (3 separate 100-mg injections) subcutaneously once every 4 weeks **AND**
4. Quantity requested does not exceed: 3/28 days **AND**
5. Patient has history or presence of asthma **AND**
6. Patient has a blood eosinophil level of 10% of leucocyte or an absolute count > 1000 cells/mm^3 **AND**
7. Patient has two or more of the following criteria:

   a. A biopsy showing histopathological evidence of eosinophilic vasculitis, or perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation;
   b. Neuropathy, mono or poly (motor deficit or nerve conduction abnormality);
   c. Pulmonary infiltrates, non-fixed;
   d. Sino-nasal abnormality;
   e. Cardiomyopathy (established by echocardiography or Magnetic Resonance Imaging);
   f. Glomerulonephritis (hematuria, red cell casts, proteinuria);
   g. Alveolar hemorrhage (by bronchoalveolar lavage);
   h. Palpable purpura;
   i. Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinease **AND**
8. Patient must have blood eosinophils > 150 cells/uL within 6 weeks of dosing **AND**
9. Patient has had trial and failure of a 3-month trial of a glucocorticoid (e.g. prednisone, methylprednisolone) or an immunosuppressant (e.g. methotrexate or azathioprine), unless contraindicated or clinically significant adverse events are experienced **AND**
10. Nucala is not prescribed concurrently with Cinqair, Fasenra, Dupixent, Tezspire, or Xolair **AND**
11. Prescribed by or in consultation with a pulmonologist, allergist, rheumatologist, or immunologist

Diagnosis: for Hypereosinophilic syndrome (HES)

1. Patient has a diagnosis of Hypereosinophilic syndrome (HES) **AND**
2. Patient is 12 years of age or older **AND**
3. Dosage and direction of use: administered 300 mg (3 separate 100-mg injections) subcutaneously once every 4 weeks **AND**
4. Quantity requested does not exceed: 3/28 days **AND**
5. Patient has had HES for at least 6 months **AND**
6. Patient has had HES flares while on stable HES therapy (i.e., high-dose oral corticosteroids, immunosuppressents, or cytotoxic therapy) **AND**
7. Patient has had at least two HES flares within the past 12 months **AND**
8. Patient does not have an identifiable non-hematologic secondary HES (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy) **AND**
9. Patient is FIP1L1-PDGFRα kinase- negative **AND**
10. Patient has a blood eosinophil count greater than or equal to 1000 cells/mcL within the past 3 months **AND**
11. Patient had an adequate trial of at least one other treatment for hypereosinophilic syndrome (i.e., systemic corticosteroids, hydroxyurea, cyclosporine, imatinib, methotrexate, tacrolimus, and azathioprine) **AND**
12. Nucala is not prescribed concurrently with Cinqair, Fasenra, Dupixent, Tezspire, or Xolair **AND**
13. Prescribed by or in consultation with a pulmonologist, allergist, hematologist, rheumatologist, or immunologist

Diagnosis: for Chronic rhinosinusitis with nasal polyps (CRSwNP)

1. Patient has a diagnosis of Chronic rhinosinusitis with nasal polyps (CRSwNP)**AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 100 mg administered subcutaneously once every 4 weeks **AND**
4. Quantity requested does not exceed: 1/28 days **AND**
5. Patient has two or more of the following symptoms for 12 weeks or more:
   a. Nasal blockage/congestion
   b. Nasal discharge
   c. Facial pain/pressure
   d. Reduction of smell **AND**
6. Patient had an inadequate treatment response, intolerance, or contraindication to a two- month trial of a saline nasal irrigation and TWO nasal corticosteroid sprays (i.e., mometasone, fluticasone, budesonide, or triamcinolone) **AND**
7. Patient has one of the following:

a. An inadequate treatment response, intolerance, or contraindication to a 5 day or more treatment course of oral corticosteroids in the past 2 years **OR**
b. Patient has had a prior surgery for nasal polyps **AND**

8. Patient is currently on and will continue current maintenance therapy with intranasal corticosteroids, unless contraindicated
9. Nucala is not prescribed concurrently with Cinqair®, Fasenra®, Dupixent®, Tezspire, or Xolair® **AND**
10. Prescribed by or in consultation with an otolaryngologist, allergist, or immunologist

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 12 months.

RENEWALS

✓ Patient responds positively to treatment.
✓ Approval duration for renewal: 1 year.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Revised	Created	9.2019
Update	Update Format	6.2020
Annual review	Added new diagnosis requirement for HES to the criteria sections and updated default denial message	7.2021
Update	Added expanded indication, new diagnosis requirement to the criteria sections: chronic rhinosinusitis with nasal polyps and updated default denial message	9.2021
Annual Review	No change	7.2022
Annual Review	Updated references Asthma: updated severe asthma dx requirements, added Tezspire to excluded concomitant meds; added requirement to continue maintenance treatment CRSwNP: updated symptom wording, added Tezspire to excluded concomitant meds; updated t/f duration per guidelines; added requirement for OCS or surgery; updated prescriber requirements HES/EGPA: updated prescriber requirements; added Tezspire to excluded concomitant meds	6.2023
Annual Review	Updated references Asthma: updated uncontrolled asthma requirements	5.2023

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2. Nucala (mepolizumab) [product monograph]. Mississauga, Ontario, Canada: GlaxoSmithKline Inc; July 2018.
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13. Global Initiative for Asthma: Global strategy for asthma management and prevention (2023 update). Available at: https://ginasthma.org/wp-content/uploads/2023/05/GINA-2023-Full-Report-2023-WMS.pdf/. Accessed May 24, 2023.

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Prior Authorization Criteria for NUPLAZID® (pimavanserin) capsules and tablets

1. Patient has a diagnosis of hallucinations and delusions associated with Parkinson's disease psychosis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: 34 mg taken orally once daily, without titration **AND**
4. Quantity requested does not exceed: 30 capsules/30 days (34mg daily) **AND**
5. Prescribed by or in consultation with a neurologist.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Combined Antipsychotic Drug (High Dollar)	5.2021
Annual Review	No Changes	5.2022
Annual Review	Remove t/f of quetiapine based on guidelines	5.2023
Annual Review	Created separate criteria for Nuplazid, updated denial message, and updated format.	8.2023
Annual Review	No changes	3.2024

REFERENCE:

1. Black KJ. Treatment of Parkinson's disease psychosis. Med Int Rev. 2017 Dec;27(109):266-271. Epub 2018 Feb 3. PMID: 30140115; PMCID: PMC6103448.
2. Horn S, Richardson H, Xie SX, Weintraub D, Dahodwala N. Pimavanserin versus quetiapine for the treatment of psychosis in Parkinson's disease and dementia with Lewy bodies. Parkinsonism Relat Disord. 2019 Dec;69:119-124. doi: 10.1016/j.parkreldis.2019.11.009. Epub 2019 Nov 11. PMID: 31751863; PMCID: PMC7061324.
3. Maddalena AS, Fox M, Hofmann M, Hock C. Esophageal dysfunction on psychotropic medication. A case report and literature review. *Pharmacopsychiatry.* 2004;37(3):134-138. doi: 10.1055/s-2004-818993.[PubMed 15138897]
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6. Nuplazid (17 mg pimavanserin) [prescribing information]. San Diego, CA: Acadia Pharmaceuticals Inc; June 2018.
7. Reus VI, Fochtmann LJ, Eyler AE, et al. American Psychiatric Association practice guideline on the use of antipsychotics to treat agitation or psychosis in patients with dementia. First edition. *Am J Psychiatry.* 2016;173(5):543-546.[PubMed 27133416]
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Prior Authorization Criteria for NUZYRA® (omadacycline tablet)

FDA-Approved Indications

- Treatment of adult patients with community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible isolates), Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae, and Chlamydophila pneumonia
- Treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by the following susceptible microorganisms: Staphylococcus aureus (methicillin-susceptible and -resistant isolates), Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus grp. (includes S. anginosus, S. intermedius, and S. constellatus), Enterococcus faecalis, Enterobacter cloacae, and Klebsiella pneumoniae

1. Patient has diagnosis of community-acquired bacterial pneumonia (CABP) or acute bacterial skin and skin structure infections (ABSSSI) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use:
    a. Loading Dose:
        i. CABP-300 mg orally twice daily on day 1
        ii. ABSSSI-450 mg orally once daily on days 1 and 2
    b. Maintenance Dose: 300 mg once daily for 7-14 days **AND**
4. Quantity requested does not exceed: 15 tablets/14 days **AND**
5. Culture and sensitivity report shows organism is susceptible to omadacycline **AND**
6. One of the following:
    a. Patient has had an inadequate response or contraindication to one preferred generic formulary alternative to which organism is susceptible **OR**
    b. Request is for a continuation of Nuzyra therapy initiated in an inpatient setting **AND**
7. Prescribed by or in consultation with an infectious disease specialist

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 14 days

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Annual Review	No changes	2.2024

REFERENCE:

1. Nuzyra (omadacycline) [prescribing information]. Boston, MA: Paratek Pharmaceuticals, Inc; October 2018.
2. Lionel A. Mandell and others, Infectious Diseases Society of America/American Thoracic Society Consensus Guidelines on the Management of Community-Acquired Pneumonia in Adults, *Clinical Infectious Diseases*, Volume 44, Issue Supplement_2, March 2007, Pages S27–S72.
3. Dennis L. Stevens and others, Practice Guidelines for the Diagnosis and Management of Skin and Soft Tissue Infections: 2014 Update by the Infectious Diseases Society of America, *Clinical Infectious Diseases*, Volume 59, Issue 2, 15 July 2014, Pages e10–e52.

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Prior Authorization Criteria for OCALIVA® (obeticholic acid)

FDA-APPROVED INDICATION

- Treatment of adult patients with primary biliary cholangitis (PBC):
  - without cirrhosis or
  - with compensated cirrhosis who do not have evidence of portal hypertension

1. Patient has diagnosis of primary biliary cholangitis (PBC) **AND**
2. Patient meets ONE of the following criteria
   a. Patient does not have cirrhosis **OR**
   b. Patient has compensated cirrhosis without evidence of portal hypertension **AND**
3. Patient is 18 years of age and older **AND**
4. Dosage and direction of use: 5 mg once daily for the first 3 months; Max dosage of 10 mg once daily **AND**
5. Quantity requested does not exceed: 30 tablets/30 days **AND**
6. Patient meets one of the following:
   a. Patient had an inadequate response to a 12 month trial of optimally dosed ursodiol or ursodeoxycholic acid (UDCA) and will continue to use ursodiol or UDCA in combination with Ocaliva **OR**
   b. Patient has intolerance to or contraindication to UDCA or ursodiol **AND**
7. Prescribed by or in consultation with a hepatologist or gastroenterologist.

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 1 year

RENEWALS

✓ Documentation of positive clinical response to therapy has been provided when the current chart notes, and other pertinent information demonstrate patient has experienced a positive response.
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2021
Reviewed	No Changes	7.2022
Annual review	Updated diagnosis pathway format for clarity; added duration of 12 month to t/f of UDCA per guidelines	7.2023
Annual review	No changes	2.2024

REFERENCE:

1. Actigall (ursodiol) [prescribing information]. Irvine, CA: Allergan; May 2018.
2. Lindor KD, Bowlus CL, Boyer J, Levy C, Mayo M. Primary biliary cholangitis: 2018 practice guidance from the American Association for the Study of Liver Diseases. Hepatology. 2019;69(1):394-419. doi: 10.1002/hep.30145.[PubMed 30070375]
3. Ocaliva (obeticholic acid) [prescribing information]. New York, NY: Intercept Pharmaceuticals Inc; May 2021.
4. Ocaliva (obeticholic acid) [product monograph]. Mississauga, Ontario, Canada: Intercept Pharmaceuticals Inc; October 2018.
5. Nittono H, Tokita A, Hayashi M, et al. Ursodeoxycholic acid therapy in the treatment of biliary atresia. Biomed Pharmacother. 1989;43(1): 37-41. [PubMed 2730950]

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Prior Authorization Criteria for ODOMZO (sonidegib)

FDA-Approved Indications

- Treatment of adult patients with locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Update	Updated duration of approval; added FDA approved dx and age; added indication section	5.2024
Annual Review	No Changes	7.2024

REFERENCE:

1. ODOMZO. [Prescribing Information]. Cranbury, NJ. Sun Pharmaceutical Industries, Inc.: August 2023.

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Prior Authorization Criteria for OFEV® (nintedanib)

FDA-APPROVED INDICATIONS:

- Idiopathic Pulmonary Fibrosis (IPF): Treatment of idiopathic pulmonary fibrosis (IPF)
- Chronic Fibrosing Interstitial Lung Diseases (ILDS): Treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype
- Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD): Slowing the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD)

Idiopathic Pulmonary Fibrosis (IPF):

1. Patient has diagnosis of idiopathic pulmonary fibrosis (IPF) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 150 mg twice daily approximately 12 hours apart **AND**
4. Quantity requested does not exceed: 60 tablets/30 days **AND**
5. Diagnosis is confirmed by one of the following (documentation required):
    a. Usual interstitial pneumonia (UIP) patterns from high-resolution computed tomography (HRCT) demonstrated peripheral (subpleural), bibasilar reticular opacities associated with architectural distortion, including honeycomb changes and traction bronchiectasis or bronchiolectasis **OR**
    b. Lung biopsy with pathology confirming UIP **OR**
    c. The combination of HRCT and biopsy pattern are both indicative of probable UIP **AND**
6. Patient does not have any other known causes of interstitial lung disease (i.e., environmental exposure, radiation, systemic lupus erythematosus, and rheumatoid arthritis, HIV, cancer, etc.) **AND**
7. Patient does not have severe hepatic impairment or end-stage liver disease **AND**
8. Patient does not have end-stage renal disease **AND**
9. Patient is confirmed to be a non-smoker **AND**
10. Patient has documentation of a predicted FVC ≥50% **AND**
11. Patient has diffusion capacity of the lung for carbon monoxide (%DL_{CO}) ≥30% **AND**
12. Patient will not be taking Esbriet concomitantly **AND**
13. Prescribed by or in consultation with a pulmonologist.

Chronic Fibrosing Interstitial Lung Diseases (ILD)

1. Patient has diagnosis of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 150 mg twice daily approximately 12 hours apart **AND**
4. Quantity requested does not exceed: 60 tablets/30 days **AND**
5. Presence of fibrotic ILD as determined by evidence of pulmonary fibrosis on HRCT **AND**
6. Patient is presenting clinical signs of progression evidenced by a forced vital capacity (FVC) decline ≥10% of the predicted value, or FVC decline ≥5% to ≤10% with worsening symptoms and/or worsening imaging **AND**
7. Patient will not be taking Esbriet concomitantly **AND**
8. Prescribed by or in consultation with a pulmonologist.

Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)

1. Patient has diagnosis of systemic sclerosis-associated interstitial lung disease **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 150 mg twice daily approximately 12 hours apart **AND**
4. Quantity requested does not exceed: 60 tablets/30 days **AND**
5. Presence of interstitial lung disease as determined by evidence of pulmonary fibrosis on HRCT; **AND**
6. Additional signs of systemic sclerosis are identified (one of the following): **AND**
    a. Skin thickening of the fingers (e.g., puffy fingers, sclerodactyly of the fingers)
    b. Fingertip lesions (e.g., digital tip ulcers, fingertip pitting scars)
    c. Telangiectasia
    d. Abnormal nailfold capillaries
    e. Pulmonary arterial hypertension
    f. Raynaud's phenomenon

g. SSc-related autoantibodies (e.g., anticentromere, anti-topoisomerase I, anti-RNA polymerase III)

7. Patient will not be taking Esbriet concomitantly **AND**
8. Prescribed by or in consultation with a pulmonologist or a rheumatologist.

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 1 year

RENEWALS

✓ Documentation of positive clinical response to therapy has been provided
✓ Must be non-smoker
✓ The patient has not had a decline in percent predicted FVC >10% or >15% in DLCO
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Revised	Created	9.2019
Updated	Add Denial Message	2.2020
Updated	Add ILD and SSc-ILD indication	8.2020
Updated	Separated criteria per individual indication; Updated Indication and Denial Message	12.2020
Annual Review	Update denial message	12.2021
Annual Review	No change, update references	12.2022
Annual review	Updated the verbiage for FDA-approved indications	11.2023

REFERENCE:

1. Ofev (nintedanib) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; January 2018.
2. Ofev (nintedanib) [product monograph]. Burlington, Ontario, Canada: Boehringer Ingelheim (Canada) Ltd; August 2018.
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Prior Authorization Criteria for OGSIVEO™ (nirogacestat hydrobromide)

1. Patient has progressing desmoid tumors who require systemic treatment **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction: 150 mg orally twice daily **AND**
4. Quantity requested does not exceed: 60 tablets/30 days **AND**
5. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
6. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created from CAB 12.14.2023	12.2023
Annual Review	Updated dosing to account for new strengths	5.2024

REFERENCE:

1. <800> Hazardous Drugs—Handling in Healthcare Settings. *United States Pharmacopeia and National Formulary* (USP 43-NF 38). Rockville, MD: United States Pharmacopeia Convention; 2020:74-92.
2. Gounder M, Ratan R, Alcindor T, et al. Nirogacestat, a γ-secretase inhibitor for desmoid tumors. *N Engl J Med*. 2023;388(10):898-912. doi:10.1056/NEJMoa2210140[PubMed 36884323]
3. Ogsiveo (nirogacestat) [prescribing information]. Stamford, CT: SpringWorks Therapeutics, Inc; April 2024.
4. US Department of Health and Human Services; Centers for Disease Control and Prevention; National Institute for Occupational Safety and Health. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings 2016. https://www.cdc.gov/niosh/docs/2016-161/default.html. Accessed November 30, 2023.

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Prior Authorization Criteria for OJEMDA™ (tovorafenib)

FDA-Approved Indications

- Treatment of patients 6 months of age and older with relapsed or refractory pediatric low grade glioma (LGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist.

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 5.16.2024	5.2024
Update	Oncology template updated	8.2024

REFERENCE:

1. Ojemda (tovorafenib) [prescribing information]. Brisbane, CA: Day One Biopharmaceuticals, Inc; April 2024.
2. van Tilburg CM, Kilburn LB, Perreault S, et al. LOGGIC/FIREFLY-2: a phase 3, randomized trial of tovorafenib vs. chemotherapy in pediatric and young adult patients with newly diagnosed low-grade glioma harboring an activating RAF alteration. BMC Cancer. 2024;24(1):147. doi:10.1186/s12885-024-11820-x [PubMed 38291372]

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Prior Authorization Criteria for OLPRUVA™ (sodium phenylbutyrate packet therapy pack)

1. Patient has a diagnosis of urea cycle disorders (UCDs), involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS) confirmed by enzymatic, biochemical, or genetic testing **AND**
2. Dosage and Direction for Use: 9.9 -13 g/m2 /day in 3-6 divided doses **AND**
3. Quantity requested does not exceed: 20 grams per day **AND**
4. Patient weighs 20 kg or greater **AND**
5. Patient has a body surface area (BSA) of 1.2 m^2 or greater **AND**
6. Confirm that medication will be used in conjunction with dietary protein restriction with or without dietary supplements **AND**
7. Patient will not be taking Olpruva concurrently with Ravicti, Buphenyl, or Pheburane **AND**
8. Confirm Olpruva is not being used for the treatment of acute hyperammonemia **AND**
9. Prescribed by or in consultation with a metabolic specialist.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Documentation of clinical response to therapy is provided.
✓ Confirm continued use of dietary protein restriction and/or amino acid supplementation.
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 6.29.2023	6.2023
Annual Review	Update format; Addition of diagnosis requirements; Update renewal criteria	6.2024

REFERENCE:

1. Olpruva (sodium phenylbutyrate) [prescribing information]. Newton, MA: Acer Therapeutics Inc; December 2022.

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Prior Authorization Criteria for OMVOH® (mirikizumab-mrkz)

1. Patient has diagnosis of moderately to severely active ulcerative colitis (UC) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: Induction dosage is 300 mg administered by intravenous infusion over 30 minutes at weeks 0, 4, and 8; Maintenance dose is 200 mg (given as 2 consecutive subcutaneous injections of 100 mg each) at week 12 and every 4 weeks thereafter **AND**
4. Quantity requested does not exceed:
    a. Induction dose: 300 mg/28 days for 3 doses
    b. Maintenance dose: 2 pens/28 days **AND**
5. Patient has had an adequate trial and failure of at least ONE oral systemic agent (e.g., 6-mercaptopurine, azathioprine, methotrexate, cyclosporine, tacrolimus, corticosteroid (e.g., prednisone). A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis **AND**
6. Patient has failed to achieve symptom control after adequate treatment with, or has labeled contraindications to Adalimumab*, Skyrizi SC, Stelara, or Zymfentra **AND**
7. Patient is not taking another disease modifying agent concomitantly with Omvoh **AND**
8. Prescribed by or in consultation with a gastroenterologist.

INITIAL APPROVALS

- ✓ * Please review formulary for current preferred adalimumab products. The trial of more than one preferred adalimumab product counts as one preferred product.
- ✓ Prescriber attestation that labs/notes indicate patient has the disease or requires the medication
- ✓ Initial authorization will be granted for a period of 1 year.

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created from CAB 11.16.2023	11.2023
Annual Review	Added requirement to require a trial of adalimumab or Stelara	3.2024
Annual Review	Updated trial and failure requirement to include Zymfentra; updated wording for oral systemic agent	5.2024
Update	Added Skyrizi SC to trial and failure options	7.2024

REFERENCE:

1. Omvoh (mirikizumab-mrkz). [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company: October 2023.

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Prior Authorization Criteria for ONUREG® (azacitidine)

FDA-Approved Indications

- Continued treatment of adult patients with acute myeloid leukemia who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
- ✓ Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created from CAB 9.24.20	10.2020
Annual Review	No Changes	10.2021
Annual Review	Format update	10.2022
Annual Review	Updated criteria to include Onureg should be used as a single agent therapy; Added prescriber/consultation with a hematologist, and updated denial message	8.2023/10.2023
Update	Updated duration of approval; updated to oncology drug format	5.2024
Annual Review	No Changes	9.2024

REFERENCE:

1. Onureg Prescribing Information. Summit, NJ: Celgene Corporation; May 2021
2. National Comprehensive Cancer Network. Acute Myeloid Leukemia (AML) (Version 1.2022). https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf.Accessed October 12, 2021.

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Prior Authorization Criteria for OPFOLDA™ (miglustat) & POMBILITI™ (cipaglucosidase alfa-atga)

1. Patient has a diagnosis of late-onset Pompe disease **AND**
2. Patient is 18 years and older **AND**
3. Dosage and Direction for Use:
    A. Pombiliti: 20 mg/kg (of actual body weight) administered every other week as an intravenous infusion over approximately 4 hours **AND**
    B. Opfolda: (based on actual body weight), administered orally every other week, is: 260 mg for patients weighing ≥50 kg and 195 mg for patients weighing ≥40 kg to <50 kg given 1 hour prior to Pombiliti infusion **AND**
4. Quantity requested does not exceed: dosed by weight, please optimize quantity based on prescribed dosing scheduling **AND**
5. Patient weighs at least 40 kg **AND**
6. Patient has Pompe disease confirmed enzyme assay showing a deficiency of acid alpha-glucosidase (GAA) or with a genetic test showing a mutation in the GAA gene **AND**
7. Patient has presence of clinical signs and symptoms of the disease (i.e., cardiac hypertrophy, respiratory distress, skeletal muscle weakness, etc.) **AND**
8. Patient has had inadequate response to prior therapy with Lumizyme or Nexviazyme **AND**
9. Patient will be using Pombiliti in combination with Opfolda **AND**
10. Patient has documentation of baseline percent-predicted forced vital capacity (FVC) and 6-minute walk test (6MWT) **AND**
11. Prescribed by or in consultation with a specialist in metabolic or genetic diseases.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Approval duration for renewal: 1 year
✓ Patient has positive response to therapy as evidenced by an improvement or stabilization in percent-predicted FVC and or 6MWT.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 10.19.2023	10.2023

REFERENCE:

1. Pombiliti (cipaglucosidase alfa) [prescribing information]. Philadelphia, PA: Amicus Therapeutics UF, LLC; September 2023.
2. Opfolda (miglustat) [prescribing information]. Philadelphia, PA: Amicus Therapeutics US LLC; September 2023.

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Prior Authorization Criteria for OPZELURA™ (ruxolitinib phosphate)

FDA-Approved Indications

- Topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adult and pediatric patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
- Topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older

Diagnosis: Mild to moderate atopic dermatitis

1. Patient has a diagnosis of mild to moderate atopic dermatitis **AND**
2. Patient is 12 years of age or older **AND**
3. Dosage and Direction for Use: Apply a thin layer twice daily to affected areas of up to 20% of body surface area up to 60 grams per week **AND**
4. Quantity requested does not exceed: 60 grams per week or four-60 gram tubes per month **AND**
5. Patient has atopic dermatitis involvement estimated to affect ≤ 20% of the body surface area **AND**
6. Patient had a trial and failure of, contraindication to, or intolerance to both of the following:
    a. Moderate to high potency topical corticosteroid **AND**
    b. Topical calcineurin inhibitor (pimecrolimus, tacrolimus) **AND**
7. Patient is non-immunocompromised **AND**
8. Prescribed by or in consultation with a specialist such as a dermatologist

Diagnosis: Nonsegmental Vitiligo

1. Patient has a diagnosis of Nonsegmental Vitiligo **AND**
2. Patient is 12 years of age or older **AND**
3. Dosage and Direction for Use: Apply a thin layer twice daily to affected areas of up to 10% of body surface area up to 60 grams per week **AND**
4. Quantity requested does not exceed: 60 grams per week or four-60 gram tubes per month **AND**
5. Patient has vitiligo involvement that is estimated to affect ≤ 10% of the body surface area **AND**
6. Patient had a trial and failure of, contraindication to, or intolerance to both of the following:
    a. Moderate to high potency topical corticosteroid **AND**
    b. Topical calcineurin inhibitor (pimecrolimus, tacrolimus) **AND**
7. Prescribed by or in consultation with a specialist such as a dermatologist

INITIAL APPROVALS

- ✓ For atopic dermatitis: Initial approval will be granted for a period of 6 months
- ✓ For Nonsegmental Vitiligo: Initial approval will be granted for 6 months

RENEWALS

- ✓ Patient has a positive response to therapy (documentation provided)
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 10.7.2021	10.2021
Annual Review	Updated criteria to include expanded indication of Nonsegmental Vitiligo and updated approval duration.	10.2022; 11.2022
Updated	Edited denial statement	1.2023
Updated	Removed requirement “Opzelura is not used in combination with therapeutic biologics, other JAK inhibitors or potent immunosuppressants”.	7.2023
Annual Review	No changes	10.2023
Annual Review	Removed patient is non-immunocompromised for vitiligo based on package insert; updated trial and failure to both a calcineurin inhibitor and a mid to high potency topical corticosteroid; update initial approval to 6 months	9.2024

REFERENCE:

1. Opzelura (ruxolitinib) [prescribing information]. Wilmington, DE: Incyte Corporation; August 2024.
2. Atopic dermatitis. National Eczema Association website. Accessed October 4, 2021. https://nationaleczema.org/eczema/types-of-eczema/atopic-dermatitis/
3. Avena-Wood C. Overview of atopic dermatitis. Am J Manag Care. 2017;23:S115-S123. https://www.ajmc.com/view/overview-of-atopic-dermatitis-article
4. Eichenfield LF, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014;71(1):116-132. doi:10.1016/j.jaad.2014.03.023
5. Chiesa Fuxench ZC, et al. Atopic Dermatitis in America Study: A cross-sectional study examining the prevalence and disease burden of atopic dermatitis in the US adult population. J Invest Dermatol. 2019;139(3):583-590. doi:10.1016/j.jid.2018.08.028
6. Gawkrodger DJ, Ormerod AD, Shaw L, et al. Guideline for the diagnosis and management of vitiligo. Br J Dermatol. 2008;159(5):1051-1076. doi:10.1111/j.1365-2133.2008.08881.
7. Taieb A, Alomar A, Böhm M, et al. Guidelines for the management of vitiligo: the European Dermatology Forum consensus. Br J Dermatol. 2013;168(1):5-19. doi:10.1111/j.1365-2133.2012.11197
8. Mohammed GF, Gomaa AH, Al-Dhubaibi MS. Highlights in pathogenesis of vitiligo. World J Clin Cases 2015; 3:221.
9. Whitton M, Pinart M, Batchelor JM, et al. Evidence-based management of vitiligo: summary of a Cochrane systematic review. Br J Dermatol 2016; 174:962.

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Prior Authorization Criteria for ORAL CGRP - NURTEC™ ODT (rimegepant)

FDA Approved Indications:

- Acute treatment of migraine with or without aura in adults
- Preventive treatment of episodic migraine in adults

Diagnosis of acute treatment of migraine

1. Patient has diagnosis of migraine **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: 75 mg as needed. Not to exceed 18 doses in a 30-day period **AND**
4. Quantity requested does not exceed: 75 mg in a 24 hr period 18/month (standard QL: 8/fill) **AND**
5. Patient has an adequate trial of at least **TWO** generic triptans, unless contraindicated as follow:
    a. History of coronary artery disease or cardiac accessory conduction pathway disorders **OR**
    b. History of stroke, transient ischemic attack, peripheral vascular disease **OR**
    c. Ischemic bowel disease; uncontrolled hypertension, or severe hepatic impairment **OR**
    d. Diagnosis of complicated headaches, hemiplegic, or basilar migraine **AND**
6. Medication is not prescribed concurrently with another CGRP inhibitor when used for the treatment of migraine

Diagnosis of preventive treatment of episodic migraine

1. Patient has diagnosis of episodic migraine (4-14 headache days per month or headaches that last longer than 12 hours) **AND**
2. Patient is at least 18 years of age **AND**
3. Dosage and directions for use: 75 mg every other day. Max dose is 75 mg in a 24 hr period **AND**
4. Quantity requested does not exceed: 16 tablets/30 days (standard QL: 8/fill) **AND**
5. Patient has a trial and failure of **TWO** prophylactic medications from at least two different therapeutic classes, each consisting of an 8-week trial unless clinically significant adverse effects are experienced, or all are contraindicated:
    a. antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate)
    b. beta-blockers (e.g., metoprolol, propranolol, timolol)
    c. antidepressants (e.g., amitriptyline, venlafaxine) **AND**
6. Medication is not prescribed concurrently with another CGRP inhibitor when used for migraine prevention

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Approval duration for renewal: 1 year

✓ Episodic migraine: Patient has experienced a positive response with a reduction in headache frequency, duration orintensity

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Oral CGRP PA Criteria for Nurtec created based on CAB 3.26.2020	3.2020
Updated	Added criteria regarding no concomitant use with other oral CGRP	4.2020
Update	Added standard QL for reference	11.2020
Updated	Updated criteria and QLL regarding expanded indication of Nurtec ODT for preventive treatment of episodic migraine.	8.2021
Annual Review	Updated criteria regarding concomitant use with Botox	12.2021
Added	Updated monthly quantity fill, concurrent administration with other CGRPs	04.2022
Updated	Split oral CGRP criteria for Nurtec, Qulipta, and Ubrelvy into separate documents.	10.2022
Annual Review / Updated	Updated criteria to remove "patient may use Nurtec ODT with a different oral agent for preventative treatment", updated ST edit – removed t/f of Injectable CGRP, and updated format; added 8-week trial of preventative therapy and contraindications to triptans	10.2023

REFERENCE:

1. A Burch R. Headache in pregnancy and the puerperium. Neurol Clin. 2019;37(1):31-51. doi: 10.1016/j.ncl.2018.09.004.[PubMed 30470274]
2. Ailani J, Lipton RB, Goadsby PJ, et al; ADVANCE Study Group. Atogepant for the preventive treatment of migraine. N Engl J Med. 2021;385(8):695-706. doi:10.1056/NEJMoa2035908[PubMed 34407343]
3. American Family Physician. Treatment of Acute Migraine Headache. Gilmore and Michael. Am Fam Physician. 2011; 83:271-280. Accessed August 30, 2022.
4. American Headache Society. Information for Clinicians: Practice Parameters, Guidelines and Classification. Accessed January 10, 2020.
5. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. Headache. 2019;59:1-18.
6. Boinpally R, Jakate A, Butler M, Borbridge L, Periclou A. Single-dose pharmacokinetics and safety of atogepant in adults with hepatic impairment: results from an open-label, phase 1 trial. Clin Pharmacol Drug Dev. 2021;10(7):726-733. doi:10.1002/cpdd.916[PubMed 33501783]
7. Burch R, et al. The prevalence and burden of migraine and severe headache in the United States: updated statistics from government health surveillance studies. Headache. 2015;55(1):21-34. doi:10.1111/head.12482 Migraine.com. How common is migraine? Published April 19, 2021. Accessed August 30, 2022. https://migraine.com/migraine-statistics
8. Croop R, Goadsby PJ, Stock DA, et al. Efficacy, safety, and tolerability of rimegepant orally disintegrating tablet for the acute treatment of migraine: a randomised, phase 3, double-blind, placebo-controlled trial. Lancet. 2019;394(10200):737-745. doi: 10.1016/S0140-6736(19)31606-X.[PubMed 31311674]
9. Nurtec ODT (rimegepant) [prescribing information]. New Haven, CT: Biohaven Pharmaceuticals Inc; February 2020.
10. Pellesi L, Do TP, Ashina H, Ashina M, Burstein R. Dual therapy with anti-CGRP monoclonal antibodies and botulinum toxin for migraine prevention: is there a rationale? Headache. 2020;60:1056-1065.
11. Qulipta (atogepant) [prescribing information]. North Chicago, IL: AbbVie Inc; October 2021.
12. Ubrelvy (ubrogepant) [prescribing information]. Madison, NJ: Allergan USA, Inc; December 2019.
13. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. Headache. 2019;59:1-18.

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Prior Authorization Criteria for ORAL CGRP – QULIPTA™ (atogepant)

Diagnosis of preventive treatment of episodic migraine

1. Patient has diagnosis of one of the following:
    a. Episodic migraine (4-14 headache days per month or headaches that last longer than 12 hours) **OR**
    b. Chronic migraine (15 or more headache days per month for more than 3 months) **AND**
2. Patient is at least 18 years of age **AND**
3. Dosage and directions for use:
    a. Episodic migraine: 10 mg, 30 mg, or 60 mg taken orally once daily **OR**
    b. Chronic migraine: 60 mg taken once daily **AND**
4. Quantity requested does not exceed: 30 tablets/30 days (standard QL: 1/day) **AND**
5. Patient has a trial and failure of **TWO** prophylactic medications from at least two different therapeutic classes, each consisting of an 8-week trial unless clinically significant adverse effects are experienced, or all are contraindicated:
    a. antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate)
    b. beta-blockers (e.g., metoprolol, propranolol, timolol)
    c. antidepressants (e.g., amitriptyline, venlafaxine) **AND**
6. Medication is not prescribed concurrently with another CGRP inhibitor when used for migraine prevention

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Patient has experienced a positive response with a reduction in headache frequency, duration, or intensity
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Added	Criteria created for Qulipta from CAB 10.21.2021 and added to group Oral CGRPs	10.2021
Added	Updated criteria regarding concomitant use with Botox	12.2021
Updated	Updated monthly quantity fill, concurrent administration with other CGRPs	2.2022
Annual Review	Split oral CGRP criteria for Nurtec, Qulipta, and Ubrelvy into separate documents.	10.2022
Updated	Updated denial message to remove trial of preferred injectable CGRP inhibitor	6.2023
Annual Review / Updated	Updated criteria to include expanded indication of chronic migraine and updated denial message; added 8-week trial of preventative therapy	10.2023

REFERENCE:

1. A Burch R. Headache in pregnancy and the puerperium. Neurol Clin. 2019;37(1):31-51. doi: 10.1016/j.ncl.2018.09.004.[PubMed 30470274]
2. Ailani J, Lipton RB, Goadsby PJ, et al; ADVANCE Study Group. Atogepant for the preventive treatment of migraine. N Engl J Med. 2021;385(8):695-706. doi:10.1056/NEJMoa2035908[PubMed 34407343]
3. American Family Physician. Treatment of Acute Migraine Headache. Gilmore and Michael. Am Fam Physician. 2011; 83:271-280. Accessed August 30, 2022.
4. American Headache Society. Information for Clinicians: Practice Parameters, Guidelines and Classification. Accessed January 10, 2020.
5. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. Headache. 2019;59:1-18.

6. Boinpally R, Jakate A, Butler M, Borbridge L, Periclou A. Single-dose pharmacokinetics and safety of atogepant in adults with hepatic impairment: results from an open-label, phase 1 trial. Clin Pharmacol Drug Dev. 2021;10(7):726-733. doi:10.1002/cpdd.916[PubMed 33501783]
7. Burch R, et al. The prevalence and burden of migraine and severe headache in the United States: updated statistics from government health surveillance studies. Headache. 2015;55(1):21-34. doi:10.1111/head.12482 Migraine.com. How common is migraine? Published April 19, 2021. Accessed August 30, 2022. https://migraine.com/migraine-statistics
8. Croop R, Goadsby PJ, Stock DA, et al. Efficacy, safety, and tolerability of rimegepant orally disintegrating tablet for the acute treatment of migraine: a randomised, phase 3, double-blind, placebo-controlled trial. Lancet. 2019;394(10200):737-745. doi: 10.1016/S0140-6736(19)31606-X.[PubMed 31311674]
9. Nurtec ODT (rimegepant) [prescribing information]. New Haven, CT: Biohaven Pharmaceuticals Inc; February 2020.
10. Pellesi L, Do TP, Ashina H, Ashina M, Burstein R. Dual therapy with anti-CGRP monoclonal antibodies and botulinum toxin for migraine prevention: is there a rationale? Headache. 2020;60:1056-1065.
11. Qulipta (atogepant) [prescribing information]. North Chicago, IL: AbbVie Inc; October 2021.
12. Ubrelvy (ubrogepant) [prescribing information]. Madison, NJ: Allergan USA, Inc; December 2019.
13. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. Headache. 2019;59:1-18.
14.

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Prior Authorization Criteria for ORAL CGRP – UBRELVY™ (ubrogepant)

1. Patient has diagnosis of migraine **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: 50 mg to 100 mg as needed **AND**
4. Quantity requested does not exceed: 200 mg in a 24 hr period (standard QL: 10/fill) **AND**
5. Patient has an adequate trial of at least two generic triptans, unless contraindicated as follows:
    a. History of coronary artery disease or cardiac accessory conduction pathway disorders **OR**
    b. History of stroke, transient ischemic attack, peripheral vascular disease **OR**
    c. Ischemic bowel disease, uncontrolled hypertension, or severe hepatic impairment **OR**
    d. Diagnosis of complicated headaches, hemiplegic, or basilar migraine **AND**
6. Medication is not prescribed concurrently with another CGRP inhibitor when used for the treatment of migraine

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Oral CGRP criteria for Ubrelvy created based on CAB 1.30.2020	2.2020
Updated	Added criteria regarding no concomitant use with other oral CGRP	4.2020
Update	Added standard QL for reference	11.2020
Annual Review	No Changes	4.2021
Added	Updated criteria regarding concomitant use with Botox	12.2021
Updated	Updated monthly quantity fill, concurrent administration with other CGRPs	04.2022
Annual Review	Split oral CGRP criteria for Nurtec, Qulipta, and Ubrelvy into separate documents.	10.2022
Annual Review/ Updated	Updated criteria to remove "patient may use medication with a different oral agent for preventative treatment" and updated format; added contraindications to triptans	10.2023

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2. Ailani J, Lipton RB, Goadsby PJ, et al; ADVANCE Study Group. Atogepant for the preventive treatment of migraine. N Engl J Med. 2021;385(8):695-706. doi:10.1056/NEJMoa2035908[PubMed 34407343]
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7. Burch R, et al. The prevalence and burden of migraine and severe headache in the United States: updated statistics from government health surveillance studies. Headache. 2015;55(1):21-34. doi:10.1111/head.12482 Migraine.com. How common is migraine? Published April 19, 2021. Accessed August 30, 2022. https://migraine.com/migraine-statistics
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Prior Authorization Criteria for ORGOVYX® (relugolix)

1. Patient has diagnosis of advanced prostate cancer **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: A loading dose of 360 mg on the first day of treatment followed by 120 mg taken orally once daily, at approximately the same time every day **AND**
4. Quantity requested does not exceed: 30 tablets/30 days **AND**
5. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
6. Prescribed by or in consultation with an oncologist or urologist.

INITIAL APPROVAL

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
- ✓ Initial approval duration will be 1 year

RENEWAL

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 1.14.2021	1.2021
Annual Review	No changes	1.2022
Annual Review	Update diagnosis criteria for advanced prostate cancer.	1.2023
Update	Updated criteria to remove additional diagnosis criteria and trial and failure requirement.	5.2023
Annual review	Updated approval duration; added requirement to follow appropriate sequence of therapy	12.2023

REFERENCE:

1. Keating NL, O'Malley AJ, Smith MR. Diabetes and cardiovascular disease during androgen deprivation therapy for prostate cancer. J Clin Oncol. 2006;24(27):4448-4456. doi:10.1200/JCO.2006.06.2497[PubMed 16983113]
2. Levine GN, D'Amico AV, Berger P, et al; American Heart Association Council on Clinical Cardiology and Council on Epidemiology and Prevention, the American Cancer Society, and the American Urological Association. Androgen-deprivation therapy in prostate cancer and cardiovascular risk. A science advisory from the American Heart Association, American Cancer Society, and American Urological Association: endorsed by the American Society for Radiation Oncology. Circulation. 2010;121(6):833-840. doi:10.1161/CIRCULATIONAHA.109.192695[PubMed 20124128]
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6. National Comprehensive Cancer Network. Prostate Cancer (Version 1.2023).https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed May 17, 2023

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Prior Authorization Criteria for ORIAHNN™ (elagolix-estradiol-norethindrone acetate 300-1-0.5mg & elagolix 300mg cap pack), ORILISSA® (elagolix)

FDA-APPROVED INDICATIONS

- Moderate to severe pain associated with endometriosis
- Management of heavy menstrual bleeding associated with uterine fibroids (ORIAHNN)

Diagnosis: Moderate to severe pain associated with endometriosis (ORILISSA)

1. Patient has a diagnosis of moderate to severe pain associated with endometriosis **AND**
2. Patient is aged 18 years of age or older **AND**
3. Dosage and direction of use:
    - 150 mg once daily for up to 24 months (mild hepatic impairment or normal liver function) OR
    - 200 mg twice daily for up to 6 months (mild hepatic impairment or normal liver function) OR
    - 150 mg once daily for up to 6 months (moderate hepatic impairment) **AND**
4. Quantity requested does not exceed: 400mg (two-200mg tablets/day) **AND**
5. Patient has tried and failed at least one NSAID (i.e., ibuprofen, meloxicam) or opioids (i.e., tramadol) unless labeled contraindication or clinical significant adverse effects are experienced **AND**
6. Patient has tried and failed one of the following: hormonal contraceptives or progestins (i.e., norethindrone) **AND**
7. Patient does not have any of the following contraindications:
    - Known osteoporosis with documentation of a DEXA-scan **OR**
    - Pregnant **OR**
    - Severe hepatic impairment **OR**
    - Organic anion transporting polypeptide (OATP) 1B1 inhibitors **AND**
8. Patient has not previously received ≥24 months of therapy combined with Orilissa, Oriahn, or Myfembree **AND**
9. Prescribed by or in consultation with a specialist such as a gynecologist.

Diagnosis: Management of heavy menstrual bleeding associated with uterine fibroids (ORIAHNN)

1. Patient has diagnosis of heavy menstrual bleeding associated with uterine fibroids **AND**
2. Patient is aged 18 years of age or older **AND**
3. Dosage and direction of use: one capsule (elagolix 300 mg, estradiol 1 mg, norethindrone acetate 0.5 mg) in the morning and one capsule (elagolix 300 mg) in the evening **AND**
4. Quantity requested does not exceed: Two capsules daily for up to 24 months **AND**
5. Patient is premenopausal **AND**
6. Patient has tried and failed one of the following generic alternatives: hormonal contraceptives, progestins (i.e., norethindrone), or injectable gonadotropin-release hormone agonists (i.e., leuprolide) **AND**
7. Patient does not have any of the following contraindications:
    a. History of arterial, venous thrombotic, or thromboembolic disorder OR at high risk for these events (i.e., women over age of 35 years and smoke, uncontrolled hypertension) **OR**
    b. Known osteoporosis with documentation of a DEXA-scan **OR**
    c. Pregnant **OR**
    d. Known hepatic impairment or disease **OR**
    e. Undiagnosed abnormal uterine bleeding **AND**
    f. Organic anion transporting polypeptide (OATP) 1B1 inhibitors **AND**
8. Patient does not have current or history of breast cancer or other hormonally-sensitive malignancies such as those with mutations in BRCA genes **AND**

9. Patient has not previously received ≥24 months of therapy combined with Orilissa, Oriahn, or Myfembree
AND
10. Prescribed by or in consultation with a specialist such as a gynecologist.

INITIAL APPROVALS

- ✓ ORILISSA Initial authorization will be granted for a period of 6 months. One time authorization for 6 months will be granted for patients with moderate hepatic impairment or for patients taking ORILISSA 200 mg twice daily
- ✓ ORIAHNN Initial authorization will be granted for a period of 6 months.

RENEWALS

- ✓ Documentation of positive clinical response
- ✓ ORILISSA approval duration for renewal: 6 months up to a maximum of 24 months for patients taking 150mg once daily in mild to normal liver function.
- ✓ ORIAHNN approval duration up to 24 total months of therapy
- ✓ Patient has not previously received ≥24 months of therapy combined with Orilissa, Oriahn, or Myfembree

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	3.2019
Update	Update Format/Add Denial Message	3.2020
Add	Added Oriahnn based on CAB 6.18.2020	6.2020
Annual Review	Updated PA criteria and added Myfembree	6.2021
Reviewed	Created a separate document for Myfembree. No Changes for Orilissa and Oriahnn	9.2022
Annual Review	Updated criteria and format	6.2023
Annual review	Removed duplicative criteria	6.2024

REFERENCE:

1. American College of Obstetricians and Gynecologists. Practice bulletin: clinical management guidelines for obstetrician-gynecologist: management of endometriosis. Am J Obstet Gynecol 2010; 116(1):223-236.
2. De la Cruz MS, et al. 2017. Uterine fibroids: diagnosis and treatment. Am Fam Physician. 95(2):100-107.
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5. Orilissa (elagolix) [prescribing information]. North Chicago, IL: AbbVie Inc; August 2019.
6. Simon JA, et al. 2020. Elagolix treatment for up to 12 months in women with heavy menstrual bleeding and uterine leiomyomas. Obstet Gynecol. 135:1313–26.
7. Stewart EA. Uterine fibroids (leiomyomas): Treatment overview. UpToDate website. UpToDate. Accessed June 17, 2020.
8. Struthers RS, Nicholls AJ, Grundy J, et al. Suppression of gonadotropins and estradiol in premenopausal women by oral administration of the nonpeptide gonadotropin-releasing hormone antagonist elagolix. J Clin Endocrinol Metab. 2009;94(2):545-551. doi:10.1210/jc.2008-1695.
9. Myfembree (relugolix, estradiol, and norethindrone) [prescribing information]. Brisbane, CA: Myovant Sciences Inc; May 2021.

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Prior Authorization Criteria for ORSERDU™ (elacestrant hydrochloride)

1. Patient has a diagnosis of ER+/HER2−, ESR1-mutated advanced or metastatic breast cancer **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: 345 mg tablet taken orally once a day **AND**
4. Quantity requested does not exceed: 30 tabs/30 days **AND**
5. Prescriber attestation that disease has progressed following at least one line of endocrine therapy (e.g., fulvestrant, anastrozole, exemestane, letrozole, tamoxifen) **AND**
6. Prescribed by or in consultation with a specialist such as a hematologist or oncologist.

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
- ✓ Initial authorization will be granted for a period of 1 year
- ✓

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 2.23.2023	2.2023
Annual Review	Updated diagnosis to confirm "ESR1-mutated" breast cancer, updated criteria requirement based on package insert/NCCCN guidelines, updated initial and renewal duration period, denial message, format, and references	2.2024

REFERENCE:

1. Bidard FC, Kaklamani VG, Neven P, et al. Elacestrant (oral selective estrogen receptor degrader) versus standard endocrine therapy for estrogen receptor-positive, human epidermal growth factor receptor 2-negative advanced breast cancer: results from the randomized phase III EMERALD trial. J Clin Oncol. 2022;40(23):3246-3256. doi:10.1200/JCO.22.00338[PubMed 35584336]
2. Bidard FC, et al. Elacestrant (oral selective estrogen receptor degrader) versus standard endocrine therapy for estrogen receptor-positive, human epidermal growth factor receptor 2-negative advanced breast cancer: results from the randomized Phase III EMERALD trial. J Clin Oncol. 2022;40(28):3246–3256. doi:10.1200/JCO.22.00338.
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Prior Authorization Criteria for OTEZLA® (apremilast)

FDA-APPROVED INDICATIONS

- Psoriatic arthritis (PsA): Adult patients with active psoriatic arthritis
- Plaque psoriasis (PP):
  - Adult patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
  - Pediatric patients 6 years of age and older and weighing at least 20 kg with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- Oral Ulcers: Adult patients with oral ulcers associated with Behçet's Disease

Diagnosis: for Psoriatic Arthritis (PsA)

1. Patient has diagnosis of Psoriatic Arthritis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: titrate as follows to a final dose of 30 mg PO twice daily. Day 1: 10 mg PO in the morning. Day 2: 10 mg PO twice daily. Day 3: 10 mg PO in the morning and 20 mg PO in the evening. Day 4: 20 mg PO twice daily. Day 5: 20 mg PO in the morning and 30 mg PO in the evening. Day 6 and thereafter: 30 mg PO twice daily. **AND**
4. Quantity requested does not exceed: 60 tablets/30 days (confirm if starter pack is requested) **AND**
5. Patient has had an inadequate response or has labeled contraindications to at least one non-biologic disease modifying anti-rheumatic drugs (DMARDs) (i.e., methotrexate or leflunomide) **AND**
6. Patient is not receiving medication in combination with other biologic DMARDs **AND**
7. Prescribed by or in consultation with a rheumatologist

Diagnosis: for Plaque Psoriasis (PP)

1. Patient has diagnosis of moderate to severe chronic plaque psoriasis **AND**
2. PP is affecting more than 3% of body surface area (BSA) or affecting crucial body areas (e.g., hands, feet, face, or genitals) **AND**
3. Patient is 6 years of age or older **AND**
4. Patient weighs at least 20 kg **AND**
5. Dosage and direction of use:
   a. 18 years of age and older: Titrate as follows to a final dose of 30 mg PO twice daily. Day 1: 10 mg PO in the morning. Day 2: 10 mg PO twice daily. Day 3: 10 mg PO in the morning and 20 mg PO in the evening. Day 4: 20 mg PO twice daily. Day 5: 20 mg PO in the morning and 30 mg PO in the evening. Day 6 and thereafter: 30 mg PO twice daily
   b. Pediatric patients less than 18 years of age: Titrate per package insert to a total dose of 20 mg twice daily if weight is between 20 kg to less than 50 kg and to 30 mg twice daily if weight is 50 kg or greater **AND**
6. Quantity requested does not exceed: 60 tablets/30 days (confirm if starter pack is requested) **AND**
7. Patient has had an adequate trial and failure of both UV or systemic treatments (methotrexate, acitretin, cyclosporine) **AND**
8. Patient has had an adequate trial and failure to topical therapy (corticosteroids, calcipotriene, calcitriol, tazarotene, tacrolimus) **AND**
9. Patient is not receiving medication in combination with other biologic DMARDs **AND**
10. Prescribed by or in consultation with a dermatologist

Diagnosis: for Oral Ulcers with Behçet's Disease

1. Patient has diagnosis of Behçet's Disease **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: titrate as follows to a final dose of 30 mg PO twice daily. Day 1: 10 mg PO in the morning. Day 2: 10 mg PO twice daily. Day 3: 10 mg PO in the morning and 20 mg PO in the evening. Day 4: 20 mg PO twice daily. Day 5: 20 mg PO in the morning and 30 mg PO in the evening. Day 6 and thereafter: 30 mg PO twice daily. **AND**
4. Quantity requested does not exceed: 60 tablets/30 days (confirm if starter pack is requested) **AND**
5. Patient has at oral ulcers associated with Behçet's Disease **AND**
6. Patient has a history of recurring oral ulcers (defined as at least three occurrences within a 12-month period) **AND**
7. Patient had an adequate trial of at least two of the following medications from different classes such as topical corticosteroids, non-steroidal anti-inflammatory drugs (NSAIDs), colchicine, immunosuppressants (i.e., azathioprine, cyclosporine, cyclophosphamide), or mouthwashes containing a local anesthetic such as Xylocaine, lidocaine depending on the symptoms **AND**
8. Patient is not receiving medication in combination with other biologic DMARDs **AND**
9. Prescribed by or in consultation with a rheumatologist or dermatologist.

INITIAL APPROVALS

- ✓ Prescriber attestation that labs/notes indicate patient has the disease or requires the medication
- ✓ If all criteria met, initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided (e.g., baseline decrease in number of plaques, improvement in skin appearance, etc.) **AND**
- ✓ Patient is not receiving medication in combination with other biologic DMARDs **AND**
- ✓ Approval duration for renewal: 1 year

HISTORY

ACTION	SUMMARY OF CHANGES	DATE
Revised	Created	7.2019
Updated	Added default denial message	12.2019
Reviewed	Under Jan' 2020 CAB meeting, no change.	1.2020
Updated	Changed from trial/failure to Preferred Step-1 for PsA indication	7.2020
Annual Review	Added expanded indication for Oral Ulcers with Behçet's Disease; Updated clinical criteria for Psoriatic Arthritis to include nonsteroidal anti-inflammatory drugs (NSAIDs) or non-biologic disease modifying anti-rheumatic drugs (DMARDs).	2.2022
Annual Review	No Changes	6.2023
Updated	PP: Updated BSA to 3% per guidelines; separated out t/f criteria PsA: Removed t/f of NSAID option per guidelines Updated denial message, removed "completed by" in history section, updated format.	8.2023
Annual Review	Updated age range for plaque psoriasis to 6 years and older and greater than 20 kg; Updated references	5.2024

REFERENCE:

1. Otezla (apremilast) [prescribing information]. Thousand Oaks, CA: Amgen Inc; April 2024.
2. Menter A, Gottlieb A, Feldman SR, Van Voorhees AS, Leonardi CL, Gordon KB, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol 2008 May; 58(5):826-50.
3. Gossec L, Smolen JS, Ramiro S, et al European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update Annals of the Rheumatic Diseases Published Online First: 07 December 2015. doi: 10.1136/annrheumdis-2015-208337.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. American College of Rheumatology. 2019; 71(1):5-32. doi: 10.1002/art.40726
5. Ozguler Y, Hatemi G, Yazici H. Management of Behçet's syndrome. Curr Opin Rheumatol. 2014 May;26(3):285-91. doi: 10.1097/BOR.0000000000000050.
6. Zierhut M, Abu El-Asrar AM, Bodaghi B, et al. Therapy of ocular Behçet disease. Ocul Immunol Inflamm. 2014 Feb;22(1):64-76. doi: 10.3109/09273948.2013.866257. Epub 2013 Dec 30.
7. Hatemi G, Silman A, Bang D, et al. Management of Behçet disease: a systematic literature review for the European League Against Rheumatism evidence-based recommendations for the management of Behçet disease. Ann Rheum Dis 2009; 68:1528.
8. Ogdie A, Coates LC, Gladman DD. Treatment guidelines in psoriatic arthritis. Rheumatology (Oxford). 2020 Mar 1;59(Suppl 1):i37-i46. doi: 10.1093/rheumatology/kez383. PMID: 32159790; PMCID: PMC7065461.
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10. Mentor A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology – National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020;82(6):1445-1486.

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Prior Authorization Criteria for OTREXUP™, RASUVO® (methotrexate auto-injectors)

FDA-APPROVED INDICATIONS

- Severe Active Polyarticular Juvenile Idiopathic Arthritis (pJIA)
- Severe Active Rheumatoid Arthritis (RA)
- Severe Psoriasis

Diagnosis: Severe Active Polyarticular Juvenile Idiopathic Arthritis (pJIA)

1. Patient has diagnosis of Active Polyarticular Juvenile Idiopathic Arthritis (pJIA) **AND**
2. Patient is 2 years of age or older **AND**
3. Dosage and direction of use: starting dose at 10 mg/m^2 subcutaneously once weekly, adjust dose gradually to achieve an optimal response **AND**
4. Quantity requested does not exceed: based on body surface area per FDA-approved recommendation **AND**
5. Patient has an adequate trial of NSAIDs (e.g. naproxen, ibuprofen) **AND** oral methotrexate **AND**
6. Patient has had an adequate trial of generic methotrexate injection **AND**
7. Patient is not using requested medication in combination with another form or brand of methotrexate **AND**
8. Prescribed by or in consultation with a specialist such as rheumatologist.

Diagnosis: Severe Active Rheumatoid Arthritis (RA)

1. Patient has a diagnosis of severe rheumatoid arthritis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: initial dose of 7.5mg (1 pen) subcutaneously once weekly, adjust dose gradually to achieve an optimal response **AND**
4. Quantity requested does not exceed: 4 pens/28 days **AND**
5. Patient has an adequate trial of NSAIDs (e.g. naproxen, ibuprofen) AND oral methotrexate **AND**
6. Patient has had an adequate trial of generic methotrexate injectable **AND**
7. Patient is not using requested medication in combination with another form or brand of methotrexate **AND**
8. Prescribed by or in consultation with a specialist such as rheumatologist.

Diagnosis: for Active Psoriasis

1. Patient has a documented diagnosis of active psoriatic **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 10 to 25 mg (1 pen) subcutaneously once weekly, adjust dose gradually to achieve an optimal response **AND**
4. Quantity requested does not exceed: 4 pens/28 days **AND**
5. Patient has an adequate trial of topical corticosteroids (i.e., hydrocortisone) or other topical agents (i.e., tazarotene) **AND** oral methotrexate **AND**
6. Patient has had an adequate trial of generic methotrexate injectable **AND**
7. Patient is not using requested medication in combination with another form or brand of methotrexate **AND**
8. Prescribed by or in consultation with a specialist such as dermatologist.

INITIAL APPROVALS

- ✓ Note: not indicated for neoplastic disease
- ✓ Initial authorization will be granted for a period of 1 year
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided, examples include:
  - Rheumatoid arthritis, psoriatic arthritis, or Polyarticular Juvenile Idiopathic Arthritis: baseline decrease in joint stiffness and swelling, decrease in pain, improvement in quality of life and overall functioning
  - Plaque psoriasis: baseline decrease in number of and size plaque scales, decreased itching, improvement in quality of life improvement in skin appearance, etc.)
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	11.2019
Updated	Update Format	2.2020
Updated	Added Reditrex per CAB 11.19.2020; updated reference section to include RediTrex PI info	11.2020
Annual Review	No Changes	11.2021
Annual Review	No Changes	11.2022
Updated	Updated prescriber type for psoriasis; updated format	9.2023
Annual Review	Updated wording; removed Reditrex as discontinued from market	7.2024

REFERENCE:

1. Otrexup (methotrexate injection) [prescribing information]. Ewing, NJ: Antares Pharma Inc; March 2018.
2. Otrexup PFS (methotrexate injection prefilled syringe) [prescribing information]. Ewing, NJ: Antares Pharma Inc; June 2019.
3. Rasuvo (methotrexate) [prescribing information]. Chicago, IL: Medac Pharma Inc; March 2018.
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7. Weiss B, Lerner A, Shapiro R, et al. Methotrexate treatment in pediatric Crohn disease patients intolerant or resistant to purine analogues. J Pediatr Gastroenterol Nutr. 2009;48:526-530.[PubMed 19412004]
8. RediTrex (methotrexate injection) [prescribing information]. Nashville,TN: Cumberland Pharmaceuticals Inc; November 2020

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Prior Authorization Criteria for OXERVATE™ (cenegermin-bkbj) ophthalmic solution

1. Patient has documented diagnosis of stage 2 or 3 neurotrophic keratitis **AND**
2. Patient is 2 years of age or older **AND**
3. Dosage and direction of use: one drop of in the affected eye(s), 6 times per day at 2- hour intervals, for eight weeks (1 vial per day of the week) **AND**
4. Quantity requested does not exceed: one drop of in the affected eye(s), 6 times per day at 2- hour intervals, for eight weeks (1 vial per day of the week) **AND**
5. Patient is refractory to one or more conventional non-surgical treatments for neurotrophic keratitis (i.e., preservative-free artificial tears, gels or ointments) **AND**
6. Prescribed by or in consultation with an ophthalmologist or optometrist

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 8 weeks.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Update	Updated Denial message and criteria	8.2021
Annual Review	No Changes	8.2022
Annual Review	No Changes	8.2023
Annual Review	No Changes	2.2024
Annual Review	Removed diagnostic criteria; removed criteria for stromal melting; removed ocular infection contraindication	7.2024

REFERENCE:

1. Oxervate (cenegermin-bkbj) [prescribing information]. Boston, MA: Dompé US Inc; October 2023.
2. Sacchetti M, Lambiase A. Diagnosis and management of neurotrophic keratitis. Clin Ophthalmol. 2014;8:571-579. Published 2014 Mar 19. doi:10.2147/OPTH.S45921

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Prior Authorization Criteria for PALYNZIQ® (pegvaliase)

1. Patient has diagnosis of phenylketonuria (PKU) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: initial dosage is 2.5 mg subcutaneously once weekly for 4 weeks and titrated in a step-wise manner over at least 5 weeks based on tolerability to achieve a dosage of 20mg once daily.
    a. The dose may be increased to **40 mg** once daily in patients who have been on 20 mg once daily continuously for at least 24 weeks and who have not achieved blood Phe control (blood phenylalanine concentration ≤ 600 micromol/L).
    b. The dose may be increased to **60 mg** once daily in patients who have been on 40 mg once daily continuously for at least 16 weeks and who have not achieved blood Phe control (blood phenylalanine concentration ≤ 600 micromol/L) **AND**
4. Quantity requested does not exceed: 60mg/day or 84 single-dose prefilled syringes (60mg/day)/28 days **AND**
5. Patient has documented uncontrolled blood phenylalanine concentrations of greater than 600 micromol/L **AND**
6. Patient follows a phenylalanine restricted diet and will continue this diet during treatment with Palynziq **AND**
7. Patient has had an adequate trial of generic Kuvan (sapropterin dihydrochloride) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced **AND**
8. Patient is not receiving medication in combination with Kuvan **AND**
9. Prescribed by or in consultation with an endocrinologist, metabolic disease specialist, or genetic disease specialist.

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 1 year

RENEWALS

✓ Documentation of positive response to therapy as evidenced by improved blood phenylalanine concentration less than 600 micromol/L
✓ Patient has achieved a 20% reduction in blood phenylalanine concentration from pre- treatment baseline
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	9.2018
Annual Review	No changes	9.2019
Update	Add Denial Message	2.2020
Updated	Update PA Criteria / Update Renewals	3.2021
Annual Review	Update Criteria	3.2022
Annual Review	Updated t/f criteria to generic Kuvan (sapropterin dihydrochloride); Update References	3.2023
Annual Review	Updated format	2.2024

REFERENCE:

1. American College of Obstetricians and Gynecologists (ACOG). Management of women with phenylalanine hydroxylase deficiency (phenylketonuria): ACOG Committee opinion, number 802. Obstet Gynecol. 2020;135(4):e167-e170. doi:10.1097/AOG.0000000000003768[PubMed 32217978]
2. Harding CO, Amato RS, et al. Pegvaliase for the treatment of phenylketonuria: a pivotal, double-blind randomized discontinuation phase 3 clinical trial. Molecular Genetics and Metabolism. 2018;124:20- 26.
3. Palynziq (pegvaliase) [product monograph]. Toronto, Ontario, Canada: BioMarin Pharmaceutical (Canada) Inc; April 2023.
4. Palynziq (pegvaliase) [product monograph]. Toronto, Ontario, Canada: BioMarin Pharmaceutical (Canada) Inc; March 2022.
5. Van Wegberg AMJ, MacDonald A, Ahring A, et al. The complete European guidelines on phenylketonuria: diagnosis and treatment. Orphanet J Rare Dis. 2017;12:162

6. Vockley J, Andersson HC, Antshel KM, Braverman NE, Burton BK, Frazier DM, Mitchell J, Smith WE, Thompson BH, Berry SA; American College of Medical Genetics and Genomics Therapeutics Committee. Phenylalanine hydroxylase deficiency: diagnosis and management guideline. Genet Med. 2014 Feb;16(2):188-200. doi: 10.1038/gim.2013.157. Epub 2013 Oct 10. Erratum in: Genet Med. 2014 Apr;16(4):356. PMID: 24385074.
7. Vockley J, Andersson HC, Antshel KM, et al. Phenylalanine hydroxylase deficiency: diagnosis and management guideline. Genet Med. 2014;16(2):188-200
8. van Wegberg AMJ, MacDonald A, Ahring K, et al. The complete European guidelines on phenylketonuria: diagnosis and treatment. Orphanet J Rare Dis. 2017;12(1):162. Published 2017 Oct 12. doi:10.1186/s13023-017-0685-2

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Prior Authorization Criteria for PEGASYS (peginterferon alfa 2a)

FDA-Approved Indications

- Chronic Hepatitis C
- Chronic Hepatitis B

Diagnosis: Chronic Hepatitis C

1. Patient has diagnosis of chronic hepatitis C **AND**
2. Patient is 5 years of age or older **AND**
3. Dosage and direction of use:
    a. Adults: 180 mcg subcutaneous injection once weekly
    b. Pediatrics: 180 mcg/1.73 m^2 subcutaneous injection once weekly up to a max of 180 mcg **AND**
4. Quantity requested does not exceed: 4 doses/28 days **AND**
5. Patient has compensated liver disease **AND**
6. Requested medication is being used as part of a combination regimen unless contraindications or significant intolerances to other HCV antiviral drugs **AND**
7. Patient has not previously failed therapy with an interferon-alfa **AND**
8. Prescribed by or in consultation with a specialist such as a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

Diagnosis: Chronic Hepatitis B

1. Patient has diagnosis of chronic hepatitis B **AND**
2. Patient is 3 years of age or older **AND**
3. Dosage and direction of use:
    a. Adults: 180 mcg subcutaneous injection once weekly
    b. Pediatrics: 180 mcg/1.73 m^2 subcutaneous injection once weekly up to a max of 180 mcg **AND**
4. Quantity requested does not exceed: 4 doses/28 days **AND**
5. If patient is over the age of 18 years, all of the following:
    a. Patient has compensated liver disease **AND**
    b. Patient has evidence of viral replication **AND**
    c. Patient has evidence of liver inflammation **AND**
6. If patient is 3-17 years of age, all of the following:
    a. Patient's disease is HBeAg-positive **AND**
    b. Patient does not have cirrhosis **AND**
    c. Patient has evidence of viral replication **AND**
    d. Patient has elevation in serum ALT **AND**
7. Patient has not previously failed therapy with an interferon-alfa **AND**
8. Prescribed by or in consultation with a specialist such as a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 48 weeks

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated hepatitis B indication to have age specific diagnosis requirements	2.2024

REFERENCE:

1. Pegasys (peginterferon alfa-2a). [Prescribing Information]. South San Francisco: Genentech, Inc. November 2019.

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Prior Authorization Criteria for PEMAZYRE® (pemigatinib)

FDA Approved Indications

- For the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test.
- For the treatment of adults with relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with FGFR1 rearrangement.

1. Patient has an FDA approved diagnosis **AND**
2. Patient is 18 years of age or older **AND**
3. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
- ✓ Initial approval will be granted for a period of 12 months

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 12 months

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 5.7.2020	5.2020
Annual Review	No Changes	5.2021
Annual Review	No Changes	5.2022
Updated	Updated criteria to include expanded indication: For the treatment of adults with relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with FGFR1 rearrangement.	11.2022
Updated	Removed other rearrangement from MLN diagnosis	5.2023
Annual Review	Approval duration updated to 1 year; Updated criteria to oncology drug template	4.2024

REFERENCE:

1. Abou-Alfa GK, Sahai V, Hollebecque A, et al. Pemigatinib for previously treated, locally advanced or metastatic cholangiocarcinoma: a multicentre, open-label, phase 2 study [published online March 20, 2020]. *Lancet Oncol*. doi:10.1016/S1470-2045(20)30109-1[PubMed 32203698]
2. Pemazyre (pemigatinib) [prescribing information]. Wilmington, DE: Incyte Corporation; June 2023.
3. US Department of Health and Human Services; Centers for Disease Control and Prevention; National Institute for Occupational Safety and Health. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings 2016. http://www.cdc.gov/niosh/topics/antineoplastic/pdf/hazardous-drugs-list_2016-161.pdf. Updated September 2016. Accessed April 20, 2020.
4. Raun LT, Riester A, Oßwald-Kopp A, et al. Toward a diagnostic score in Cushing's syndrome. Front Endocrinol (Lausanne). 2019;10:766. doi:10.3389/fendo.2019.00766[PubMed 31787931]
5. National Comprehensive Cancer Network. Hepatobiliary Cancers (Version 2.2022). https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary_blocks.pdf. Accessed November 29, 2022.
6. National Comprehensive Cancer Network. Myeloid/Lymphoid Neoplams with Eosinophilia and Tyrosine Kinase Fusion Genes (Version 2.2022). https://www.nccn.org/professionals/physician_gls/pdf/mlne_blocks.pdf. Accessed November 29, 2022.

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Prior Authorization Criteria for PHEBURANE®, BUPHENYL® (sodium phenylbutyrate pellets, tablets, powder)

1. Patient has a diagnosis of urea cycle disorders (UCDs), involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC) or argininosuccinic acid synthetase (AS) **AND**
2. Dosage and Direction for Use: The recommended dosage measured as sodium phenylbutyrate is:
    a. Patients weighing < 20 kg: 450–600 mg/kg/day of sodium phenylbutyrate orally. The calculated dose should be divided into three to six doses. Maximum dosage is 20 grams per day **OR**
    b. Patients weighing ≥ 20 kg: 9.9–13.0 g/m2/day of sodium phenylbutyrate orally. The calculated dose should be divided into three to six doses. Maximum dosage is 20 grams per day **AND**
3. Quantity requested does not exceed: 20 grams per day **AND**
4. Confirm that medication will be used in conjunction with dietary protein restriction with or without dietary supplements **AND**
5. If request is for Buphenyl or Pheburane, patient has had an adequate trial of generic sodium phenylbutyrate tablets or powder **AND**
6. Patient will not be taking in combination with other phenylbutyrate products **AND**
7. Prescribed by or in consultation with a specialist such as a metabolic specialist.

INITIAL APPROVAL

- ✓ Initial approval will be granted for a period of 1 year
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation supports positive response to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 9.22.2022	9.2022
Annual Review	Added Buphenyl to criteria; updated wording	8.2023
Annual Review	Updated diagnosis wording	2.2024

REFERENCE:

1. Berry GT, Steiner RD. Long-term management of patients with urea cycle disorders. J Pediatr. 2001;138(1)(suppl):56-61.[PubMed 11148550]
2. Lee B. Urea cycle disorders: Management. In: UpToDate, Waltham, MA Wolters Kluwer Health; 2016. Available at UpToDate.com. Accessed April 8, 2016.
3. Buphenyl (sodium phenylbutyrate) [prescribing information]. Deerfield, IL: Horizon Therapeutics USA, Inc; July 2022.
4. Pheburane (sodium phenylbutyrate) [prescribing information]. Bryn Mawr, PA: Medunik USA Inc; June 2022.

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Prior Authorization Criteria for PIQRAY® (alpelisib)

FDA-APPROVED INDICATIONS

- Indicated in combination with fulvestrant for the treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
- ✓ Initial approval will be for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	6.2019
Update	Add Denial Message	1.2020
Annual Review	No change	6.2021
Annual Review	No change	6.2022
Annual Review	No Change	6.2023
Annual Review	Updated duration of approval to 1 year; updated to oncology drug format	5.2024

REFERENCE:

1. Piqray [Prescribing information] East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; May 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/212526s000lbl.pdf. Accessed June 19, 2019.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed June 19, 2019.
3. André F, Ciruelos E, Rubovszky G, et al; SOLAR-1 Study Group. Alpelisib for PIK3CA-mutated, hormone receptor-positive advanced breast cancer. *N Engl J Med*. 2019;380(20):1929-1940.
4. National Comprehensive Cancer Network. Breast Cancer (Version 4.2023). https://www.nccn.org/professionals/physician_gls/pdf/breast_blocks.pdf. Accessed May 10, 2023.

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Prior Authorization Criteria for POMALYST® (pomalidomide)

FDA-APPROVED INDICATIONS

- Multiple Myeloma:
  - Adult patients in combination with dexamethasone, for patients with multiple myeloma (MM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy
- Kaposi Sarcoma:
  - Adult patients with AIDS-related Kaposi sarcoma (KS) after failure of highly active antiretroviral therapy (HAART) or in patients with KS who are HIV negative.

1. Patient has an FDA approved diagnosis **AND**
2. Patient is 18 years of age or older **AND**
3. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided (no evidence of disease progression qualifies as positive response to therapy)
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA Criteria created based on CAB 2.18.20	2.2020
Update	Added expanded indication for Kaposi Sarcoma; Added denial message; update formatting	8.2021
Annual Review	No Change	2.2022
Annual Review	Format update	2.2023
Annual Review	Updated criteria to include FDA-approved indications and NCCN guidelines based on package insert. Updated initial approval duration, updated denial message, and updated format	2.2024

REFERENCE:

1. Pomalyst (pomalidomide) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; March 2023.
2. Pomalyst (pomalidomide) [prescribing information]. Summit, NJ: Celgene Corporation; October 2019.
3. The NCCN Guidelines® and Clinical Resources. Available at www.nccn.org. Accessed August 6, 2023.
4. National Comprehensive Cancer Network. Multiple Myeloma (Version 2.2024). https://www.nccn.org/professionals/physician_gls/pdf/myeloma_blocks.pdf. Accessed February 5, 2024.
5. National Comprehensive Cancer Network. Kaposa Sarcoma (Version 1.2024). https://www.nccn.org/professionals/physician_gls/pdf/kaposi_blocks.pdf. Accessed February 5, 2024.

6. Attal M, Richardson PG, Rajkumar SV, et al; ICARIA-MM Study Group. Isatuximab plus pomalidomide and low-dose dexamethasone versus pomalidomide and low-dose dexamethasone in patients with relapsed and refractory multiple myeloma (ICARIA-MM): a randomised, multicentre, open-label, phase 3 study. Lancet. 2019;394(10214):2096-2107. doi: 10.1016/S0140-6736(19)32556-5.[PubMed 31735560]
7. Richardson PG, Siegel D, Baz R, et al, "Phase I Study of Pomalidomide MTD, Safety and Efficacy in Patients With Refractory Multiple Myeloma Who Have Received Lenalidomide and Bortezomib," Blood, 2013, 121(11):1961-7.[PubMed 23243282]

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Prior Authorization Criteria for PRETOMANID® (pretomanid)

1. Patient has diagnosis of pulmonary extensively drug resistant (XDR-TB) or treatment-intolerant or nonresponsive multidrug-resistant (MDR-TB) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: 200mg orally daily for 26 weeks **AND**
4. Quantity requested does not exceed: 200mg orally daily (1 tablet/day) for 26 weeks **AND**
5. Patient has documentation of susceptibility result and indicates multi-drug-resistant TB **AND**
6. Confirm that Pretomanid is used as part of a combination regimen with bedaquiline and linezolid for the treatment of adults with XDR-TB and MDR-TB **AND**
7. Prescribing provider should be an infectious disease specialist or pulmonologist

INITIAL APPROVALS

✓ Initial approval: One-time for 26 weeks.

RENEWALS

✓ Approval duration for renewal: 26 weeks.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA Criteria created based on CAB 11.21.19	12.2019
Annual Review	No Change	12.2020
Annual Review	No Change	12.2021
Annual Review	No Change	12.2022

REFERENCE:

1. Pretomanid [prescribing information]. Hyderabad, India: The Global Alliance for TB Drug Development (TB Alliance); August 2019.
2. US Department of Health and Human Services; Centers for Disease Control and Prevention; National Institute for Occupational Safety and Health. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings 2016. http://www.cdc.gov/niosh/topics/antineoplastic/pdf/hazardous-drugs-list_2016-161.pdf. Updated September 2016. Accessed September 20, 2019.
3. Talwar A, Tsang CA, Price SF, et al. Tuberculosis — United States, 2018. MMWR Morb Mortal Wkly Rep 2019;68:257–262. DOI: http://dx.doi.org/10.15585/mmwr.mm6811a2. Accessed September 23, 2021.
4. WHO consolidated guidelines on drug-resistant tuberculosis treatment. Geneva: World Health Organization; 2019. Licence: CC BY-NC-SA 3.0 IGO. Available at: https://apps.who.int/iris/bitstream/handle/10665/311389/9789241550529-eng.pdf. Accessed December 22, 2022.

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Prior Authorization Criteria for PREVYMIS® (letermovir)

FDA-Approved Indications

- Prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)
- Prophylaxis of CMV disease in adult kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-]).

Diagnosis: HSCT

1. Medication is prescribed for prophylaxis of cytomegalovirus (CMV) infection and disease in CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT) **AND**
2. Patient is at least 18 years of age **AND**
3. Dosage and direction of use:
    - If co-administered with cyclosporine:
        - 240 mg orally or intravenously (over one hour), daily through day 100 post-transplantation. In patients at risk for late CMV infection and disease, PREVYMIS may be continued through 200 days post-HSCT
    - If not co-administered with cyclosporine:
        - 480 mg orally or intravenously (over one hour), daily through day 100 post-transplantation. In patients at risk for late CMV infection and disease, PREVYMIS may be continued through 200 days post-HSCT **AND**
4. Quantity requested does not exceed: 100 tabs or infusions/100 days **AND**
5. Patient has an adequate trial and failure of at least one standard of care agent such as valganciclovir, valacyclovir, or ganciclovir unless contraindicated or clinically significant adverse effects are experienced **AND**
6. Patient is CMV seropositive recipient (R+) of an allogenic hematopoietic stem cell transplant (HSCT) **AND**
7. Patient has received or is scheduled to receive allogeneic HSCT, and the initiation of therapy is between day 0 and day 28 post-transplantation **AND**
8. Patient is NOT taking any of the following: pimozide, ergot alkaloids or pitavastatin and simvastatin co-administered with cyclosporine **AND**
9. If request is for IV Prevymis, documentation is provided to support inability to use oral therapy **AND**
10. Prescribed by or in consultation with a specialist such as an infectious disease specialist, hematologist, oncologist, or transplant specialist.

Diagnosis: Kidney transplant

1. Medication is prescribed for prophylaxis of CMV disease in adult kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-])**AND**
2. Patient is at least 18 years of age **AND**
3. Dosage and direction of use:
    - If co-administered with cyclosporine:
        - 240 mg orally or intravenously (over one hour), daily through day 200 post-transplantation
    - If not co-administered with cyclosporine:
        - 480 mg orally or intravenously (over one hour), daily through day 200 post-transplantation **AND**
4. Quantity requested does not exceed: 200 tabs or infusions/200 days **AND**
5. Patient has an adequate trial and failure of at least one standard of care agent such as valganciclovir, ganciclovir unless contraindicated or clinically significant adverse effects are experienced **AND**
6. Patient is high risk for CMV disease **AND**
7. Patient has received or is scheduled for Kidney transplant, and the initiation of therapy is between day 0 and Day 7 post-transplant and continue through Day 200 post-transplant **AND**
8. Patient is NOT taking any of the following: pimozide, ergot alkaloids or pitavastatin and simvastatin co-administered with cyclosporine **AND**

9. If request is for IV Prevymis, documentation is provided to support inability to use oral therapy **AND**
10. Prescribed by or in consultation with a specialist such as an infectious disease specialist, hematologist, oncologist, or transplant specialist.

APPROVALS

✓ Approval will be granted one time, through 100 to 200 days post-transplantation.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Revised	Created	8.2018; 2019
Updated	Update Format/Add Denial Message; added alternatives options and specialist.	8.2020
Annual review	No change	8.2021
Annual review	No change	8.2022
Annual review	Updated format and added expanded indication for prophylaxis of CMV disease in adult kidney transplant recipients at high risk	8.2023
Annual review	Clarified requirement for contraindicated co-administered medications	2.2024

REFERENCE:

1. Prevymis (letermovir) tablets and injection [prescribing information]. Rahway, NJ: Merck Sharp & Dohme LLC; June 2023.
2. Limaye AP, Budde K, Humar A, et al. Letermovir vs valganciclovir for prophylaxis of cytomegalovirus in high-risk kidney transplant recipients: a randomized clinical trial. JAMA. Published online June 6, 2023. doi:10.1001/jama.2023.9106[PubMed 37279999]
3. Marty FM, Ljungman P, Chemaly RF, et al. Letermovir prophylaxis for cytomegalovirus in hematopoietic-cell transplantation. N Engl J Med. 2017;377(25):2433-2444. doi:10.1056/NEJMoa1706640[PubMed 29211658]
4. Ljungman P, de La Camara R, Milpied N, Volin L, Russell CA, Crisp A, Webster A; Valacyclovir International Bone Marrow Transplant Study Group. Randomized study of valacyclovir as prophylaxis against cytomegalovirus reactivation in recipients of allogeneic bone marrow transplants. Blood. 2002;99:3050-6.
5. Boeckh M, Ljungman P. How we treat cytomegalovirus in hematopoietic cell transplant recipients. Blood 2009; 113:5711-9.

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Prior Authorization Criteria for PROGRAF®
(tacrolimus granules for suspension)

1. Medication is prescribed for prophylaxis of organ rejection in patients receiving allogenic renal (kidney), cardiac (heart), or hepatic (liver) transplant, or lung transplant **AND**
2. Patient is less than 18 years of age **AND**
3. Dosage and directions: **AND**

Diagnosis	Initial Oral Dose
Kidney Transplant	0.3 mg/kg/day capsules or oral suspension, divided in two doses, every 12 hours
Liver Transplant	0.15-0.2 mg/kg/day capsules or 0.2 mg/kg/day oral suspension, divided in two doses, every 12 hours
Heart Transplant	0.3 mg/kg/day capsules or oral suspension, divided in two doses, every 12 hours. Dose at 0.1 mg/kg/day if antibody induction treatment is administered.
Lung Transplant	0.3 mg/kg/day capsules or oral suspension, divided in two doses, every 12 hours. Dose at 0.1 mg/kg/day if antibody induction treatment is administered.

4. Quantity limit does not exceed: weight-based dosage and direction **AND**
5. Patient has clinical documentation supporting the need of an oral suspension (i.e., unable to swallow tablets/difficulty swallowing) **AND**
6. Prescribed by a specialist such as a nephrologist, cardiologist, hepatologist, or transplant specialist etc.

INITIAL APPROVALS

✓ Initial approval will be for a period of 12 months

RENEWALS

✓ Patient has a positive response to therapy
✓ May renew up to 12-month intervals at a time with current chart notes and other pertinent information (e.g. lab).

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Revised	Created	5.2019
Update	Add Denial Message	2.2020
Update	Added new diagnosis requirement to the criteria sections; Update initial dose; Update denial message	7.2021
Update	Update expanded indication	3.2022
Annual Review	Updated dosage form to granules; added patient has need for oral suspension	3.2023
Annual Review	Updated diagnosis verbiage based on package insert	3.2024

REFERENCE:

1. Abu-Elmagd KM, Costa G, Bond GJ, et al. Evolution of the immunosuppressive strategies for the intestinal and multivisceral recipients with special reference to allograft immunity and achievement of partial tolerance. Transpl Int. 2009a;22(1):96-109.[PubMed 18954362]

2. Baughman RP, Meyer KC, Nathanson I, et al. Monitoring of nonsteroidal immunosuppressive drugs in patients with lung disease and lung transplant recipients: American College of Chest Physicians evidence-based clinical practice guidelines. Chest. 2012;142(5):e1Se111S.[PubMed 23131960]
3. Furlong T, Storb R, Anasetti C, et al, "Clinical Outcome After Conversion to FK 506 (Tacrolimus) Therapy for Acute Graft-Versus-Host Disease Resistant to Cyclosporine or for Cyclosporine-Associated Toxicities," Bone Marrow Transplant, 2000, 26(9):985-91.[PubMed 11100278]
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Prior Authorization Criteria for PROMACTA® (eltrombopag olamine)

FDA-APPROVED INDICATIONS:

- Chronic Immune Thrombocytopenia:
  - Treatment of thrombocytopenia in adult and pediatric patients 1 year and older with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.
- Chronic Hepatitis C-associated Thrombocytopenia:
  - Treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy.
- Severe Aplastic Anemia:
  - In combination with standard immunosuppressive therapy for the first line treatment of adult and pediatric patients 2 years and older with severe aplastic anemia
  - Treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.

Diagnosis: Chronic Immune Thrombocytopenia (ITP)

1. Patient has diagnosis of chronic immune thrombocytopenia (ITP) **AND**
2. Patient is 1 years of age or older **AND**
3. Dosage and Direction for Use: adjust dose to achieve target platelet count
   a. 1 to 5 years of age: 25 mg once daily
   b. 6 years of age or older: 50 mg once daily
4. Quantity requested does not exceed: 75 mg once daily (30 tablets or packets/30 days) **AND**
5. Patient has had an insufficient response to corticosteroids, immunoglobulins, or splenectomy **AND**
6. Patient has low baseline platelet counts (e.g., < 30 x 10^9/L) **AND**
7. Prescribing provider is a specialist such as a hematologist.

Diagnosis: Chronic Hepatitis C-associated Thrombocytopenia

1. Patient has a diagnosis of Hepatitis C-associated Thrombocytopenia **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for use: 25 mg once daily for all patients; adjust dose to achieve target platelet count required to initiate antiviral therapy. Max dose of 100 mg/day **AND**
4. Quantity requested does not exceed: 100 mg/day (two-50mg tablets) **AND**
5. Patient will use Promacta concomitantly with interferon-based therapy **AND**
6. Patient has a low platelet count (e.g., < 75 x 10^9/L) **AND**
7. Prescribing provider is a specialist such as a gastroenterologist, infectious disease specialist, etc.

Diagnosis: Aplastic Anemia

1. Patient has a diagnosis of Aplastic Anemia **AND**
2. Patient is 2 years of age or older **AND**
3. Dosage and Direction for use:
   a. *First-Line Severe Aplastic Anemia:*
      i. 2 to 5 years old: 2.5 mg/kg once daily
      ii. 6 to 11 years old: 75 mg once daily
      iii. 12 years of age and older: 150 mg once daily
   b. *Refractory Severe Aplastic Anemia:*
      i. 50 mg once daily
4. Quantity requested does not exceed: 150 mg/day (two-75mg tablets) **AND**

5. Patient is taking Promacta with standard immunosuppressive therapy or has had an insufficient response to immunosuppressive therapy (i.e., cyclophosphamide, cyclosporine) **AND**
6. Patient has low baseline platelet counts (e.g., < 30 x 10^9/L) **AND**
7. Prescribing provider is a specialist such as a hematologist.

INITIAL APPROVALS

- ✓ Initial approval will be granted for a period of
- ✓ 4 months

RENEWALS

- ✓ Patient has a an adequate response to therapy (e.g., increase in platelet count from baseline)
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA Criteria created based on CAB 4.23.2020	5.2020
Updated	Update Quantity oral suspension	3.2021
Annual Review	No Changes	5.2022
Annual Review	Updated baseline platelet count criteria based on clinical trials to < 30 x 10^9/L based for Chronic ITP and aplastic anemia; 75 x 10^9/L for Chronic Hepatitis C-associated Thrombocytopenia.	5.2023
Annual Review	Updated criteria verbiage and initial approval duration for monitoring of platelet count based in package insert	5.2024

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15. Peslak SA, Olson T, Babushok DV. Diagnosis and Treatment of Aplastic Anemia. Curr Treat Options Oncol. 2017 Nov 16;18(12):70. doi: 10.1007/s11864-017-0511-z. PMID: 29143887; PMCID: PMC5804354.

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Prior Authorization Criteria for ADCIRCA®, alyq (tadalafil tablet)

1. Patient must have diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 40 mg (two 20 mg tablets) once daily, with or without food **AND**
4. Quantity requested does not exceed: 60 tablets/30 days **AND**
5. Diagnosis of PAH WHO Group I confirmed by right heart catheterization **AND**
6. Patient will not use requested medication in combination with a guanylate cyclase stimulator (for example: riociguat) **AND**
7. Patient will not use requested medication in combination with nitrates **AND**
8. Patient has documentation of other medications that will be used concomitantly for this indication **AND**
9. Prescribed by or in consultation with a specialist such as a pulmonologist or cardiologist.

INITIAL APPROVALS

- ✓ Initial approval will be granted for a period of 1 year
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation of positive response to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created from CAB 10.2022	10.2022
Annual Review	Created separate PAH drug criteria	9.2023
Annual Review	Updated format	8.2024

REFERENCE:

1. Adcirca. [Prescribing Information]. Indianapolis, IN: United Therapeutics Corp.; June 2023.
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Prior Authorization Criteria for ADEMPAS® (riociguat)

1. Patient has diagnosis of one of the following:
    a. Pulmonary arterial hypertension (PAH) (WHO Group 1)
    b. Persistent/recurrent Chronic Thromboembolic Pulmonary Hypertension (CTEPH) (WHO Group 4) **AND**
2. Patient is 18 years of age and older **AND**
3. Dosage and Direction for Use: initiate 1mg three times a day; Increase by 0.5mg every 2 weeks up to maximum of 2.5mg three times a day (7.5mg/day) **AND**
4. Quantity requested does not exceed: 84 tablets/28 days (three-2.5mg tablets/day) **AND**
5. If diagnosis of PAH WHO Group I, diagnosis confirmed by right heart catheterization **AND**
6. If diagnosis of CTEPH, requested medication is being used after surgical treatment or CTEPH is inoperable **AND**
7. Prescriber attestation that patient does **not** have any of the following contraindications:
    a. Patient will not be using this in combination with a phosphodiesterase-5 inhibitor (e.g., sildenafil, tadalafil) **AND**
    b. Patient will not be using this in combination with nitrates or nitric oxide **AND**
    c. Patient does not have pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP) **AND**
    d. Patient is not pregnant and an effective form of contraception will be used in females of reproductive potential **AND**
8. Documentation of other medications that will be used concomitantly for this indication **AND**
9. Prescriber is a specialist such as a pulmonologist or cardiologist.

INITIAL APPROVALS

- ✓ Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive response to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	12.2019
Update	Update PA Criteria for PAH	2.1.2020
Update	Added Liqrev based on CAB 6.1.23	6.2023
Update	Created separate criteria for pulmonary hypertension drugs	8.2023
Annual Review	Updated formatting	8.2024

REFERENCE:

1. Adempas (riociguat) [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc; September 2021.
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3. ESC/ERS Guidelines for the Diagnosis and Treatment of Pulmonary Hypertension 2015. *Eur Heart J* 2015;Aug 29
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Prior Authorization Criteria for LETAIRIS® (ambrisentan)

1. Patient has diagnosis of pulmonary arterial hypertension WHO Group 1 **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: Initiate treatment at 5 mg once daily; titrate at 4-week intervals as needed and tolerated up to 10mg once daily **AND**
4. Quantity requested does not exceed: 28 tablets/28 days (1 tablet/day) **AND**
5. Diagnosis of PAH WHO Group I confirmed by right heart catheterization **AND**
6. Prescriber attestation that patient does **not** have any of the following contraindications:
    a. Patient does not have Idiopathic Pulmonary Fibrosis **AND**
    b. Patient is not pregnant and an effective form of contraception will be used in females of reproductive potential **AND**
7. Prescriber is a specialist such as a pulmonologist or cardiologist.

INITIAL APPROVALS

- ✓ Initial approval will be granted for a period of 1 year
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation of positive response to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	12.2019
Update	Update PA Criteria for PAH	2.1.2020
Update	Added Liqrev based on CAB 6.1.23	6.2023
Created	Created separate criteria for pulmonary hypertension drugs; updated formatting; added age range	8.2023

REFERENCE:

1. ESC/ERS Guidelines for the Diagnosis and Treatment of Pulmonary Hypertension 2015. Eur Heart J 2015;Aug 29
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Prior Authorization Criteria for OPSUMIT® (macitentan)

1. Patient has diagnosis of one of the following pulmonary arterial hypertension (PAH, WHO Group I) **AND**
2. Dosage and Direction for Use: 10 mg once daily **AND**
3. Quantity requested does not exceed: 28 tablets/28 days (1 tablet/day) **AND**
4. Diagnosis of PAH WHO Group I confirmed by right heart catheterization **AND**
5. Prescriber attestation that patient is not pregnant and an effective form of contraception will be used in females of reproductive potential **AND**
6. Documentation of other medications that will be used concomitantly for this indication **AND**
7. Prescriber is a specialist such as a pulmonologist or cardiologist.

INITIAL APPROVALS

- ✓ Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive response to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	12.2019
Update	Update PA Criteria for PAH	2.2020
Update	Added Liqrev based on CAB 6.1.23	6.2023
Update	Created separate criteria for pulmonary hypertension drugs; updated format	8.2023
Annual Review	No changes	8.2024

REFERENCE:

1. ESC/ERS Guidelines for the Diagnosis and Treatment of Pulmonary Hypertension 2015. Eur Heart J 2015;Aug 29
2. Attridge RL, Moote R, Levine DJ. Chapter 17. Pulmonary Arterial Hypertension. In: DiPiro JT., Talbert RL, Yee GC. Matzke GR., Wells BG.,
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Prior Authorization Criteria for OPSYNVI® (macitentan-tadalafil)

1. Patient has diagnosis of pulmonary arterial hypertension (PAH, WHO Group I) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: Recommended starting dose of 10 mg/20 mg tablet once daily. If tolerated, titrate to 10 mg/40 mg tablet once daily as maintenance dose **AND**
4. Quantity requested does not exceed: 28 tablets/28 days (1 tablet/day) **AND**
5. Diagnosis of PAH WHO Group I confirmed by right heart catheterization **AND**
6. Prescriber attestation that patient is not pregnant and an effective form of contraception will be used in females of reproductive potential **AND**
7. Patient will not use requested medication in combination with a guanylate cyclase stimulator (for example: riociguat) **AND**
8. Patient will not use requested medication in combination with nitrates **AND**
9. Documentation of other medications that will be used concomitantly for this indication **AND**
10. Prescriber is a specialist such as a pulmonologist or cardiologist.

INITIAL APPROVALS

- ✓ Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive response to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 4.18.24	4.2024
Annual Review	Added exclusion for use in combination with nitrates or guanylate cyclase stimulator	8.2024

REFERENCE:

1. Opsynvi [Prescribing information] Titusville, NJ: Actelion Pharmaceuticals US, Inc. March 2024.
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Prior Authorization Criteria for ORENITRAM®, ORENITRAM® TITRATION KIT (treprostinil)

1. Patient has diagnosis of pulmonary arterial hypertension (PAH, WHO Group I) **AND**
2. Dosage and Direction for Use: Starting dose: 0.125 mg TID or 0.25 mg BID. Titrate by 0.125 mg TID or by 0.25 mg or 0.5 mg BID, not more frequently, than every 3 to 4 days as tolerated up to 120 mg maximum daily dose **AND**
3. Quantity requested does not exceed: 120 mg/day **AND**
4. Diagnosis of PAH WHO Group I confirmed by right heart catheterization **AND**
5. Documentation of other medications that will be used concomitantly for this indication **AND**
6. Prescriber is a specialist such as a pulmonologist or cardiologist.

INITIAL APPROVALS

- ✓ Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Approval duration for renewal: 1 year
- ✓ Documentation of positive response to therapy

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	12.2019
Update	Update PA Criteria for PAH	2.1.2020
Update	Added Liqrev based on CAB 6.1.23	6.2023
Update	Created separate criteria for pulmonary hypertension drugs; updated format	8.2023
Annual Review	Added maximum daily dose	8.2024

REFERENCE:

1. ESC/ERS Guidelines for the Diagnosis and Treatment of Pulmonary Hypertension 2015. Eur Heart J 2015;Aug 29
2. Attridge RL, Moote R, Levine DJ. Chapter 17. Pulmonary Arterial Hypertension. In: DiPiro JT., Talbert RL, Yee GC. Matzke GR., Wells BG.,
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10. Orenitram (treprostinil) [prescribing information]. Research Triangle Park, NC: United Therapeutics Corp; February 2023.
11. Galiè N, Barberà JA, Frost AE, et al. Initial Use of Ambrisentan plus Tadalafil in Pulmonary Arterial Hypertension. N Engl J Med 2015;373:834-44.
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Prior Authorization Criteria for TYVASO®, TYVASO DPI® (treprostinil)

FDA Approved Indications

- Pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability
- Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability

Diagnosis: Pulmonary Arterial Hypertension (PAH; WHO Group 1)

1. Patient has diagnosis of pulmonary arterial hypertension WHO Group 1 **AND**
2. Dosage and Direction for Use:
    a. Tyvaso (inhalation): initial dose of 18 mcg four times/day, maintenance dose of 54 mcg to 72 mcg
    b. Tyvaso DPI (inhalation): the Initial dose is one 16 mcg cartridge per treatment session, four times daily; the target maintenance dose is 48 mcg to 64 mcg per treatment session **AND**
3. Quantity requested does not exceed:
    a. Tyvaso: 72 mcg of treprostinil four times daily
    b. Tyvaso DPI: Dose does not exceed 256 mcg [4 cartridges] per day or 64 mcg (1 cartridge) per treatment session four times daily **AND**
4. Diagnosis of PAH WHO Group I confirmed by right heart catheterization **AND**
5. Prescribed by or in consultation with a specialist such as a pulmonologist or cardiologist.

Diagnosis: Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3)

1. Patient has diagnosis of pulmonary hypertension associated with interstitial lung disease WHO Group 3 **AND**
2. Patient is 18 years of age and older **AND**
3. Dosage and Direction for Use:
    a. Tyvaso (inhalation): initial dose of 18 mcg (or 3 inhalations with 6 mcg per inhalation) 4 times/day, maintenance dose of 54 mcg to 72 mcg (9 to 12 breaths per treatment session)
    a. Tyvaso DPI (inhalation): the Initial dose is one 16 mcg cartridge per treatment session, 4 times daily; the target maintenance dose is 48 mcg to 64 mcg per treatment session
4. Quantity requested does not exceed:
    a. Tyvaso: 72 mcg of treprostinil four times daily **AND**
    b. Tyvaso DPI: Dose does not exceed 256 mcg [4 cartridges] per day or 64 mcg (1 cartridge) per treatment session four times daily with the Tyvaso DPI inhaler.
5. Patients with connective tissue disease have a baseline forced vital capacity < 70% **AND**
6. Patient has evidence of diffuse parenchymal lung disease on computed tomography of the chest **AND**
7. Diagnosis of pulmonary hypertension associated with interstitial lung disease WHO Group 3 confirmed by right heart catheterization **AND**
8. Prescribed by or in consultation with a specialist such as a pulmonologist or cardiologist.

INITIAL APPROVALS

- ✓ Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Approval duration for renewal: 1 year
- ✓ Documentation of positive response to therapy

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	12.2019
Update	Update PA Criteria for PAH	2.2020
Annual Review	No Changes	12.2020
Annual Review	No Change	12.2021
Update	Include expanded indication of Tyvaso/Tyvaso DPI for Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability. Created a separate criteria document for PAH – treprostinil medications.	10.2022
Update	Created separate criteria for treprostinil dosage forms	9.2023
Annual Review	Updated formatting	8.2024

REFERENCE:

1. ESC/ERS Guidelines for the Diagnosis and Treatment of Pulmonary Hypertension 2015. Eur Heart J 2015;Aug 29
2. Attridge RL, Moote R, Levine DJ. Chapter 17. Pulmonary Arterial Hypertension. In: DiPiro JT., Talbert RL, Yee GC. Matzke GR., Wells BG.,
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13. Duo-ji MM, Long ZW. Comparative efficacy and acceptability of endothelin receptor antagonists for pulmonary arterial hypertension: A network meta-analysis. Int J Cardiol. 2017;234:90-98.
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Prior Authorization Criteria for UPTRAVI® (selexipag)

1. Patient has diagnosis of one of the following pulmonary arterial hypertension (PAH, WHO Group I) **AND**
2. Dosage and Direction for Use: initial dose 200 mcg twice daily then increase by 200mcg twice daily at weekly intervals to 1600mcg twice daily **AND**
3. Quantity requested does not exceed: 56/28 days (2 tablets/day) **AND**
4. Diagnosis of PAH WHO Group I confirmed by right heart catheterization **AND**
5. Prescriber attestation that patient is not taking with strong CYP2C8 inhibitors (i.e., gemfibrozil) **AND**
6. Documentation of other medications that will be used concomitantly for this indication **AND**
7. Prescriber is a specialist such as a pulmonologist or cardiologist.

INITIAL APPROVALS

- ✓ Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive response to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	12.2019
Update	Update PA Criteria for PAH	2.2020
Update	Added Liqrev based on CAB 6.1.23	6.2023
Update	Created separate criteria for pulmonary hypertension drugs; updated format	8.2023
Annual Review	No changes	8.2024

REFERENCE:

1. ESC/ERS Guidelines for the Diagnosis and Treatment of Pulmonary Hypertension 2015. Eur Heart J 2015;Aug 29
2. Attridge RL, Moote R, Levine DJ. Chapter 17. Pulmonary Arterial Hypertension. In: DiPiro JT., Talbert RL, Yee GC. Matzke GR., Wells BG.,
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7. Poms, A.D., Turner, M., Farber, H., Comorbid Conditions and Outcomes in Patients With Pulmonary Arterial Hypertension : A REVEAL Registry Analysis. Chest. 2014;146(2):449-475. doi:10.1378/chest.14-0793. http://dx.doi.org.pacificlib.idm.oclc.org/10.1378/chest.11-3241
8. Taichman DB, Ornelas J, Chung L, et al. Pharmacologic therapy for pulmonary arterial hypertension in adults: CHEST guideline and expert panel report. Chest. 2014;146(2):449-75.
9. Opsumit (macitentan) [prescribing information]. Titusville, NJ: Actelion Pharmaceuticals US Inc; July 2022.
10. Opsumit (macitentan) [prescribing information]. Titusville, NJ: Actelion Pharmaceuticals US Inc; May 2023.
11. Opsumit (macitentan) [product monograph]. Toronto, Ontario, Canada: Jassen Inc; November 2022.
12. Galiè N, Corris PA, Frost A, et al. Updated treatment algorithm of pulmonary arterial hypertension. J Am Coll Cardiol. 2013;62(25 Suppl):D60-72.
13. Galiè N, Barberà JA, Frost AE, et al. Initial Use of Ambrisentan plus Tadalafil in Pulmonary Arterial Hypertension. N Engl J Med 2015;373:834-44.
14. Jain S, Khera R, Girotra S, et al. Comparative Effectiveness of Pharmacologic Interventions for Pulmonary Arterial Hypertension: A Systematic Review and Network Meta-Analysis. Chest. 2017;151(1):90-105.
15. Duo-ji MM, Long ZW. Comparative efficacy and acceptability of endothelin receptor antagonists for pulmonary arterial hypertension: A network meta-analysis. Int J Cardiol. 2017;234:90-98.

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Prior Authorization Criteria for VENTAVIS® (iloprost)

1. Patient has diagnosis of pulmonary arterial hypertension WHO Group 1 **AND**
2. Patient is 18 years of age and older **AND**
3. Dosage and Direction for Use:
    a. Initial dose: 2.5 mcg by inhalation six to nine times per day
    b. Maintenance dose: 5mcg by inhalation six to nine times per day **AND**
4. Quantity does not exceed: 45 mcg/day **AND**
5. Diagnosis of pulmonary arterial hypertension WHO Group 1 confirmed by right heart catheterization **AND**
6. Documentation of other medications that will be used concomitantly for this indication **AND**
7. Prescriber is a specialist such as a pulmonologist or cardiologist.

INITIAL APPROVALS

- ✓ Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive response to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	12.2019
Update	Update PA Criteria for PAH	2.1.2020
Update	Added Liqrev based on CAB 6.1.23	6.2023
Update	Created separate criteria for pulmonary hypertension drugs; Updated format and wording for clarity; Added age limit and maximum quantity	8.2023

REFERENCE:

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13. Duo-ji MM, Long ZW. Comparative efficacy and acceptability of endothelin receptor antagonists for pulmonary arterial hypertension: A network meta-analysis. Int J Cardiol. 2017;234:90-98.

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Prior Authorization Criteria for WINREVAIR™ (sotatercept-csrk)

1. Patient has diagnosis of pulmonary arterial hypertension (PAH, WHO Group I) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: Recommended starting dose of 0.3 mg/kg by subcutaneous injection every 3 weeks; Increase to target dose of 0.7 mg/kg every three weeks **AND**
4. Quantity requested does not exceed: 0.7 mg/kg every three weeks **AND**
5. Diagnosis of PAH WHO Group I confirmed by right heart catheterization **AND**
6. Documentation of other medications that will be used concomitantly for this indication **AND**
7. Prescriber is a specialist such as a pulmonologist or cardiologist.

INITIAL APPROVALS

- ✓ Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive response to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 4.18.24	4.2024

REFERENCE:

1. Winrevair [Prescribing information] Rahway, NJ: Merck Sharpe & Dohme. March 2024.
2. ESC/ERS Guidelines for the Diagnosis and Treatment of Pulmonary Hypertension 2015. Eur Heart J 2015;Aug 29
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Prior Authorization Criteria for TRACLEER® (bosentan)

1. Patient has diagnosis of pulmonary arterial hypertension WHO Group 1 **AND**
2. Patient is 3 years of age and older **AND**
3. Dosage and Direction for Use:

Age/Weight	Initial Dose for 4 weeks	Maintenance (after 4 weeks)
>12 years old and >40kg	62.5mg twice daily	125mg twice daily
>12 years old and <40kg	62.5mg twice daily	62.5mg twice daily
Patients ≤12 years of age	≥4-8kg: 16mg twice daily >8-16kg: 32mg twice daily >16-24kg: 48mg twice daily >24-40kg: 64mg twice daily	≥4-8kg: 16mg twice daily >8-16kg: 32mg twice daily >16-24kg: 48mg twice daily >24-40kg: 64mg twice daily

4. Quantity requested does not exceed: dosed by age and weight, please optimize quantity based on prescribed dosing scheduling **AND**
5. Diagnosis of pulmonary arterial hypertension WHO Group 1 confirmed by right heart catheterization **AND**
6. If request is for brand TRACLEER, patient had an adequate trial of generic bosentan **AND**
7. Prescriber attests all of the following baseline tests: LFTs transaminase (ALT and AST) levels will be measured prior to initiation of therapy and monthly **AND**
8. Prescriber attests patient is not pregnant and an effective form of contraception will be used in females of reproductive potential **AND**
9. Prescriber is a specialist such as a pulmonologist or cardiologist.

INITIAL APPROVALS

- ✓ Initial approval will be granted for a period of 1 year
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation of positive response to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	12.2019
Update	Update PA Criteria for PAH	2.2020
Update	Added Liqrev based on CAB 6.1.23	6.2023
Update	Created separate criteria for pulmonary hypertension drugs; Updated format and wording for clarity; Updated denial message	8.2023

REFERENCE:

1. Tracleer (bosentan) [prescribing information]. Titusville, NJ: Actelion Pharmaceuticals US Inc; June 2023.
2. ESC/ERS Guidelines for the Diagnosis and Treatment of Pulmonary Hypertension 2015. Eur Heart J 2015;Aug 29
3. Attridge RL, Moote R, Levine DJ. Chapter 17. Pulmonary Arterial Hypertension. In: DiPiro JT., Talbert RL, Yee GC. Matzke GR., Wells BG.,
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13. Duo-ji MM, Long ZW. Comparative efficacy and acceptability of endothelin receptor antagonists for pulmonary arterial hypertension: A network meta-analysis. Int J Cardiol. 2017;234:90-98.

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Prior Authorization Criteria for REVATIO®, LIQREV® (sildenafil citrate)

1. Patient has diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) **AND**
2. Patient is 1 year of age or older **AND**
3. Dosage and Direction for Use:
    a. Adults: 20 mg three times a day, may be titrated to a maximum of 80 mg three times daily
    b. Pediatrics <18 years of age: 10-20 mg three times daily, may be titrated to a maximum of 50 mg three times daily for pediatric patients >45 kg **AND**
4. Quantity requested does not exceed: 360 tablets/30 days or 720 mL/30 days **AND**
5. Diagnosis of PAH WHO Group I confirmed by right heart catheterization **AND**
6. If request is for brand, documented trial of generic sildenafil (generic for REVATIO) **AND**
7. If request is for oral solution, patient has clinical documentation supporting the need of an oral solution (i.e., unable to swallow tablets/difficulty swallowing) **AND**
8. Patient will not use requested medication in combination with a guanylate cyclase stimulator (for example: riociguat) **AND**
9. Patient will not use requested medication in combination with nitrates **AND**
10. Documentation of other medications that will be used concomitantly for this indication is provided **AND**
11. Prescriber is a specialist such as a pulmonologist or cardiologist.

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 1 year
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation of positive response to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Update	Created a separate criteria for Revatio and added Liqrev based on CAB 6.1.2023.	6.2023
Update	Updated format; clarified wording	8.2023
Annual Review	Updated dosing and quantity requested does not exceed to account for titration up to 80 mg tid	8.2024

REFERENCE:

1. Attridge RL, Moote R, Levine DJ. Chapter 17. Pulmonary Arterial Hypertension. In: DiPiro JT., Talbert RL, Yee GC. Matzke GR., Wells BG.,
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Posey L (Eds)., Pharmacotherapy: A Pathophysiologic Approach, 9e. New York: McGraw-Hill Medical, 2014, Chapter 17. Access Pharmacy. Web. Jan 2017.
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Prior Authorization Criteria for PURIXAN (mercaptopurine solution)

FDA-Approved Indications

- Treatment of patients with acute lymphoblastic leukemia (ALL) as part of a combination chemotherapy maintenance regimen

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated duration of approval; added FDA approved dx and age; added indication section	5.2024

REFERENCE:

1. PURIXAN. [Prescribing Information]. Franklin, TN. Nova Laboratories, Ltd: April 2020.

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Prior Authorization Criteria for PYRUKYND® (mitapivat)

1. Patient has diagnosis of hemolytic anemia due to pyruvate kinase deficiency (PKD) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 5 mg orally twice daily up to 50 mg twice daily with or without food **AND**
4. Quantity requested does not exceed: 60 tablets/30 days **AND**
5. Patient has diagnosis of PKD with at least two mutant alleles in the PKLR gene, of which at least one is a missense mutation **AND**
6. Physician confirms that patient is not homozygous for the R479H mutation or does not have two non-missense variants, without the presence of another missense variant, in the PKLR gene **AND**
7. Patient meets **one** of the following:
    a. Patient has had no more than 4 transfusions in 1 year (52 weeks) and no transfusion in the preceding 3-month period and patient's baseline hemoglobin level is currently ≤10 g/dL **OR**
    b. Patient has had a minimum of 6 transfusion episodes in the preceding 52 weeks **AND**
8. Prescribed by or in consultation with a specialist such as a hematologist.

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 3 months.

RENEWALS

✓ Documentation of a positive response including an increase in Hb ≥1.5 g/dL over baseline and/or reduction in transfusion burden.
✓ Approval duration for renewal: 6 months
✓ If documentation does not provide evidence of positive clinical response to Pyrukynd therapy, allow for dose titration with discontinuation of therapy. Authorization will be issued for 4 weeks.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 3.24.22	3.2022
Annual review	Updated criteria to include: patient meets one of the following: patient has had no more than 4 transfusions in 1 year and no transfusion in the preceding 3-month period and patient's baseline hemoglobin level is currently ≤10 g/dL OR Patient has had a minimum of 6 transfusion episodes in the preceding 52 weeks; Pyrukynd is used for the treatment of hemolytic anemia; Added renewal period for discontinuation of therapy to taper medication.	3.2023
Annual review	Updated criteria verbiage, updated denial message, and updated format	1.2024

REFERENCE:

1. Al-Samkari H, et al. Mitapivat, a novel pyruvate kinase activator, for the treatment of hereditary hemolytic anemias. Ther Adv Hematol. 2021;12:20406207211066070. Published December 21, 2021. doi:10.1177/20406207211066070
2. Boscoe AN, et al. Comorbidities and complications in adults with pyruvate kinase deficiency. Eur J Haematol. 2021;106(4):484-492. doi:10.1111/ejh.13572
3. Enegela OA, et al. Pyruvate Kinase Deficiency. [Updated December 8, 2021]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022. https://www.ncbi.nlm.nih.gov/books/NBK560581/
4. National Organization for Rare Disorders (NORD) Rare Disease Database. Pyruvate Kinase Deficiency. Updated 2019. Accessed March 8, 2022. https://rarediseases.org/rare-diseases/pyruvate-kinase-deficiency/
5. Pyrukynd (mitapivat) [prescribing information]. Cambridge, MA: Agios Pharmaceuticals Inc; February 2022.
6. Grace RF, Barcellini W. Management of pyruvate kinase deficiency in children and adults. Blood: September 10, 2020; 136 (11): 1241-1249.

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Prior Authorization Criteria for QELBREE® (viloxanize hcl)

1. Patient has diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) **AND**
2. Patient must be 6 years and older **AND**
3. Dosage and direction of use:
    - 6 to 11 years of age: starting dosage is 100 mg once daily up to 400 mg once daily **OR**
    - 12 to 17 years of age: starting dosage is 200 mg once daily up to 400 mg once daily **AND**
    - Adults: 200 mg once daily up to 600 mg once daily **AND**
4. Quantity requested does not exceed: **6 to 17 years of age**: 60/30days; **Adults**: 90/30 days for 200 mg **AND**
5. Patient has had an adequate trial of atomoxetine or patient has an inability to swallow capsules/tablets (documentation provided)

INITIAL APPROVALS

✓ Initial authorization may be granted for a period of a year

RENEWALS

✓ Approval duration for renewal: one year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 5.6.21	5.2021
Updated	Updated expanded indication to include adults with updated dose and QLL.	5.2022
Annual Review	No changes	5.2023
Annual Review	Updated criteria to include "patient has an inability to swallow capsules/tablets (documentation provided)"	4.2024

REFERENCE:

1. Qelbree (viloxazine) [prescribing information]. Rockville, MD: Supernus Pharmaceuticals Inc; April 2021.
2. Vetter VL, Elia J, Erickson CH, et al; American Heart Association Council on Cardiovascular Disease in the Young Congenital Cardiac Defects Committee; American Heart Association Council on Cardiovascular Nursing. Cardiovascular monitoring of children and adolescents with heart disease receiving medications for attention deficit/hyperactivity disorder [corrected]: a scientific statement from the American Heart Association Council on Cardiovascular Disease in the Young Congenital Cardiac Defects Committee and the Council on Cardiovascular Nursing. Circulation. 2008;117(18):2407-2423.[PubMed 18427125]
3. Wolraich M, Brown L, Brown RT, et al: Subcommittee on Attention-Deficit/Hyperactivity Disorder; Steering Committee on Quality Improvement and Management. ADHD: Clinical practice guideline for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder in children and adolescents. Pediatrics. 2011;128(5):1007-1022.[PubMed 22003063]
4. Yu C, Garcia-Olivares J, Candler S, Schwabe S, Maletic V. New insights into the mechanism of action of viloxazine: serotonin and norepinephrine modulating properties. J Exp Pharmacol. 2020;12:285-300. doi:10.2147/JEP.S256586[PubMed 32943948]
5. Wolraich ML, et al. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. Pediatrics. 2019;144(4):e20192528. doi:10.1542/peds.2019-2528

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Prior Authorization Criteria for RADICAVA, RADICAVA ORS (edaravone)

1. Patient has a diagnosis of amyotrophic lateral sclerosis (ALS) **AND**
2. Patient is 18 years of age and older **AND**
3. Dosage and Direction for Use:
    a. Radicava: 60 mg intravenous infusion daily for 14 days, followed by 14 day drug free period for initial cycle, then 60 mg intravenous infusion daily for 10 days out of 14 day periods, followed by 14 day drug free periods for all subsequent cycles
    b. Radicava ORS: 105 mg (5 mL) orally in the morning for 14 days, followed by 14 days drug free period for initial cycle, then 105 mg (5 mL) daily for 10 days out of 14 day periods, followed by 14 day drug free periods for all subsequent cycles **AND**
4. Quantity requested does not exceed: 64 doses/168 days **AND**
5. Patient has baseline ALS Functional Rating Scale (ALSFRS-R) score of ≥ 2 points on each item of the ALSFRS-R at the start of treatment **AND**
6. Patient does not have tracheostomy or permanent assisted ventilation **AND**
7. Prescribed by or in consultation with a specialist such as a neurologist with expertise in ALS.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 6 months

RENEWALS

✓ Patient has a positive response to therapy
✓ Patient does not have tracheostomy or permanent assisted ventilation
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated references	5.2024

REFERENCE:

1. Radicava [prescribing information]. Jersey City, NJ. Mitsubishi Tanabe Pharmacy America, Inc:December 2023.
2. Makam AN, et al. AMX0035 and Oral Edaravone for ALS; Final Evidence Report. Institute for Clinical and Economic Review, September 13, 2022. Accessed October 24, 2022. https://icer.org/wp-content/uploads/2022/02/ICER-ALS-Final-Report-09152022.pdf

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Prior Authorization Criteria for REBYOTA™ (fecal microbiota, live - jslm)

1. Patient has a diagnosis of at least two recurrent CDI episodes (≥3 total CDI episodes) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: a single-dose of 150 mL administered rectally 24 to 72 hours after the last dose of antibiotics for CDI in a healthcare setting **AND**
4. Quantity requested does not exceed: one-time treatment, single dose of 150 mL **AND**
5. Documentation that CDI is refractory to standard antibiotic therapy (i.e., vancomycin, Dificid) **AND**
6. Patient has tried and failed an alternative therapy (i.e., Zinplava) **AND**
7. Patient's current episode of CDI must be controlled (<3 unformed/loose stools/day for 2 consecutive days) **AND**
8. Patient has a positive stool test for C. difficile within 30 days before prior authorization request **AND**
9. Administration will occur 24–72 hours following completion of antibiotic course for CDI treatment **AND**
10. Prescribed by or in consultation with an infectious disease specialist or gastroenterologist

INITIAL APPROVALS

✓ Initial approval will be granted for one-time treatment

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 12.29.2022	12.2022
Annual Review	Added prescriber requirements	12.2023

REFERENCE:

1. Rebyota (fecal microbiota) [prescribing information]. Roseville, MN: Ferring Pharmaceuticals; November 2022
2. McDonald LC, Gerding DN, Johnson S, et al. Clinical practice guidelines for Clostridium difficile infection in adults and children: 2017 update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). Clin Infect Dis. 2018;66(7):e1-e48. https://doi.org/10.1093/cid/cix1085
3. Gupta S, et al. Fecal microbiota transplantation: in perspective. Therap Adv Gastroenterol. 2016;9(2):229–239. doi:10.1177/1756283X15607414
4. Stuart Johnson, Valéry Lavergne, Andrew M Skinner, Anne J Gonzales-Luna, Kevin W Garey, Ciaran P Kelly, Mark H Wilcox, Clinical Practice Guideline by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 Focused Update Guidelines on Management of *Clostridioides difficile* Infection in Adults, *Clinical Infectious Diseases*, Volume 73, Issue 5, 1 September 2021, Pages e1029–e1044, https://doi.org/10.1093/cid/ciab549

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Prior Authorization Criteria for RELISTOR® (methylnaltrexone bromide)

FDA-Approved Indications

- For the treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.
- For the treatment of OIC in adults with advanced illness or pain caused by active cancer who require opioid dosage escalation for palliative care.

Diagnosis: OIC in adults with chronic non-cancer pain (applies to subcutaneous injection and tablet)

1. Patient has a diagnosis of opioid-induced constipation **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use:
    a. Tablets: 450 mg once daily in the morning (3 tablets/day)
    b. Subcutaneous Injections: 12 mg once daily **AND**
4. Quantity requested does not exceed: max subcutaneously:
    a. Tablets: 450mg/day (90/30)
    b. Subcutaneous Injections: 30 prefilled syringe/month (may vary depending on package)
5. Patient does not have any known or suspected mechanical gastrointestinal obstruction **AND**
6. Patient has tried and failed at least TWO generic alternatives such as stimulant laxatives, stool softeners, osmotic agents including bisacodyl, docusate, laxatives **AND**
7. Patient had an adequate trial of ALL of the following preferred formulary agents: Movantik and Symproic **AND**
8. Patient has been taking opioid(s) for at least four weeks (discontinue if opioid medications are discontinued).

Diagnosis: OIC in adults with advanced illness due to cancer pain (applies to subcutaneous injection only)

1. Patient has diagnosis of opioid-induced constipation (OIC) with advanced illness or pain caused by active cancer due to opioid dosage calculation for palliative care **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: subcutaneous dose is based on patient's body weight. Administer 1 dose (of 8 mg or 12 mg) every other day as needed but not to exceed one dose in 24-hour period **AND**
4. Quantity requested does not exceed: max dose of 1 dose/24 hours (may vary depending on weight); 30 prefilled syringe or single-dose vial/ month **AND**
5. Patient does not have any known or suspected mechanical gastrointestinal obstruction (labeled contraindication) **AND**
6. Patient has tried and failed at least TWO of generic alternatives such as stimulant laxatives, stool softeners, osmotic agents including bisacodyl, docusate, laxatives **AND**
7. Patient has been taking opioids for at least four weeks (discontinue if opioid medications is discontinued).

INITIAL APPROVALS

Diagnosis: OIC in adults with chronic non-cancer pain

✓ Initial authorization will be granted for a period of 1 year or planned length of duration (whichever is shorter)

Diagnosis: OIC in adults with advanced illness or cancer-related pain

✓ Initial authorization will be granted for a period of 6 months or planned length of duration (whichever is shorter)

RENEWALS

Diagnosis: OIC in adults with chronic non-cancer pain

- ✓ Continuation of opioid therapy
- ✓ Approval duration for renewal: 1 year

Diagnosis: OIC in adults with advanced illness or cancer-related pain

- ✓ Documentation of positive clinical response to therapy has been provided (determine the medical necessity for continuation of treatment) **AND**
- ✓ Authorizations may be extended at 6 months intervals upon documentation from the prescriber that the member's condition has improved as a result of treatment
- ✓ Approval duration for renewal: 6 months

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Revised	Created	9.2019
Annual Review	Add Denial Message	2.5.2020/9.2020
Annual Review	No Changes	9.2021
Annual Review	No Changes	9.2022
Annual Review	Update format	9.2023
Annual Review	No Changes	2.2024

REFERENCE:

1. Relistor (methylnaltrexone) [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals Inc; April 2020.
2. Thomas J, "Opioid-Induced Bowel Dysfunction," J Pain Symptom Manage, 2008, 35(1):103-13.[PubMed 17981003]
3. Thomas J, Karver S, Cooney GA, et al, "Methylnaltrexone for Opioid-Induced Constipation in Advanced Illness," N Engl J Med, 2008, 358(22):2332-43.[PubMed 18509120]
4. Yuan CS, "Methylnaltrexone Mechanisms of Action and Effects on Opioid Bowel Dysfunction and Other Opioid Adverse Effects," Ann Pharmacother, 2007, 41(6):984-93.[PubMed 17504835]

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Prior Authorization Criteria for PCSK9 – REPATHA® (evolucumab)

FDA-APPROVED INDICATIONS

- Reduction in CV Risk: to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease.
- Primary hyperlipidemia (including heterozygous familial hypercholesterolemia (HeFH)):
  - As an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for treatment of adult patients with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol (LDL-C)
  - As an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 10 years and older with HeFH, to reduce LDL-C
- Homozygous Familial Hypercholesterolemia (HoFH):
  - As an adjunct to other LDL-C-lowering therapies in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH), to reduce LDL-C

Diagnosis: for reduction in CV risk

1. Patient has diagnosis of clinical atherosclerotic cardiovascular disease **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction for use: 140 mg every 2 weeks or 420 mg once monthly **AND**
4. Quantity requested does not exceed: 420 mg/month
5. Patient has a history of at least one of the following evident ASCVD events (documentation required):
   - Myocardial infarction (MI)
   - A past history of stroke or transient ischemic attack
   - Symptomatic peripheral arterial disease
   - Acute coronary syndrome
   - Stable or unstable angina, coronary or other arterial revascularization (CABG, PCI, etc.)
   - CT angiogram or catheterization consistent with clinical ASCVD **AND**
6. One of the following:
   a. Patient has been compliant (at least 12 weeks) with the maximum tolerated dose of a statin and will continue the statin while taking requested medication **OR**
   b. If patient has statin intolerance, confirm one of the following (documentation required)
      i. The patient has had two retrials with lower dose statins, alternative statins, or less frequent dosing **OR**
      ii. The patient has had experienced rhabdomyolysis or muscle symptoms with CK elevation > 10 times ULN **AND**
7. Patient has had a trial of concomitant therapy with ezetimibe in combination with statin therapy (or alone if statin intolerant) for at least 12 weeks **AND**
8. Patient has a current LDL-C level ≥70 mg/dL after at least three months treatment with maximally tolerated statin dose, unless statin intolerant, and ezetimibe **AND**
9. This agent is not being taken with another PCSK9 inhibitor, Juxtapid, or Kynamro **AND**
10. Prescribed by or in consultation with a specialist such as a cardiologist, an endocrinologist, or a physician who focuses in the treatment of cardiovascular (CV) risk management and/or lipid disorders.

Diagnosis: Primary hyperlipidemia

1. Patient has diagnosis of primary hyperlipidemia (not associated with ASCVD or familial hypercholesterolemia) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction for use: 140 mg every 2 weeks or 420 mg once monthly **AND**
4. Quantity requested does not exceed: 420 mg/month
5. Patient's untreated LDL-C level was ≥190 mg/dL before starting any lipid lowering therapy **AND**
6. Patient has ASCVD risk of >7.5% **AND**

7. One of the following:
   a. Patient has been compliant (at least 12 weeks) with the maximum tolerated dose of a statin and will continue the statin while taking requested medication **OR**
   b. If patient has statin intolerance, confirm one of the following (documentation required)
      iii. The patient has had two retrials with lower dose statins, alternative statins, or less frequent dosing **OR**
      iv. The patient has had experienced rhabdomyolysis or muscle symptoms with CK elevation >10 times ULN **AND**
8. Patient has had a trial of concomitant therapy with ezetimibe in combination with statin therapy (or alone if statin intolerant) for at least 12 weeks **AND**
9. Patient has a current LDL-C level ≥100 mg/dL after at least three months treatment with maximally tolerated statin dose, unless intolerant, and ezetimibe **AND**
10. This agent is not being taken with another PCSK9 inhibitor, Juxtapid, or Kynamro **AND**
11. Prescribed by or in consultation with a specialist such as a cardiologist, an endocrinologist, or a physician who focuses in the treatment of cardiovascular (CV) risk management and/or lipid disorders.

Diagnosis: Heterozygous familial hypercholesterolemia (HeFH)

1. Patient has diagnosis of heterozygous familial hypercholesterolemia **AND**
2. Patient is 10 years of age or older **AND**
3. Dosage and direction for use: Administered subcutaneously 140 mg every 2 weeks or 420 mg once monthly **AND**
4. Quantity requested does not exceed: 420 mg/month **AND**
5. Patient diagnosis is confirmed through one of the following supporting documents:
   a. Genetic testing (LDLR, APOB, or PCSK9 gene mutations)
   b. WHO Dutch Lipid Clinic Network diagnostic score of 8 or higher
   c. Simon-Broome Diagnostic Criteria **AND**
6. Patient has been compliant with physician recommended diet **AND**
7. One of the following:
   a. Patient has been compliant (at least 12 weeks) with the maximum tolerated dose of a statin and will continue the statin while taking requested medication **OR**
   b. If patient has statin intolerant, confirm one of the following (documentation required)
      i. The patient has had two retrials with lower dose statins, alternative statins or less frequent dosing **OR**
      ii. The patient has had experienced rhabdomyolysis or muscle symptoms with CK elevation >10 times ULN **AND**
8. Patient has tried and failed concomitant therapy with ezetimibe in combination with statin therapy (or alone if statin intolerant) for at least 12 weeks **AND**
9. Patient has a current LDL-C level ≥100 mg/dL (or >70 mg/dL in the presence of hypertension, diabetes or stage 3 OR 4 chronic kidney disease) after at least three months treatment with maximally tolerated statin dose, unless statin intolerant, and ezetimibe **AND**
10. This agent is not being taken with another PCSK9 inhibitor, Juxtapid, or Kynamro **AND**
11. Prescribed by or in consultation with a specialist such as a cardiologist, an endocrinologist, or a physician who focuses in the treatment of cardiovascular (CV) risk management and/or lipid disorders.

Diagnosis: Homozygous familial hypercholesterolemia (HoFH)

1. Patient has diagnosis of homozygous familial hypercholesterolemia **AND**
2. Patient is 10 years of age or older
3. Dosage and direction for use: Administered subcutaneously 420 mg once monthly. The dosage can be increased to 420 mg every 2 weeks if a clinically meaningful response is not achieved in 12 weeks **AND**
4. Quantity requested does not exceed: 840 mg/month

5. The diagnosis is confirmed by one of the following (clinical documentation and lab results required):
    a. The diagnosis is supported by genetic testing showing TWO generic mutations for LDLR, APOB, PCSK9 or ARH adaptor protein 1/LDLRAP1 gene locus **OR**
    b. Patient has an untreated low-density lipoprotein cholesterol (LDL-C) level >500 mg/dL or a treated LDL-C ≥300 mg/dL AND one of the following:
        i. Both parents have documented elevated LDL-C before lipid-lowering treatment (pre-treatment) consistent with a diagnosis of heterozygous familial hypercholesterolemia [e.g. untreated LDL-C >190 mg/dL] **OR**
        ii. Presence of cutaneous or tendon xanthoma before 10 years of age
6. Patient has been compliant (at least 12 weeks) with the maximum tolerated dose of a statin and will continue the statin while taking this PCSK9 agent **AND**
7. Patient has tried and failed concomitant therapy with ezetimibe in combination with statin therapy (or alone if statin intolerant) for at least 12 weeks **AND**
8. If patient has statin intolerant, confirm one of the following (documentation required) **AND**
    a. The patient has had two retrials with lower dose statins, alternative statins or less frequent dosing
    b. The patient has had experienced rhabdomyolysis or muscle symptoms with CK elevation >10 times ULN
9. Patient has a current LDL-C level of >100 mg/dL (without ASCVD) or >70 mg/dL (with ASCVD) or >55mg/dL (with extreme risk designation) after at least three months treatment with maximally tolerated statin dose, unless statin intolerant, and ezetimibe **AND**
10. This agent is not being taken with another PCSK9 inhibitor, Juxtapid, or Kynamro **AND**
11. Prescribed by or in consultation with a specialist such as a cardiologist, an endocrinologist, or a physician who focuses in the treatment of cardiovascular (CV) risk management and/or lipid disorders.

INITIAL APPROVALS

✓ Initial approval will be for a period of 12 months.

RENEWALS

✓ Confirm this is continuation of treatment and patient is responding positively to therapy
✓ May renew in up to 12 month intervals

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Updated	Formatted based on existed criteria, added New Indication	3.2018
Updated	Updated Lipid level requirement and history of failure requirement based on 2018 AHA/ACC cholesterol guideline.	3.2019
Updated	Combined criteria of Praluent and Repatha; Add Denial Message	9.2020
Annual Review	No Change	3.2021
Updated	Annual Review: update expanded indication for Praluent for HoFH. Update criteria to include expand indication for Repatha for patients >10 years of age and older for HeFH and HoFH. Updated denial message.	3.2022
Annual Review	Updated format	3.2023
Reviewed	Created separate criteria for PCSK9 agents; Update dx and LDL level requirements based on 2019 AHA/ACA cholesterol guidelines Updated and added clinical rules; Update dosages; Updated default denial message.	8.2023

Annual Review	Format and references updated	8.2024

REFERENCE:

1. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA guideline on the management of blood cholesterol [published online November 10, 2018]. Circulation. 2018. doi: 10.1161/CIR.0000000000000625.[PubMed 30586774]
2. Jacobson TA, Ito MK, Maki KC, et al. National lipid association recommendations for patient-centered management of dyslipidemia: part 1--full report. J Clin Lipidol. 2015;9(2):129-169. doi: 10.1016/j.jacl.2015.02.003.[PubMed 25911072]
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5. Praluent (alirocumab) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis US LLC; April 2019.
6. Robinson JG, Farnier M, Krempf M, et al. Efficacy and safety of alirocumab in reducing lipids and cardiovascular events. N Engl J Med. 2015;372(16):1489-1499.[PubMed 25773378]
7. Rosenson RS. Low density lipoprotein-cholesterol (LDL-C) lowering after an acute coronary syndrome. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed December 4, 2018.
8. Roth EM, Taskinen MR, Ginsberg HN, et al. Monotherapy with the PCSK9 inhibitor alirocumab versus ezetimibe in patients with hypercholesterolemia: results of a 24 week, double-blind, randomized Phase 3 trial. Int J Cardiol. 2014;176(1):55-61.[PubMed 25037695]
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12. Bruckert E, Blaha V, Stein EA, et al. Trial Assessing Long-Term Use of PCSK9 Inhibition in Patients with Genetic LDL Disorders (TAUSSIG): Efficacy and Safety in Patients with Homozygous Familial Hypercholesterolemia Receiving Lipid Apheresis. Circulation. 2014;130(s2):17016 [Abstract from 2014 AHA/ASA meeting].
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19. Sabatine MS, Giugliano RP, Keech AC, et al: FOURIER Steering Committee and Investigators. Evolocumab and clinical outcomes in patients with cardiovascular disease. N Engl J Med. 2017;376(18):1713-1722. doi: 10.1056/NEJMoa1615664.[PubMed 28304224]

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Prior Authorization Criteria for RETEVMO® (selpercatinib)

FDA-APPROVED INDICATIONS

- Non-Small Cell Lung Cancer
  - Treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with a rearranged during transfection (RET) gene fusion, as detected by an FDA-approved test.
- Thyroid Cancer
  - Treatment of adult and pediatric patients 2 years of age and older with advanced or metastatic medullary thyroid cancer (MTC) with a RET mutation, as detected by an FDA-approved test, who require systemic therapy
  - Treatment of adult and pediatric patients 2 years of age and older with advanced or metastatic thyroid cancer with a RET gene fusion, as detected by an FDA-approved test, who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate)
- Solid Tumors
  - Treatment of adult and pediatric patients 2 years of age and older with locally advanced or metastatic solid tumors with a RET gene fusion detected by an FDA-approved test that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling)
4. Prescribed by or in consultation with an oncologist.

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 6.4.2020	6.2020
Annual Review	No Change	6.2021
Annual Review	No Change	6.2022
Updated	Added solid tumor indication	6.2023
Annual Review	Updated duration to 1 year; added FDA indication section; updated to oncology drug format	6.2024

REFERENCE:

1. Retevmo (selpercatinib) [prescribing information]. Indianapolis, IN: Lilly USA LLC; April 2024.
2. Solomon BJ, Tan L, Lin JJ, et al. RET solvent front mutations mediate acquired resistance to selective RET inhibition in RET-driven malignancies. J Thorac Oncol. 2020;15(4):541-549. doi:10.1016/j.jtho.2020.01.006[PubMed 31988000]
3. Bongarzone I, et al. RET/NTRK1 Rearrangements in Thyroid Gland Tumors of the Papillary Carcinoma Family: Correlation with Clinicopathological Features. Clin Cancer Res. 1998;4(1):223-228.
4. National Comprehensive Cancer Network. Small Cell Lung Cancer (Version 3.2022). https://www.nccn.org/professionals/physician_gls/pdf/nscl_blocks.pdf. Accessed June 6, 2022.
5. National Comprehensive Cancer Network. Thyroid Cancer (Version 2.2022). https://www.nccn.org/professionals/physician_gls/pdf/nscl_blocks.pdf. Accessed June 6, 2022.

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Prior Authorization Criteria for REVLIMID® (lenalidomide)

FDA-APPROVED INDICATIONS

- Multiple myeloma (MM), in combination with dexamethasone
- MM, as maintenance following autologous hematopoietic stem cell transplantation (auto-HSCT)
- Transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities
- Mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib
- Previously treated follicular lymphoma (FL), in combination with a rituximab product
- Previously treated marginal zone lymphoma (MZL), in combination with a rituximab product

1. Patient has an FDA approved diagnosis **AND**
2. Patient is 18 years of age or older **AND**
3. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ If request is for brand Revlimid, patient had an adequate trial of generic lenalidomide unless contraindicated
- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Documentation of positive clinical response to therapy has been provided (no evidence of disease progression qualifies as positive response to therapy)
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA Criteria created based on CAB 2.18.20	2.2020
Annual Review	No changes	2.2021
Annual Review	Formatting changes	2.2022
Annual Review	Updated criteria under initial approvals to include "If request is for brand Revlimid, patient had an adequate trial of generic lenalidomide unless contraindicated"	2.2023
Annual Review	Updated criteria to include general oncology verbiage for FDA-approved indications based on package insert and NCCN Guidelines, and updated initial approval duration.	2.2024

REFERENCE:

1. Revlimid (lenalidomide) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; March 2023.
2. National Comprehensive Cancer Network. Multiple Myeloma Version 2.2024. Available at: http://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed February 15, 2024.
3. National Comprehensive Cancer Network. Myeloplastic Syndromes. Version 1.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed February 15, 2024.
4. National Comprehensive Cancer Network. B-cell Lymphomas Version 1.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed February 15, 2024.

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Prior Authorization Criteria for REYVOW™ (lasmiditan)

1. Patient has diagnosis of migraine **AND**
2. Requested medication is being used for acute treatment of migraine **AND**
3. Patient is 18 years of age or older **AND**
4. Dosage and Direction for Use: 50, 100, or 200 mg single dose; maximum: 1 dose in 24 hours **AND**
5. Quantity requested does not exceed: 8 tabs/month **AND**
6. Patient has an adequate trial of two oral generic triptans, unless contraindicated as follow:
    a. History of coronary artery disease or cardiac accessory conduction pathway disorders;
    b. History of stroke, transient ischemic attack, peripheral vascular disease
    c. Ischemic bowel disease; uncontrolled hypertension, or severe hepatic impairment

d. Diagnosis of complicated headaches, hemiplegic or basilar migraine

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA Criteria created based on CAB 2.13.20	2.2020
Annual review	No Changes	1.2021
Annual review	Updated clinical criteria; Updated denial message	1.2022
Annual review	No Changes	1.2023
Updated	Updated format and added contraindication requirement for triptans	9.2023
Annual review	Added requested medication is being used for the acute treatment of a migraine; Removed requirement for prophylaxis if over QL	1.2024

REFERENCE:

1. Ashina M, Vasudeva R, Jin L, et al. Onset of efficacy following oral treatment with lasmiditan for the acute treatment of migraine: integrated results from 2 randomized double-blind placebo-controlled phase 3 clinical studies. Headache. 2019;59(10):1788-1801. doi: 10.1111/head.13636.[PubMed 31529622]
2. Nelson DL, Phebus LA, Johnson KW, et al. Preclinical pharmacological profile of the selective 5-HT1F receptor agonist lasmiditan. Cephalalgia. 2010;30(10):1159-1169. doi: 10.1177/0333102410370873.[PubMed 20855361]
3. Reyvow (lasmiditan) [prescribing information]. Indianapolis, IN: Lilly USA, LLC; January 2020.
4. Ailani J, Burch RC, Robbins MS; Board of Directors of the American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. 2021 Jul;61(7):1021-1039. doi: 10.1111/head.14153. Epub 2021 Jun 23. PMID: 34160823.

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Prior Authorization Criteria for REZDIFFRA™ (resmetirom)

1. Patient has a diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) confirmed by biopsy or Noninvasive tests (NITs) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: The recommended dosage of REZDIFFRA is based on actual body weight. For patients weighing:
   a) <100 kg, the recommended dosage is 80 mg orally once daily
   b) ≥100 kg, the recommended dosage is 100 mg orally once daily **AND**
4. Quantity requested does not exceed: 100 mg orally once daily **AND**
5. Confirm patient does not have decompensated liver cirrhosis **AND**
6. Requested medication will be used in conjunction with diet and exercise **AND**
7. Prescribed by or in consultation with a specialist such as a gastroenterologist/hepatologist.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Patient has positive response to therapy
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 4.4.2024	4.2024

REFERENCE:

1. Rezdiffra (resmetirom) [prescribing information]. West Conshohocken, PA: Madrigal Pharmaceuticals Inc; March 2024.
2. Singh S, et al. Fibrosis progression in nonalcoholic fatty liver vs nonalcoholic steatohepatitis: a systematic review and meta-analysis of paired-biopsy studies. Clin Gastroenterol Hepatol. 2015;13(4):643-54. doi: 10.1016/j.cgh.2014.04.014
3. U.S. Department of Health and Human Services, FDA, CDER. Noncirrhotic Nonalcoholic Steatohepatitis With Liver Fibrosis: Developing Drugs for Treatment, Draft Guidance. 2018. Available from: https://www.fda.gov/media/119044/download. Accessed July 18, 2022.
4. Dufour JF, et al. Combination therapy for non-alcoholic steatohepatitis: rationale, opportunities and challenges. Gut. 2020;69(10):1877-1884. doi:10.1136/gutjnl-2019-319104
5. Harrison SA, et al. Noninvasive tests (NITs) in the management of nonalcoholic steatohepatitis (NASH). Gastroenterol Hepatol. 2020;16(8 suppl 1):1-16.
6. Rinella ME, Neuschwander-Tetri BA, Siddiqui MS, Abdelmalek MF, Caldwell S, Barb D, Kleiner DE, Loomba R. AASLD Practice Guidance on the clinical assessment and management of nonalcoholic fatty liver disease. Hepatology. 2023 May 1;77(5):1797-1835. doi: 10.1097/HEP.0000000000000323. Epub 2023 Mar 17. PMID: 36727674; PMCID: PMC10735173.

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Prior Authorization Criteria for REZUROCK™ (belumosudil mesylate)

1. Patient has a diagnosis of chronic graft-versus-host disease (chronic GVHD) **AND**
2. Patient is 12 years of age or older **AND**
3. Dosage and Direction for Use: 200 mg taken orally once daily with food **AND**
4. Quantity requested does not exceed: 200 mg (1 tablet) daily **AND**
5. Patient has had an adequate trial of at least two prior lines of systemic therapy (i.e., prednisone, tacrolimus, mycophenolate) **AND**
6. Prescribed by or in consultation with a specialist such as an oncologist.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 8.12.2021	8.2021
Annual Review	No Changes	8.2022
Annual Review	Updated criteria to remove requirement of PPI and updated format.	8.2023
Annual Review	Updated references	2.2024

REFERENCE:

1. Cutler CS, Lee SJ, Arai S, et al. Belumosudil for chronic graft-versus-host disease (cGVHD) after 2 or more prior lines of therapy: the ROCKstar study. *Blood*. Published online July 15, 2021. doi:10.1182/blood.2021012021[PubMed 34265047]
2. Jagasia M, Lazaryan A, Bachier CR, et al. ROCK2 inhibition with belumosudil (KD025) for the treatment of chronic graft-versus-host disease. *J Clin Oncol*. 2021;39(17):1888-1898. doi:10.1200/JCO.20.02754[PubMed 33877856]
3. Rezurock (belumosudil) [prescribing information]. Warrendale, PA: Kadmon Pharmaceuticals LLC; November 2023.
4. US Department of Health and Human Services; Centers for Disease Control and Prevention; National Institute for Occupational Safety and Health. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings 2016. http://www.cdc.gov/niosh/topics/antineoplastic/pdf/hazardous-drugs-list_2016-161.pdf. Updated September 2016. Accessed July 26, 2021.
5. Miklos D, et al. Ibrutinib for chronic graft-versus-host disease after failure of prior therapy. Blood. 2017;130(21):2243-2250. doi:10.1182/blood-2017-07-793786
6. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology. Hematopoietic Cell Transplantation. Version 1.2022. Published July 2021. Accessed August 29, 2022. https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf.
7. Zeiser R, et al. Ruxolitinib for glucocorticoid-refractory chronic graft-versus-host disease. N Engl J Med. 2021;385(3):228-238. doi:10.1056/NEJMoa2033122

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Prior Authorization Criteria for ribavirin oral tablet, capsules

1. Patient has diagnosis of chronic hepatitis C **AND**
2. Patient is one of the following:
    a. Ribavirin capsules: 3 years of age or older **OR**
    b. Ribavirin tablets: 5 years of age or older **AND**
3. Dosage and direction of use:
    a. Adults: 800 mg-1,400 mg based on body weight in two divided doses daily
    b. Pediatrics: 15 mg/kg/day in two divided doses **AND**
4. Requested medication is being used in combination with one of the following:
    a. Ribavirin capsules: PegIntron or Intron A **OR**
    b. Ribavirin tablets: Pegasys **AND**
5. Prescribed by or in consultation with a specialist such as a gastroenterologist, hepatologist, infectious disease physician, or a liver transplant physician.

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 48 weeks

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	No changes	4.2024

REFERENCE:

1. Ribavirin capsule. [Prescribing Information]. Pennington, NJ: Zydus Pharmaceuticals USA, Inc. November 2022.
2. Ribavirin tablet. [Prescribing Information}. East Windsor, NJ: Aurobindo Pharma Limited: June 2023.

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Prior Authorization Criteria for RINVOQ™ (upadacitinib)

FDA-APPROVED INDICATIONS

- Rheumatoid arthritis (RA): Adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers.
- Psoriatic arthritis (PsA): Adults and pediatric patients 2 years of age and older with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers
- Atopic Dermatitis (AD): Adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable.
- Crohn's disease (CD): Adults with moderately to severely active Crohn's disease who have had an inadequate response or intolerance to one or more TNF blockers.
- Ulcerative colitis (UC): Adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers.
- Ankylosing spondylitis (AS): Adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers
- Non-radiographic Axial Spondyloarthritis: Adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy
- Polyarticular Juvenile Idiopathic Arthritis: Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis (pJIA) who have had an inadequate response or intolerance to one or more TNF blockers

Diagnosis: Moderate to severe Rheumatoid Arthritis (Rinvoq)

1. Patient has diagnosis of moderate to severe Rheumatoid arthritis
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 15 mg orally once daily **AND**
4. Quantity requested does not exceed: 30 tablets/30 days **AND**
5. Patient has had an inadequate response or has contraindications to at least one non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide) **AND**
6. Patient has failed to achieve symptom control after adequate therapy with, or has labeled contraindications to at least one of the following: Enbrel or Adalimumab* **AND**
7. Patient is not receiving Rinvoq in combination with other biologic DMARDs **AND**
8. Prescribed by or in consultation with a rheumatologist.

Diagnosis: Psoriatic Arthritis (Rinvoq/Rinvoq LQ)

1. Patient has diagnosis of active psoriatic arthritis **AND**
2. Patient is 2 years of age or older **AND**
3. Dosage and direction of use:
    a. Adults 18 years of age and older: 15 mg orally once daily **AND**
    b. Pediatric patients less than 18 years of age: Optimize dose based on weight
4. Quantity requested does not exceed: 30 tablets/30 days or 360 ml/30 days **AND**
5. Patient has had an inadequate response or has contraindications to at least one non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide) **AND**
6. Patient has failed to achieve symptom control after adequate therapy with, or has labeled contraindications to at least one of the following: Enbrel or Adalimumab* **AND**
7. Patient is not receiving requested medication in combination with other biologic DMARDs **AND**
8. Prescribed by or in consultation with a rheumatologist

Diagnosis: Moderate to severe Atopic Dermatitis (Rinvoq)

1. Patient has diagnosis of moderate to severe atopic dermatitis **AND**
2. Patient is 12 years of age or older **AND**

3. Dosage and direction of use:
    a. Pediatric patients 12 years of age and older weighing at least 40 kg and adults less than 65 years of age: 15 mg PO once daily. May increase to 30 mg orally once daily if an adequate response is not achieved.
    b. Adults 65 years of age and older: 15 mg once daily **AND**
4. Quantity requested does not exceed: 30 tablets/30 days **AND**
5. Failure of all of the following, unless contraindicated or clinically significant adverse effects are experienced:
    a) Two formulary medium to very high potency topical corticosteroids, each used for at least 2 weeks **AND**
    b) One non-steroidal topical therapy*: topical calcineurin inhibitor (e.g., tacrolimus 0.03% ointment and pimecrolimus 1% cream) or Eucrisa®, each used for at least 4 weeks; * These agents may require prior authorization **AND**
    c) One or more of the following systemic agents: corticosteroids, azathioprine, methotrexate, mycophenolate mofetil, or cyclosporine **AND**
6. Patient is not receiving Rinvoq in combination with other biologics DMARDs **AND**
7. Prescribed by or in consultation with a dermatologist

Diagnosis: Crohn's Disease (Rinvoq)

1. Patient has diagnosis of moderate to severe Crohn's disease **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use:
    a. Initial dose: 45 mg by mouth once daily for 12 weeks.
    b. Maintenance dose: decrease dose to 15 mg PO once daily. May consider 30 mg once daily for patients with refractory, severe, or extensive disease **AND**
4. Quantity requested does not exceed:
    a. Induction dose: 45 mg/day (28 tablets/28 days) **AND**
    b. Maintenance dose: 30 mg/day (30 tablets/30 days) **AND**
5. Patient has had an inadequate response or has labeled contraindications to conventional therapies for CD (e.g., corticosteroids, non-biologic DMARDs, etc.). Conventional therapies for CD may include azathioprine, 6-mercaptopurine, methotrexate, glucocorticoids. A trail of mesalamine product does not count as systemic therapy for Crohn's disease **AND**
6. Patient has failed to achieve symptom control after adequate therapy with, or has labeled contraindications to at least one of the following: Adalimumab* **AND**
7. Patient is not receiving Rinvoq in combination with other biologic therapies **AND**
8. Prescribed by or in consultation with a gastroenterology specialist.

Diagnosis: Ulcerative Colitis (Rinvoq)

1. Patient has diagnosis of moderately to severely active ulcerative colitis (UC) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use:
    a. Initial dose: 45 mg by mouth once daily for 8 weeks.
    b. Maintenance dose: decrease dose to 15 mg PO once daily. May consider 30 mg once daily for patients with refractory, severe, or extensive disease **AND**
4. Quantity requested does not exceed:
    a. Induction dose: 45 mg/day (28 tablets/28 days) **AND**
    b. Maintenance dose: 30 mg/day (30 tablets/30 days) **AND**
5. Patient has the patient had an adequate trial and failure of at least ONE oral systemic agent for UC (e.g., 6-mercaptopurine, azathioprine, methotrexate, cyclosporine, tacrolimus, corticosteroid (e.g., prednisone)). A trail of mesalamine product does not count as systemic therapy for ulcerative colitis **AND**
6. Patient has failed to achieve symptom control after adequate treatment with, or has labeled contraindications to Adalimumab* **AND**
7. Patient is not receiving Rinvoq in combination with other biologic therapies **AND**
8. Prescribed by or in consultation with a gastroenterology specialist.

Diagnosis: Ankylosing Spondylitis (Rinvoq)

1. Patient has diagnosis of active ankylosing spondylitis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 15 mg PO once daily **AND**
4. Quantity requested does not exceed: 30 tablets/30 days **AND**
5. Patient has had trial and failure of TWO scheduled/maintenance NSAIDs, each used for a duration of at least four weeks **AND**
6. Patient has failed to achieve symptom control after adequate therapy with, or has labeled contraindications to at least one of the following: Enbrel or Adalimumab* **AND**
7. Patient is not receiving Rinvoq in combination with other biologic DMARDs **AND**
8. Prescribed by or in consultation with a rheumatologist

Diagnosis: Non-radiographic axial Spondyloarthritis (nr-axSpA) (Rinvoq)

1. Patient has diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 15 mg PO once daily **AND**
4. Quantity requested does not exceed: 30 tablets/30 days **AND**
5. Patient's non-radiographic axial spondyloarthritis presents with objective signs of inflammation (one of the following):
    a. C-reactive protein (CRP) elevated beyond the upper limit of normal OR
    b. Sacroiliitis reported on magnetic resonance imaging (MRI); **AND**
6. Patient has had trial and failure of TWO scheduled/maintenance NSAIDs, each used for a duration of at least four weeks **AND**
7. Patient has failed to achieve symptom control after adequate therapy with, or has labeled contraindications to Cimzia **AND**
8. Patient is not receiving Rinvoq in combination with other biologic DMARDs **AND**
9. Prescribed by or in consultation with a rheumatologist

Diagnosis: Polyarticular Juvenile Idiopathic Arthritis (Rinvoq/Rinvoq LQ)

1. Patient has diagnosis of active polyarticular juvenile idiopathic arthritis (pJIA) **AND**
2. Patient is 2 years of age or older **AND**
3. Dosage and direction of use:
    a. 10 kg to <20 kg: 3 mg (3 ml) Rinvoq LQ twice daily
    b. 20 kg to <30 kg: 4 mg (4 ml) Rinvoq LQ twice daily
    c. ≥30 kg: 6 mg (6 ml) twice Rinvoq LQ twice daily or 15 mg Rinvoq tablet once daily **AND**
4. Quantity requested does not exceed: 360 ml/30 days or 30 tablets/30 days **AND**
5. Patient has had an inadequate response or has contraindications to at least one non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide) **AND**
6. Patient has failed to achieve symptom control after adequate therapy with, or has labeled contraindications to at least one of the following: Adalimumab* or Enbrel **AND**
7. Patient is not receiving Rinvoq in combination with other biologic DMARDs **AND**
8. Prescribed by or in consultation with a rheumatologist

INITIAL APPROVALS

- ✓ * Please review formulary for current preferred adalimumab products. The trial of more than one preferred adalimumab product counts as one preferred product.
- ✓ Prescriber attestation that labs/notes indicate patient has the disease or requires the medication
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive response to the therapy (e.g. decreased disease activity and improved functioning from baseline) **AND**
- ✓ Patient is not receiving Rinvoq in combination with other biologic DMARDs or potent immunosuppressants (e.g., other TNF-inhibitors, Kineret, azathioprine, cyclosporine, etc.)
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Revised	Created	10.2019
Updated	Added default denial message	12.2019
Reviewed	Under Jan' 2020 CAB meeting, no change.	1.2020
Reviewed	Reviewed, no change	12.2020
Updated	Annual Review: Added expanded indication for Psoriatic Arthritis; Updated criterias; Added denial message.	1.2022
Updated	Update: Added expanded indication of atopic dermatitis; update denial message.	2.2022
Updated	Added expanded indication for Ulcerative Colitis; Updated denial message.	4.2022
Updated	Updated Moderate to severe Rheumatoid arthritis & active Psoriatic arthritis diagnosis and denial message; Added expanded indication for Ankylosing Spondylitis; Added denial message; Added references. Updated t/f criteria for Atopic dermatitis.	5.2022
Updated	Added expanded indication for Non-radiographic axial spondyloarthritis; added denial message. For Atopic Dermatitis: removed t/f criteria: Patient has had an adequate trial of a biologic (i.e., Dupixent or Adbry). Atopic Dermatitis drugs (Rinvoq, Cibinqo, Dupixent and Adbry) must be at parity with one another, if covered.	12.2022
Annual Review	Added expanded indication for Crohn's Disease; Updated t/f criteria for RA/PsA, AS, & UC; Updated initial approval verbiage to include: Prescriber attestation that labs/notes indicate patient has the disease or requires the medication; Updated denial messages; Removed TB test requirement.	6.2023
Updated	Updated criteria to include trial of adalimumab, updated initial approval verbiage, updated denial message, and removed "completed by" in history section.	8.2023
Annual Review	Updated trial and failure verbiage; Added pJIA expanded indication; Split up PsA and RA indications; updated PsA age range to 2 years and older; added new indication for juvenile idiopathic arthritis	5.2024

REFERENCE:

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2. Rinvoq (upadacitinib) [prescribing information]. North Chicago, IL: AbbVie Inc; August 2019.
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Prior Authorization Criteria for ROZLYTREK™ (entrectinib)

FDA-Approved Indications

- Adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive.
- Adult and pediatric patients 1 month of age and older with solid tumors that:
    - Have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation
    - Are metastatic or where surgical resection is likely to result in severe morbidity, and
    - Have progressed following treatment or have no satisfactory alternative therapy

Diagnosis: ROS1-Positive Non-Small Cell Lung Cancer

1. Patient has diagnosis metastatic non-small cell lung cancer (NSCLC) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 600 mg (three-200mg capsules) orally once daily **AND**
4. Quantity requested does not exceed: max dose of 600mg/day (84 tablets/28 days) **AND**
5. Patient's tumor has ROS1-positive **AND**
6. Prescribed by or consultation with an oncologist.

Diagnosis: NTRK Gene Fusion-Positive Solid Tumors

1. Patient has a diagnosis of a solid tumor **AND**
2. Patient is 1 month of age or older **AND**
3. Dosage and direction of use:
    a. Adults: 600 mg (three-200mg capsules) orally once daily
    b. Pediatrics >6 months: Based on BSA
        i. BSA > 1.50 m^2: 600 mg once daily
        ii. BSA 1.11 to 1.50 m^2: 500 mg once daily
        iii. BSA 0.91 to 1.10 m^2: 400 mg once daily
    c. Pediatrics >1 month to $\leq$6 months: 250 mg/m^2 orally once daily
4. Quantity requested does not exceed:
    a. Adults: max dose of 600mg/day (84 tablets/28 days) **AND**
    b. Pediatrics >12 years: Based on BSA
5. Patient's tumor is positive for an NTRK (NTRK1, NTRK2, NTRK3, or ALK) gene infusion detected by lab an FDA-approved testing **AND**
6. Patient does not have a known acquired resistance mutation **AND**
7. Patient is not a candidate for surgical resection as it is likely to result in severe morbidity **AND**
8. Patient's disease has progressed following initial treatment or have no alternative therapy **AND**
9. Prescribed by or consultation with an oncologist.

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided **AND**
- ✓ Approval duration for renewal: 1 year.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2019
Update	Add Denial Message; Annual Review: No Change	2.2020/8.2020
Annual Review	No Change	8.2021
Annual Review	Added dosage based on BSA for pediatric patients with solid tumor.	8.2022
Annual Review	Updated format	8.2023
Update	Updated age range for solid tumors to 1 month or older; updated approval duration to 1 year	11.2023

REFERENCE:

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5. National Comprehensive Cancer Network. Small Cell Lung Cancer (Version 3.2023). https://www.nccn.org/professionals/physician_gls/pdf/nscl_blocks.pdf. Accessed August 17, 2023.
6. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 17, 2023.

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Prior Authorization Criteria for RUBRACA (rucaparib)

FDA Indications

- Maintenance treatment of adult patients with a deleterious *BRCA* mutation (germline and/or somatic)- associated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy
- Treatment of adult patients with a deleterious *BRCA* mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated duration of approval; added FDA approved age	5.2024

REFERENCE:

1. RUBRACA [Prescribing Information]. Boulder, CO. Clovis Oncology, Inc: December 2022.

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Prior Authorization Criteria for RYDAPT (midostaurin)

FDA Indications

- In combination with standard cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) who are FLT3 mutation-positive, as detected by an FDA approved test
- Treatment of adult patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated duration of approval; added FDA age	5.2024

REFERENCE:

1. RYDAPT [Prescribing Information]. East Hanover, NJ. Novartis Pharmaceuticals Corporation: May 2023.

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Prior Authorization Criteria for SANDOSTATIN™ (octreotide acetate)

FDA APPROVED INDICATIONS

- Acromegaly
- Severe diarrhea/flushing episodes associated with metastatic carcinoid tumors
- Profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas)

Diagnosis: Acromegaly

1. Patient has diagnosis of Acromegaly **AND**
2. Patients is 6 years of age or older **AND**
3. Dosage and Direction for Use: 50 mcg SQ or IV three times daily up to 100 mcg three times daily. Some patients may require up to 1,500 mcg a day. Titrate to achieve target growth hormone (GH) and insulin-like growth factor 1 (IGF-1) levels **AND**
4. Quantity requested does not exceed: 1,500 mcg daily (500 mcg three times daily) **AND**
5. Patient had an inadequate response to or cannot be treated with surgical resection, radiotherapy, or dopamine agonist (i.e., bromocriptine mesylate at maximally tolerated doses) **AND**
6. If requested medication is brand Sandostatin, patient has tried and failed generic octreotide **AND**
7. Prescribed by or in consultation with an oncologist or gastroenterologist.

Diagnosis: Carcinoid Tumors

1. Patient has diagnosis of severe diarrhea/flushing episodes associated with metastatic carcinoid tumors
2. Patients is 6 years of age or older **AND**
3. Dosage and Direction for Use: 100-600 mcg daily SQ or IV in 2-4 divided doses for the first two weeks. The usual dose range is 50 to 750 mcg/day. Experience with doses above 750 mcg daily is limited, however, a continuous SubQ infusion of 1,000 to 2,000 mcg/day off label may be considered in patients who remain symptomatic on intermittent doses **AND**
4. Quantity requested does not exceed: 750 mcg mcg daily in divided doses **AND**
5. If requested medication is brand Sandostatin, patient has tried and failed generic octreotide **AND**
6. Prescribed by or in consultation with a specialist such as an oncologist.

Diagnosis: VIPomas

1. Patient has diagnosis of profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas)
2. Patients is 6 years of age or older **AND**
3. Dosage and Direction for Use: 200-300 mcg daily in 2-4 divided doses for first two weeks. Adjust the dosage to achieve a therapeutic response; daily dosage is 150 mcg to 750 mcg but usually doses above 450 mcg daily are not required **AND**
4. Quantity requested does not exceed: 750 mcg daily in divided doses **AND**
5. If requested medication is brand Sandostatin, patient has tried and failed generic octreotide **AND**
6. Prescribed by or in consultation with a specialist such as an oncologist.

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to “Off-Label Use Policy”).
- ✓ Initial approval will be granted for a period of 1 year
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Patient has a positive response to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA Criteria created based on CAB 5.22.2020	5.2020
Update	Added Sandostatin, Sandostatin LAR, Bynfezia	6.2020
Update	Added Mycapssa based on CAB 7.30.2020	8.2020
Annual Review	No Change	8.2021
Annual Review	No Change	8.2022
Annual Review	Removed Bynfezia (d/c), created separate criteria for Sandostatin/Sandostatin LAR, and Mycapssa, updated dosage, updated denial messaged, and updated format	8.2023
Update	Separated criteria for Sandostatin and Sandostain LAR	9.2023
Update	Updated initial approval duration from 6 months to 1 year	10.2023

REFERENCE:

1. Al-Hussaini A, Butzner D. Therapeutic applications of octreotide in pediatric patients. Saudi J Gastroenterol. 2012;18(2):87-94.
2. Colao A, Merola B, Ferone D, Lombardi G. Acromegaly. J Clin Endocrinol Metab. 1997;82(9):2777-2781. doi: 10.1210/jcem.82.9.4257.[PubMed 9284694]
3. Melmed S, Colao A, Barkan A, et al. Guidelines for acromegaly management: an update. J Clin Endocrinol Metab. May 2009; 94(5): 1509-1517.
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5. Neuroendodrine and adrenal tumors (Version 1.2019). National Comprehensive Cancer Network Guidelines. Available at nccn.org.
6. Octreotide acetate and octreotide acetate (LAR). National Comprehensive Cancer Network Compendium. Available at nccn.org.
7. Sandostatin (octreotide injection solution) [prescribing information]. East Hanover, NJ: Novartis; April 2019.
8. Sandostatin LAR Depot (octreotide injection suspension) [prescribing information]. East Hanover, NJ: Novartis; April 2019.
9. Katznelson L, Laws ER Jr, Melmed S, et al; Endocrine Society. Acromegaly: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2014;99(11):3933-3951. doi: 10.1210/jc.2014-2700.
10. Melmed S, Bronstein MD, Chanson P, et al. A consensus statement on acromegaly therapeutic outcomes. Nat Rev Endocrinol. 2018;14(9):552-561.[PubMed 30050156]
11. Strosberg J, El-Haddad G, Wolin E, et al. Phase 3 Trial of 177Lu-Dotatate for Midgut Neuroendocrine Tumors. N Engl J Med. 2017;376(2):125-135.[PubMed 28076709]

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Prior Authorization Criteria for SCEMBLIX® (asciminib)

FDA Indications

- Treatment of adults with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs)
- Treatment of Ph+ CML in CP with the T315I mutation in adults

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist.

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
- ✓ Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 11.18.2021	11.2021
Annual Review	No Changes	11.2022
Annual Review	Updated renewal requirements; added FDA indication section; updated format to oncology drug	10.2023
Update	Updated duration of approval; added FDA approved age	5.2024

REFERENCE:

1. National Comprehensive Cancer Network. Chronic Myeloid Leukemia (Version 1.2023). https://www.nccn.org/professionals/physician_gls/pdf/cml_blocks.pdf. Accessed November 18, 2022.
2. Rea D, Mauro MJ, Boquimpani C, et al. A phase 3, open-label, randomized study of asciminib, a STAMP inhibitor, vs bosutinib in CML after ≥2 prior TKIs. *Blood.* 2021;blood.2020009984. doi:10.1182/blood.2020009984[PubMed 34407542]
3. Scemblix (asciminib) tablets [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; April 2024.

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Prior Authorization Criteria for SECUADO® (asenapine)

1. Patient has diagnosis of Schizophrenia **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: one transdermal patch every 24 hours (recommended starting dose of Secuado is 3.8 mg/24 hours) **AND**
4. Quantity requested does not exceed: 7.6mg/24 hours (1 patch/day) **AND**
5. Patient had an adequate trial of at least two generic atypical antipsychotic indicated for the treatment of schizophrenia *(See Appendix)*
6. Prescribing provider is a specialist such as a psychiatrist.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Confirm continuation of treatment and positive response to therapy

✓ Approval duration for renewal: 1 year

APPENDIX

Examples of Antipsychotics FDA Approved for the Treatment of Schizophrenia	
Chlorpromazine	Asenapine (generic for Secuado and Saphris)
Haloperidol (generic for Haldol)	Brexiprazole (generic for Rexulti)
Loxapine	Cariprazine (generic for Vraylar)
Molindone	Clozapine (generic for Clozaril and Versacloz)
Perphenazine	Iloperidone (generic for Fanapt)
Thioridazine	Lumateperone (generic for Caplyta)
Thiothixene	Lurasidone (generic for Latuda)
Trifluoperazine	Olanzapine (generic for Zyprexa)
	Quetiapine (generic for Seroquel)
	Risperidone (generic for Risperdal)
	Ziprasidone

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA Criteria created based on CAB 1.16.20	1.2020
Annual Review	No Changes	1.2021
Annual Review	No Changes; Separated Secuado from Anti-psychotic group criteria	1.2022/8.2022
Annual Review	No Changes	1.2023
Annual Review	No Changes	12.2023
Annual Review	Added appendix for FDA approved antipsychotic medications indicated for schizophrenia	8.2024

REFERENCE:

1. Hasan A, Falkai P, Wobrock T, et al; World Federation of Societies of Biological Psychiatry (WFSBP) Task Force on Treatment Guidelines for Schizophrenia. World Federation of Societies of Biological Psychiatry (WFSBP) Guidelines for Biological Treatment of Schizophrenia, part 1: update 2012 on the acute treatment of schizophrenia and the management of treatment resistance. *World J Biol Psychiatry*. 2012;13(5):318-378. doi: 10.3109/15622975.2012.696143.
2. Secuado (asenapine) [prescribing information]. Miami, FL: Noven Therapeutics, LLC; October 2019.

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Prior Authorization Criteria for SENSIPAR® (cinacalcet)

FDA APPROVED INDICATIONS

- Secondary Hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on dialysis.
- Hypercalcemia in adult patients with Parathyroid Carcinoma (PC).
- Hypercalcemia in adult patients with primary HPT for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but who are unable to undergo parathyroidectomy.

Diagnosis: for Secondary Hyperparathyroidism

1. Patient has diagnosis of secondary hyperparathyroidism due to chronic kidney disease **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 30 mg once daily; increase dose incrementally every 2 to 4 weeks (to 60 mg once daily, 90 mg once daily, 120 mg once daily, and 180 mg once daily) as necessary to maintain intact parathyroid hormone levels **AND**
4. Quantity requested does not exceed: 60 tablets/30 days (based on max dose 180 mg/day; available in 30, 60, and 90 mg tablets) **AND**
5. Confirm patient is on dialysis **AND**
6. Lab results over the previous 3-6 months show trending increase in iPTH level or current (within the last 30 days) labs show iPTH above normal levels **AND**
7. Patient has an adequate trial and failure of a vitamin D analog (calcitriol, doxercalciferol, paricalcitol) unless contraindicated or clinical significant adverse effects are experienced **AND**
8. Patient is not receiving other calcimimetics (i.e. Parsabiv) **AND**
9. Prescribed by or in consultation with a nephrologist or endocrinologist.

Diagnosis: for Parathyroid Carcinoma

1. Patient has a diagnosis of hypercalcemia due to parathyroid carcinoma **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: Initial: 30 mg twice daily; increase dose incrementally every 2 to 4 weeks (to 60 mg twice daily, 90 mg twice daily, and 90 mg 3 to 4 times daily) as necessary to normalize serum calcium levels **AND**
4. Quantity requested does not exceed: 120 tablets/30 days (based on max dose 360 mg/day; available in 30, 60, and 90 mg tablets) **AND**
5. Patient is not receiving other calcimimetics (i.e. Parsabiv) **AND**
6. Serum calcium level is provided **AND**
7. Prescribed by or in consultation with an oncologist, nephrologist or endocrinologist.

Diagnosis: for Primary Hyperparathyroidism

1. Patient has a diagnosis of hypercalcemia due to primary hyperparathyroidism **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: Initial: 30 mg twice daily; increase dose incrementally every 2 to 4 weeks (to 60 mg twice daily, 90 mg twice daily, and 90 mg 3 or 4 times daily) as necessary to normalize serum calcium levels. **AND**
4. Quantity requested does not exceed: 120 tablets/30 days (based on max dose 360 mg/day; available in 30, 60, and 90 mg tablets) **AND**
5. Patient is not receiving other calcimimetics (i.e. Parsabiv) **AND**
6. Serum calcium level is provided **AND**
7. Prescribed by or in consultation with a nephrologist or endocrinologist.

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided **AND**
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	9.2019
Updated	Add Denial Message	9.2020
Annual Review	No Changes	9.2021
Annual Review	No Changes	9.2022
Annual Review	Format updates	9.2023
Annual Review	Updated format	8.2024

REFERENCE:

1. Sensipar (cinacalcet) [prescribing information]. Thousand Oaks, CA: Amgen Inc; March 2019.
2. Sensipar (cinacalcet) [product monograph]. Mississauga, Ontario, Canada: Amgen Canada Inc; November 2018.
3. Silverberg SJ, Rubin MR, Faiman C, et al, "Cinacalcet Hydrochloride Reduces the Serum Calcium Concentration in Inoperable Parathyroid Carcinoma," J Clin Endocrinol Metab, 2007, 92(10):3803-8. [PubMed 17666472]
4. Thomson K, Hutchinson DJ, Chablani L. Stability of extemporaneously prepared cinacalcet oral suspensions. Am J Health Syst Pharm. 2018;75(9):e236-e240. doi: 10.2146/ajhp170072.[PubMed 29691267]
5. Vera L, Oddo S, Di Iorgi N, Bentivoglio G, Giusti M. Primary hyperparathyroidism in pregnancy treated with cinacalcet: a case report and review of the literature. J Med Case Rep. 2016;10(1):361.[PubMed 27998296]

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Prior Authorization Criteria for SIGNIFOR® (pasireotide)

1. Patient has a diagnosis of Cushing's disease **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 0.3 mg-0.9 mg by subcutaneous injection twice daily **AND**
4. Quantity requested does not exceed: 0.9 mg twice daily **AND**
5. Patient has undergone pituitary surgery that was not curative or surgery is not an option **AND**
6. Patient has had a trial and failure, contraindication to, or intolerance to ketoconazole **AND**
7. Prescribed by or in consultation with an endocrinologist

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 6 months.

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided
- ✓ Approval duration for renewal: 12 months.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	No changes	2.2024

REFERENCE:

1. Signifor [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. August 2023.
2. Nieman LK, Biller BM, Findling JW, et al. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab 2015.

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Prior Authorization Criteria for SIMLANDI® (adalimumab-ryvk) & adalimumab-ryvk

FDA-APPROVED INDICATIONS

- Rheumatoid arthritis (RA): Adult patients with moderately to severely active rheumatoid arthritis
- Juvenile idiopathic arthritis (JIA): Polyarticular Juvenile Idiopathic Arthritis: Pediatric patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis
- Psoriatic arthritis (PsA): Adult patients with active psoriatic arthritis
- Ankylosing spondylitis (AS): Adult patients with active ankylosing spondylitis
- Plaque Psoriasis (PP): Adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate
- Crohn's disease (CD): Pediatric patients 6 years of age and older with moderately to severely active Crohn's
- Ulcerative colitis (UC): Adult patients 18 years of age and older with moderately to severely active ulcerative
- Hidradenitis suppurativa (HS): Moderate to severe hidradenitis suppurativa in patients 18 years of age and older
- Uveitis (UV): Adults patients 18 years of age and older with non-infectious intermediate, posterior, and panuveitis

Diagnosis: for Rheumatoid Arthritis (RA)

1. Patient has diagnosis of moderate to severe rheumatoid arthritis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 40 mg every other week or 40 mg every week or 80 mg every other week for patients that are not receiving methotrexate **AND**
4. Quantity requested does not exceed: 4 pens (40mg per pen)/28 days or 2 pens (80mg per pen)/28 days **AND**
5. Patient has had an inadequate response or has contraindications to at least one non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide) **AND**
6. Patient is not receiving medication in combination with other biologic DMARDS **AND**
7. For non-preferred Adalimumab formulations, patient has had an adequate trial of ALL preferred Adalimumab formulations **AND**
8. Prescribed by or in consultation with a rheumatologist.

Diagnosis: for Polyarticular Juvenile Idiopathic Arthritis (JIA)

1. Patient has diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis **AND**
2. Patient is 2 years of age or older **AND**
3. Dosage and direction of use:

Pediatric Weight 2 Years of Age and Older	Recommended Dosage
10 kg (22 lbs) to less than 15 kg (33 lbs)	10 mg every other week
15 kg (33 lbs) to less than 30 kg (66 lbs)	20 mg every other week
30 kg (66 lbs) and greater	40 mg every other week

AND

4. Quantity requested does not exceed: 2 pens (10, 20, or 40mg per pen)/28 days **AND**
5. Patient has had an inadequate response or has contraindications to at least one non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide) **AND**
6. Patient is not receiving medication in combination with other biologic DMARDS **AND**
7. For non-preferred Adalimumab formulations, patient has had an adequate trial of ALL preferred Adalimumab formulations **AND**
8. Prescribed by or in consultation with a rheumatologist.

Diagnosis: for Psoriatic Arthritis (PsA)

1. Patient has diagnosis of psoriatic arthritis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 40 mg every other week or 40 mg every week or 80 mg every other week for patients that are not receiving methotrexate **AND**
4. Quantity requested does not exceed: 4 pens (40mg per pen)/28 days or 2 pens (80mg per pen)/28 days
5. Patient has had an inadequate response or has contraindications to at least ONE non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide) **AND**
6. Patient is not receiving medication in combination with other biologic DMARDS **AND**
7. For non-preferred Adalimumab formulations, patient has had an adequate trial of **ALL** preferred Adalimumab formulations **AND**
8. Prescribed by or in consultation with a rheumatologist.

Diagnosis: for Ankylosing Spondylitis (AS)

1. Patient has diagnosis of ankylosing spondylitis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 40 mg every other week or 40 mg every week or 80 mg every other week for patients that are not receiving methotrexate **AND**
4. Quantity requested does not exceed: 4 pens (40mg per pen)/28 days or 2 pens (80mg per pen)/28 days
5. Patient has had an inadequate response or has contraindications to at least TWO scheduled/maintenance NSAIDs, each used for a duration of at least four weeks **AND**
6. Patient is not receiving medication in combination with other biologic DMARDS **AND**
7. For non-preferred Adalimumab formulations, patient has had an adequate trial of **ALL** preferred Adalimumab formulations **AND**
8. Prescribed by or in consultation with a rheumatologist.

Diagnosis: for Plaque Psoriasis (PP)

1. Patient has diagnosis of moderate to severe chronic plaque psoriasis
2. PP is affecting more than 3% of body surface area (BSA) or affecting crucial body areas (e.g., hands, feet, face, or genitals) **AND**
3. Patient is 18 years of age or older **AND**
4. Dosage and direction of use: Initial 80 mg as a single dose; maintenance: 40 mg every other week beginning 1 week after initial dose **AND**
5. Quantity requested does not exceed: initial dose: 3 pens/21 days (may vary depending on product package) maintenance: 2 pens (40mg per pen)/28 days **AND**
6. Patient has had an adequate trial and failure of UV or systemic therapy (methotrexate, acitretin, cyclosporine) **AND**
7. Patient has had an adequate trial of topical therapy (corticosteroids, calcipotriene, calcitriol, tazarotene, tacrolimus) **AND**
8. Patient is not receiving medication in combination with other biologic DMARDS **AND**
9. For non-preferred Adalimumab formulations, patient has had an adequate trial of **ALL** preferred Adalimumab formulations **AND**
10. Prescribed by or in consultation with a rheumatologist or dermatologist.

Diagnosis: for Ulcerative Colitis (UC)

1. Patient has diagnosis of moderately to severely active ulcerative colitis (UC) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: Initial 160 mg (given on day 1 or split and given over 2 consecutive days), then 80 mg 2 weeks later (day 15); Maintenance: 40 mg every other week beginning day 29 **AND**
4. Quantity requested does not exceed: Initial: 3 pens (80mg/pen)/28 days (may vary depending on product package); Maintenance: 4 pens (20mg or 40mg per pen)/28 days or 2 pens (80mg per pen)/28 days **AND**
5. Patient has the patient had an adequate trial and failure of at least ONE oral systemic agent (e.g., 6-mercaptopurine,

azathioprine, methotrexate, cyclosporine, tacrolimus, corticosteroid (e.g., prednisone). A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis **AND**

6. Patient is not receiving medication in combination with other biologic DMARDs **AND**
7. For non-preferred Adalimumab formulations, patient has had an adequate trial of ALL preferred Adalimumab formulations **AND**
8. Prescribed by or in consultation with a gastroenterologist.

Diagnosis: for Crohn's Disease (CD)

1. Patient has diagnosis of moderate to severe Crohn's disease **AND**
2. Patient is 6 years of age or older **AND**
3. Dosage and direction of use:
    a. Adults: Initial 160 mg (given on day 1 or split and given over 2 consecutive days), then 80 mg 2 weeks later (day 15); Maintenance: 40 mg every other week beginning day 29;
    b. Pediatric Patients 6 years and older:

Pediatric Weight	Recommended Dosage	
	Days 1 and 15	Starting on Day 29
17 kg (37 lbs) to less than 40 kg (88 lbs)	Day 1: 80 mg Day 15: 40 mg	20 mg every other week
40 kg (88 lbs) and greater	Day 1: 160 mg (single dose or split over two consecutive days) Day 15: 80 mg	40 mg every other week

AND

4. Quantity requested does not exceed: Initial: 3 pens (80mg/pen)/28 days (may vary depending on product package); Maintenance: 2 pens (40mg per pen)/28 days **AND**
5. Patient has the patient had an adequate trial and failure of at least one of the following: azathioprine, 6-mercaptopurine, methotrexate, glucocorticoids. A trial of a mesalamine product does not count as a systemic therapy for Crohn's disease **AND**
6. Patient is not receiving medication in combination with other biologic DMARDs **AND**
7. For non-preferred Adalimumab formulations, patient has had an adequate trial of ALL preferred Adalimumab formulations **AND**
8. Prescribed by or in consultation with a gastroenterologist.

Diagnosis: for Hidradenitis Suppurativa (HS)

1. Patient has diagnosis of moderate to severe Hidradenitis Suppurativa (Hurley stage II or stage III) **AND**
2. Patient is 18 years of age and older **AND**
3. Dosage and direction of use: Initial 160 mg (given on day 1 or split and given over 2 consecutive days), then 80 mg 2 weeks later (day 15); Maintenance: 40 mg every week or 80 mg every other week beginning day 29 **AND**
4. Quantity requested does not exceed: Initial: 3 pens (80mg/pen)/28 days (may vary depending on product package); Maintenance: 4 pens (40mg per pen)/28 days or 2 pens (80mg per pen)/28 days **AND**
5. Patient has had an adequate trial and failure of at least ONE of the following:
    a. Oral antibiotics for at least 12 weeks including tetracycline (e.g. doxycycline) and antibiotic combinations such as clindamycin plus rifampin;
    b. Oral retinoids;
    c. Anti-androgenic therapy (cyproterone acetate, oral contraceptive pills, spironolactone) **AND**
6. Patient is not receiving medication in combination with other biologic DMARDs **AND**
7. For non-preferred Adalimumab formulations, patient has had an adequate trial of ALL preferred Adalimumab formulations **AND**
8. Prescribed by or in consultation with a dermatologist, rheumatologist, or gastroenterologist

Diagnosis: for Uveitis

1. Patient has diagnosis of non-infectious intermediate, posterior, or panuveitis **AND**
2. Patient is 18 years of age and older **AND**
   Dosage and direction of use: Initial 80 mg as a single dose; maintenance: 40 mg every other week beginning 1 week after initial dose **AND**
3. Quantity requested does not exceed: 2 pens (10, 20, or 40mg per pen)/28 days **AND**
4. Patient had an adequate trial of topical or oral corticosteroids (e.g., prednisolone acetate, prednisone) **AND**
5. Patient had an adequate trial of a non-biologic immunosuppressant therapy (e.g., azathioprine, methotrexate, cyclosporine, tacrolimus) **AND**
6. Patient is not receiving medication in combination with other biologic DMARDs **AND**
7. For non-preferred Adalimumab formulations, patient has had an adequate trial of ALL preferred Adalimumab formulations **AND**
8. Prescribed by or in consultation with an ophthalmologist

INITIAL APPROVALS

- ✓ Please review formulary for current preferred adalimumab formulations. All non-formulary adalimumab products must first try and fail ALL preferred formulary adalimumab formulations.
- ✓ Prescriber attestation that labs/notes indicate patient has the disease or requires the medication **AND**
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided (e.g., baseline decrease in number of plaques, improvement in skin appearance, etc.) **AND**
- ✓ Patient is not receiving medication in combination with other biologic DMARDs **AND**
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB meeting 4.18.24	6.2024
Annual Review	Updated HS criteria to require one conventional therapy	7.2024

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11. Hulio (adalimumab) [product monograph]. Etobicoke, Ontario, Canada: BGP Pharma ULC; May 2023.
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Prior Authorization Criteria for SIMPONI® (golimumab)

FDA-APPROVED INDICATIONS

- Rheumatoid arthritis (RA): Adult with moderately to severely active rheumatoid arthritis in combination with methotrexate
- Psoriatic arthritis (PsA): Adult with active psoriatic arthritis (PsA) alone, or in combination with methotrexate (Simponi)
- Active ankylosing spondylitis (AS): Adult with active ankylosing spondylitis
- Ulcerative colitis (UC): Moderate to severe active ulcerative colitis (UC) who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine

Diagnosis: for Rheumatoid Arthritis (Simponi 50mg ONLY)

1. Patient has diagnosis of moderate to severe rheumatoid arthritis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: inject 50 mg subcutaneously once a month
4. Quantity requested does not exceed: 1 pen/month (may vary depending on formulation or weight) **AND**
5. Patient has had an inadequate response or has contraindications to at least one non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide) **AND**
6. Patient will receive concomitant treatment with methotrexate **AND**
7. Patient has failed to achieve symptom control after adequate treatment with, or has labeled contraindications to **two** or more of the following: Enbrel, Adalimumab*, Rinvoq, Xeljanz, Xeljanz XR, or tocilizumab SC** (documentation required) **AND**
8. Patient is not receiving medication in combination with other biologic DMARDs **AND**
9. Prescribed by or in consultation with a rheumatologist

Diagnosis: for Psoriatic Arthritis (Simponi 50mg ONLY)

1. Patient has diagnosis of psoriatic arthritis **AND**
2. Patient is 18 years of age or older
3. Dosage and direction of use: inject 50 mg subcutaneously once a month
4. Quantity requested does not exceed: 1 pen/month (may vary depending on formulation or weight) **AND**
5. Patient has had an inadequate response or has contraindications to at least one non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide) **AND**
6. Patient has failed to achieve symptom control after adequate treatment with, or has labeled contraindications to **two** or more of the following: Enbrel, Adalimumab*, Otezla, Skyrizi SC (pen/syringe), Stelara SC, Taltz, Tremfya, Xeljanz, Xeljanz XR, or Rinvoq/Rinvoq LQ (documentation required) **AND**
7. Patient is not receiving medication in combination with other biologic DMARDs **AND**
8. Prescribed by or in consultation with a rheumatologist

Diagnosis: for Ankylosing Spondylitis (Simponi 50mg ONLY)

1. Patient has diagnosis of ankylosing spondylitis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: inject 50 mg subcutaneously once a month
4. Quantity requested does not exceed: 1 pen/month (may vary depending on formulation or weight) **AND**
5. Patient has had trial and failure of TWO scheduled/maintenance NSAIDs, each used for a duration of at least four weeks **AND**
6. Patient has failed to achieve symptom control after adequate treatment with, or has labeled contraindications to **two** or more of the following: Enbrel, Adalimumab*, Taltz, Rinvoq, Xeljanz, or Xeljanz

XR (documentation required) **AND**

7. Patient is not receiving medication in combination with other biologic DMARDs **AND**
8. Prescribed by or in consultation with a rheumatologist

Diagnosis: for Ulcerative Colitis (Simponi 100 mg **ONLY**)

1. Patient has diagnosis of moderately to severely active ulcerative colitis (UC) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 200 mg at week 0, then 100 mg at week 2, followed by maintenance therapy of 100 mg every 4 weeks **AND**
4. Quantity requested does not exceed: Initial dose: 3 pens/28 days; maintenance dose: 1 pen/month; **AND**
5. Patient has the patient had an adequate trial and failure of at least ONE oral systemic agent (e.g., 6-mercaptopurine, azathioprine, methotrexate, cyclosporine, tacrolimus, corticosteroid (e.g., prednisone). A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis **AND**
6. Patient has failed to achieve symptom control after adequate treatment with, or has labeled contraindications to Adalimumab* **AND**
7. Patient is not receiving medication in combination with other biologic DMARDs (e.g. other TNF-inhibitors, Kineret, Otezla) **AND**
8. Prescribed by or in consultation with a gastroenterologist

INITIAL APPROVALS

- ✓ * Please review formulary for current preferred adalimumab products. The trial of more than one preferred adalimumab product counts as one preferred product.
- ✓ **Please review formulary for current preferred tocilizumab SC products. The trial of more than one preferred tocilizumab product counts as one preferred product.
- ✓ Prescriber attestation that labs/notes indicate patient has the disease or requires the medication
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided **AND**
- ✓ Patient is not receiving medication in combination with other biologic DMARDs
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Revised	Created	8.2019
Update	Include Rinvoq as preferred agent for RA; removed Xeljanz as part of the trail/failure agent from UC	10.2019
Updated	Added default denial message	12.2019
Reviewed	Under Jan' 2020 CAB meeting, no change.	1.2020
Reviewed	Updated criteria for RA (removed Actemra from step 1), PsA & AS (removed Actemra and added Taltz); added Simponi Aria's direction and expanded indications for PsA and pJIA in patients 2 years of age and older.	12.2020
Reviewed	Annual Review: Updated criteria for PsA, As, and JIA to include non-steroidal anti-inflammatory drugs (NSAIDs) or non-biologic disease modifying anti-rheumatic drugs (DMARDs) (i.e., methotrexate or leflunomide).	2.2022
Updated	Removed TB test exclusion criteria; Separated out denial message by indication; Updated references RA: Added Actemra to t/f options; updated wording PsA: Removed t/f of NSAID option; added Skyrizi and Rinvoq to t/f options; added pediatric dosing	6.2023

	AS: Changed t/f requirements to trial of two NSAIDs; added Rinvoq and Xeljanz to t/f options UC: updated t/f of systemic agents from two to one	
Updated	Updated criteria to include trial of adalimumab, updated initial approval verbiage, updated denial message, and removed "completed by" in history section.	8.2023
Annual Review	Added Rinvoq LQ to PsA indication; Separated out criteria for Simponi and Simponi Aria; updated trial and failure verbiage for UC	6.2024
Updated	For RA indication, replaced trial and failure of Actemra with tocilizumab	7.2024

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Prior Authorization Criteria for SIRTURO® (bedaquiline)

1. Patient has a diagnosis of Pulmonary Multidrug-Resistant Tuberculosis (MDR-TB) **AND**
2. Patient is 5 years of age or older **AND**
3. Dosage and Direction for Use: 400 mg (4 of the 100 mg tablets OR 20 of the 20 mg tablets) once daily with food for 2 weeks followed by 200 mg (2 of the 100 mg tablets OR 10 of the 20 mg tablets) 3 times per week for 22 weeks **AND**
4. Quantity requested does not exceed: 68 of the 100mg tablets or 340 of the 20mg tablets/28 days **AND**
5. Patient weights at least 15kg **AND**
6. One of the following:
    a. If patient's MDR-TB isolate has been shown to be susceptible in vitro, patient is taking requested medication in combination with at least three other drugs **OR**
    b. If in vitro testing results are unavailable and patient's MDR-TB isolate is likely to be susceptible, patient is taking requested medication in combination with at least four other drugs **AND**
7. Prescribed by or in consultation with an infectious disease specialist or pulmonologist

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 24 weeks.

RENEWALS

✓ Approval duration for renewal: addition 24 weeks if medically necessary.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 7.30.2020	8.2020
Annual review	No changes	8.2021
Annual review	No changes	8.2022
Annual review	Format update	8.2023
Annual review	Added infectious disease specialist to prescriber options; updated number of combination drugs dependent on susceptibility	2.2024

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Prior Authorization Criteria for SKYRIZI™ (risankizumab)

FDA-APPROVED INDICATIONS

- Psoriatic arthritis (PsA): Adults with active psoriatic arthritis
- Plaque psoriasis (PP): Adults with moderate to severe plaque psoriasis
- Crohn's Disease: Adults with moderate to severe Crohn's disease
- Ulcerative Colitis: Adults with moderate to severe ulcerative colitis

Diagnosis: for Psoriatic Arthritis (PsA) (Skyrizi pen or syringe)

1. Patient has diagnosis of psoriatic arthritis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 150 mg (1 syringe or pen) administered by subcutaneous injection at Week 0, Week 4 and every 12 weeks thereafter **AND**
4. Quantity requested does not exceed: Initial dose: 1 syringe or pen/28 days for 2 months; maintenance dose: 1 syringe or pen/ 84 days **AND**
5. Patient has had an inadequate response or has labeled contraindications at least one non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide) **AND**
6. Patient is not receiving Skyrizi in combination with other biologic DMARDs **AND**
7. Prescribed by or in consultation with a rheumatologist

Diagnosis: for Plaque Psoriasis (PP) (Skyrizi pen or syringe)

1. Patient has diagnosis of moderate to severe chronic plaque psoriasis **AND**
2. Psoriasis affects more than 3% of body surface area (BSA) or affects crucial body areas (e.g., hands, feet, face, or genitals) **AND**
3. Patient is 18 years of age or older **AND**
4. Dosage and direction of use: 150 mg (1 syringe or pen) administered by subcutaneous injection at Week 0, Week 4 and every 12 weeks thereafter **AND**
5. Quantity requested does not exceed: Initial dose: 1 syringe or pen/ 28 days for 2 months; maintenance dose: 1 syringe or pen/ 84 days **AND**
6. Patient has had an adequate trial and failure of UV or systemic therapy (i.e., methotrexate, acitretin, cyclosporine) **AND**
7. Patient has had an adequate trial and failure to topical therapy (i.e., corticosteroids, calcipotriene, calcitriol, tazarotene, tacrolimus) **AND**
8. Patient is not receiving Skyrizi in combination with other biologic DMARDs **AND**
9. Prescribed by or in consultation with a dermatologist

Diagnosis: for Crohn's Disease (Skyrizi on-body injector)

1. Patient has diagnosis of moderate to severe Crohn's Disease **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use:
    a. **Induction Dose:** 600 mg (1 vial) administered by intravenous infusion over a period of at least one hour at Week 0, Week 4, and Week 8.
    b. **Maintenance dose:** 180 mg or 360mg administered by subcutaneous injection at week 12 and every 8 weeks thereafter **AND**
4. Quantity requested does not exceed: maintenance dose of 180 mg/1.2 ml or 360 mg/2.4ml (1 cartridge) administered by subcutaneous injection at Week 12, and every 8 weeks thereafter **AND**
5. Patient has had an adequate trial and failure of at least one of the following: azathioprine, 6-mercaptopurine, methotrexate, glucocorticoids. A trial of a mesalamine product does not count as a systemic therapy for Crohn's disease **AND**

6. Patient is not receiving Skyrizi in combination with other biologic DMARDs **AND**
7. Prescribed by or in consultation with a gastroenterologist

Diagnosis: for Ulcerative Colitis (UC) (Skyrizi on-body injector)

1. Patient has diagnosis of moderately to severely active Ulcerative Colitis (UC) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use:
    a. **Induction Dose:** 1200 mg administered by intravenous infusion over a period of at least two hours at Week 0, Week 4, and Week 8.
    b. **Maintenance dose:** 180 mg or 360mg administered by subcutaneous injection at week 12 and every 8 weeks thereafter **AND**
4. Quantity requested does not exceed: maintenance dose of 180 mg/1.2 ml or 360 mg/2.4ml (1 cartridge) administered by subcutaneous injection at Week 12, and every 8 weeks thereafter **AND**
5. Patient had an adequate trial and failure of at least ONE oral systemic agent (e.g., 6-mercaptopurine, azathioprine, methotrexate, cyclosporine, tacrolimus, corticosteroid (e.g., prednisone). A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis **AND**
6. Patient is not receiving Skyrizi in combination with other biologic DMARDs **AND**
7. Prescribed by or in consultation with a gastroenterologist

INITIAL APPROVALS

- ✓ Prescriber attestation that labs/notes indicate patient has the disease or requires the medication
- ✓ Initial authorization will be granted for a period of 1 year.

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided (e.g., baseline decrease in number of plaques, improvement in skin appearance, etc.) **AND**
- ✓ Patient is not receiving medication in combination with other biologic DMARDs **AND**
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2019
Update	Added default denial message	12.2019
Reviewed	Under Jan' 2020 CAB meeting, no change.	1.2020
Reviewed	Reviewed, no change	12.2020
Update	Annual review: Updated to include new expanded indication PsA; Remove Humira and Enbrel from ST 1 criteria. Skyrizi is now preferred step 1.	2.2022
Update	Added new expanded indication for Crohn's disease; Added denial message.	7.2022
Update	Update criteria to include specific formulations for each disease state. For Crohn's disease, the Preferred Product is the Skyrizi subcutaneous on-body injector. For Plaque Psoriasis and Psoriatic Arthritis, the Preferred Product is the Skyrizi subcutaneous pen or syringe.	12.2022
Update	Removed TB test exclusion criteria; Updated denial language; Added references; Removed PDE4-I exclusion based on package insert Plaque psoriasis: Updated BSA to 3% per guidelines; separated out t/f criteria PsA: Removed t/f of NSAID option per guidelines CD: Updated t/f options to azathioprine, 6-mercaptopurine, methotrexate, glucocorticoids per guidelines	06.2023
Updated	Updated format and removed "completed by" in history section.	8.2023
Annual review	CD: Updated dosing and updated trial and failure wording	6.2024
Updated	Added expanded indication for ulcerative colitis	7.2024

REFERENCE:

1. Skyrizi Prescribing Information. North Chicago, IL: Abbvie Inc. June 2024.
2. Menter A, Gottlieb A, Feldman SR, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol. 2008;58:826-850.
3. Menter A, Gottlieb A, Feldman, SR, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 2. Psoriatic arthritis: overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad
4. Dermatol May 2008; 58(5): 826-50.
5. Menter A, Korman NF, Elmets CA, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 4. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol. 10.1016/j.jaad.2009.03.027
6. Feuerstein JD, Ho EY, Shmidt E, et al; American Gastroenterological Association Institute Clinical Guidelines Committee. AGA clinical practice guidelines on the medical management of moderate to severe luminal and perianal fistulizing Crohn's disease. *Gastroenterology* 2021;160:2496-2508. (https://doi.org/10.1053/j.gastro.2021.04.022)
7. Nakase H, Uchino M, Shinzaki S, etc. Evidence-based clinical practice guidelines for inflammatory bowel disease 2020. J Gastroenterol. 2021 Jun;56(6):489-526. doi: 10.1007/s00535-021-01784-1. Epub 2021 Apr 22. PMID: 33885977; PMCID: PMC8137635.
8. Coates, L.C., Soriano, E.R., Corp, N. et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. Nat Rev Rheumatol 18, 465–479 (2022). https://doi.org/10.1038/s41584-022-00798-0

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Prior Authorization Criteria for SOHONOS™ (palovarotene)

1. Patient has a diagnosis of fibrodysplasia ossificans progressiva (FOP) **AND**
2. Patient is 8 years and older if female or 10 years and older if male **AND**
3. Dosage and Direction for Use:
    a. Patients 14 years of age and older: 5 mg once daily, with an increase in dose at the time of a flare-up to 20 mg once daily for 4 weeks, followed by 10 mg once daily for 8 weeks, for a total of 12 weeks of flare-up treatment;
    b. Patients less than 14 years of age: Weight-based daily dosage ranging from 2.5 mg to 5 mg. The recommended flare-up dosing is weight based and ranges from 10 mg to 20 mg in Weeks 1– 4, and 5 mg to 10 mg in Weeks 5–12. The initial flare-up dosing is once daily for 4 weeks, then a lower flare-up dosage once daily for 8 weeks, for a total of 12 weeks of flare-up dosing **AND**
4. Quantity requested does not exceed: dosed by weight, please optimize quantity based on prescribed dosing scheduling **AND**
5. Patient has an ACVR1 R206H mutation confirmed by genetic testing **AND**
6. Prescriber attestation that patient is not pregnant and appropriate contraception methods will be used at least 1 month before treatment, during treatment and 1 month after last dose **AND**
7. Prescribed by or in consultation with a physician who specializes in rare connective tissue diseases.

INITIAL APPROVALS

- ✓ Prescriber attestation that labs/notes indicate patient has the disease or requires the medication **AND**
- ✓ Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Approval duration for renewal: 1 year
- ✓ Patient has a positive response to therapy (documentation provided)

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 9.21.2023	9.2023
Annual Review	No changes	9.2024

REFERENCE:

1. Sohonos (palovarotene) [prescribing information]. Cambridge, MA: Ipsen Biopharmaceuticals Inc; August 2023.

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Prior Authorization Criteria for SOLARAZE® (diclofenac 3% gel)

1. Patient must have diagnosis of actinic keratosis **AND**
2. Patient is 18 years or older **AND**
3. Dosage and Directions for Use: Apply to lesions twice daily for 60 to 90 days **AND**
4. Quantity requested does not exceed: One 100g tube /90 days **AND**
5. Patient has had an adequate trial of 5-fluorouracil 5% or imiquimod 5% cream
6. Prescribed by or in consultation with a dermatologist

INITIAL APPROVALS

- ✓ Initial approval will be for a period of up to 90 days.
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ With proper medical justification, may be renewed one time up to 90 days.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2019
Update	Update Format / Add Denial Message	2.2020
Annual Review	No Changes	7.2021
Annual Review	Update t/f criteria to include Patient has had an adequate trial of 5-fluorouracil or imiquimod cream	8.2022
Annual Review	Updated format	8.2023
Annual Review	Added prescriber requirement	2.2024

REFERENCE:

1. Solaraze (diclofenac sodium) [prescribing information]. Melville, NY: PharmaDerm; April 2022.
2. Eisen DB, Asgari MM, Bennett DD, Connolly SM, Dellavalle RP, Freeman EE, Goldenberg G, Leffell DJ, Peschin S, Sligh JE, Wu PA, Frazer-Green L, Malik S, Schlesinger TE. Guidelines of care for the management of actinic keratosis. J Am Acad Dermatol. 2021 Oct;85(4):e209-e233. doi: 10.1016/j.jaad.2021.02.082. Epub 2021 Apr 2. PMID: 33820677.
3. Uhlenhake EE. Optimal treatment of actinic keratoses. Clin Interv Aging. 2013;8:29-35. doi: 10.2147/CIA.S31930. Epub 2013 Jan 14. PMID: 23345970; PMCID: PMC3549675.

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Prior Authorization Criteria for SOMAVERT® (pegvisomant)

1. Patient has diagnosis of Acromegaly **AND**
2. Patients is 18 years of age or older **AND**
3. Dosage and Direction for Use: 40 mg loading dose subcutaneously under physician supervision. On day after loading dose, 10 mg daily subcutaneous injection. Dosage range is 10 mg to 30 mg once daily.
    a. **Note**: patients should adjust dosage in 5 mg increments or decrements until serum IGF-I concentrations are maintained within age-adjusted normal range. Patient should not adjust dosage based on growth hormone (GH) levels or signs or symptoms of acromegaly **AND**
4. Quantity requested does not exceed: 30mg (1 vial) daily or 30/30 days **AND**
5. Patient had an inadequate response to or cannot be treated with surgical resection, radiotherapy, or dopamine agonist **AND**
6. Patient has had an adequate trial of subcutaneous ocetreotide **AND**
7. Prescribed by or in consultation with an endocrinologist.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Patient has a positive response to therapy
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA Criteria for Acromegaly created based on CAB 5.22.2020	5.2020
Update	Update Criteria for Somavert	10.2021
Annual Review	No Changes	5.2022
Annual Review	Format update	5.2023
Annual Review	Remove liver function requirement; added dopamine agonist to options for inadequate response	4.2024

REFERENCE:

1. Colao A, Merola B, Ferone D, Lombardi G. Acromegaly. J Clin Endocrinol Metab. 1997;82(9):2777-2781. doi: 10.1210/jcem.82.9.4257.[PubMed 9284694]
2. Melmed S, Colao A, Barkan A, et al. Guidelines for acromegaly management: an update. J Clin Endocrinol Metab. May 2009; 94(5): 1509-1517.
3. Katznelson L, Laws ER Jr, Melmed S, et al; Endocrine Society. Acromegaly: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2014;99(11):3933-3951. doi: 10.1210/jc.2014-2700.
4. Katznelson L, Laws ER Jr, Melmed S, et al; Endocrine Society. Acromegaly: an endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2014;99(11):3933-3951. doi: 10.1210/jc.2014-2700.[PubMed 25356808]
5. Somavert (pegvisomant) [prescribing information]. New York, NY: Pharmacia & Upjohn Co; August 2021.

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Prior Authorization Criteria for SOTYKTU™ (deucravacitinib)

1. Patient has a diagnosis of moderate-to-severe plaque psoriasis **AND**
2. Patient's condition is affecting more than 3% of body surface area (BSA) or affecting crucial body areas (i.e., hands, feet, face, or genitals) **AND**
3. Patient is 18 years of age and older **AND**
4. Dosage and Direction for Use: 6 mg orally once daily **AND**
5. Quantity requested does not exceed: 30 tabs/30 days **AND**
6. Patient has had an adequate trial and failure of UV or systemic therapy (i.e., methotrexate, acitretin, cyclosporine) **AND**
7. Patient has had an adequate trial and failure to topical therapy (i.e., corticosteroids, calcipotriene, calcitriol, tazarotene, tacrolimus) **AND**
8. Patient is not receiving medication in combination with other biologic DMARDs **AND**
9. Prescribed by or in consultation with a specialist such as a dermatologist.

INITIAL APPROVALS

- ✓ * Please review formulary for current preferred adalimumab products. The trial of more than one preferred adalimumab product counts as one preferred product.
- ✓ Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive clinical response to Sotyktu therapy has been provided **AND**
- ✓ Patient is not receiving Sotyktu in combination with other biologic DMARDs **AND**
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 10.6.2022	10.2022
Updated	Updated criteria to include trial of two preferred products and affected area is more than 5% or affecting crucial areas; Update default message.	12.2022
Updated	Updated criteria for psoriasis, Sotyktu will be moving from Step 3A (requiring two Step 1 or 2 products) to Step 3C (requiring three step 1 products); updated denial message; Updated BSA involvement to 3% for moderate psoriasis based on guidelines; Removed negative TB test requirement; Updated denial message.	6.2023
Updated	Updated criteria to include trial of adalimumab, updated initial approval verbiage, updated denial message, and removed "completed by" in history section.	8.2023
Annual Review	Updated trial and failure requirements of first line biologics from three products to one; updated requirement to allow for trial and failure of systemic or UV treatment	3.2024
Update	Removed trial and failure requirement of other biologic agents; added renewal criteria	6.2024

REFERENCE:

1. Armstrong AW, Gooderham M, Warren RB, et al. Deucravacitinib versus placebo and apremilast in moderate to severe plaque psoriasis: efficacy and safety results from the 52-week, randomized, double-blinded, placebo-controlled phase 3 POETYK PSO-1 trial. J Am Acad Dermatol. 2022:S0190-9622(22)02256-3. doi:10.1016/j.jaad.2022.07.002[PubMed 35820547]
2. Papp K, Gordon K, Thaçi D, et al. Phase 2 trial of selective tyrosine kinase 2 inhibition in psoriasis. N Engl J Med. 2018;379(14):1313-1321. doi:10.1056/NEJMoa1806382[PubMed 30205746]
3. Smith CH, Yiu ZZN, Bale T, et al; British Association of Dermatologists' Clinical Standards Unit. British Association of Dermatologists guidelines for biologic therapy for psoriasis 2020: a rapid update. Br J Dermatol. 2020;183(4):628-637. doi:10.1111/bjd.19039[PubMed 32189327]
4. Sotyktu (deucravacitinib) [prescribing information]. Princeton, New Jersey: Bristol-Myers Squibb Company; September 2022.
5. Nast A, et al. EuroGuiDerm Guideline on the systemic treatment of psoriasis vulgaris – Part 1: treatment and monitoring recommendations. J Eur Acad Dermatol Venereol. 2020;34(11):2461-2498. doi:10.1111/jdv.16915
6. Mason AR, et al. Skin treatments for chronic plaque psoriasis. Cochrane Database Syst Rev. 2013;(3):CD005028. doi:10.1002/14651858.CD005028.pub3
7. Feldman SR. Treatment of psoriasis in adults. Dellavalle RP and Duffin KC, eds. UpToDate. Waltham, MA: UpToDate Inc. Updated August 31, 2022. Accessed October 4, 2022. https://www.uptodate.com/contents/treatment-of-psoriasis-inadults?search=Treatment%20of%20psoriasis%20in%20adults
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Prior Authorization Criteria for SPEVIGO® (spesolimab-sbzo)

FDA-APPROVED INDICATIONS

- Generalized pustular psoriasis (GPP) in adults and pediatric patients 12 years of age and older and weighing at least 40 kg
  - Intravenous Dosage for Treatment of GPP Flare
  - Subcutaneous Dosage for Treatment of GPP When Not Experiencing a Flare

Intravenous Dosage for Treatment of GPP Flare

1. Patient has a diagnosis of generalized pustular psoriasis (GPP) AND
2. Patient is 12 years of age or older and weighs at least 40 kilograms AND
3. Dosage and Direction for Use: 900 mg (15ml) dose by intravenous infusion over 90 minutes. If flare symptoms persist, an additional intravenous 900 mg dose may be administered one week after the initial dose AND
4. Quantity requested does not exceed: 1,800 mg (2 doses of 900 mg/15ml)/per treatment AND
5. Patient has a moderate to severe GPP flare based on one of the following:
   a. Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score ≥ 3 (moderate); OR
   b. Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) pustulation subscore ≥ 2 (mild); OR
   c. Erythema and pustules cover ≥ 5% of body-surface area; OR
   d. New appearance or worsening of pustules AND
6. Patient has had an adequate trial of at least one alternative therapy (i.e., cyclosporin, methotrexate, a biologic Humira) AND
7. Medication is not prescribed with other biological DMARDs, Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)], or Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] AND
8. Prescribed by or in consultation with a specialist such as a dermatologist.

Subcutaneous Dosage for Treatment of GPP When Not Experiencing a Flare

1. Patient has a diagnosis of generalized pustular psoriasis (GPP) AND
2. Patient is 12 years of age or older and weighs at least 40 kilograms AND
3. Dosage and Direction for Use: Four weeks after treatment with intravenous Spevigo, 300 mg (two 150 mg injections) administered subcutaneously every 4 weeks AND
4. Quantity requested does not exceed: 300 mg (2 doses of 150 mg injections)/per treatment AND
5. Patient has a history of two or more flares of moderate to severe intensity AND
6. Medication is not prescribed with other biological DMARDs, Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)], or Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] AND
7. Prescribed by or in consultation with a specialist such as a dermatologist.

INITIAL APPROVALS

- ✓ IV dosing: Initial approval will be granted for one fill for the treatment of GPP Flare
- ✓ Subcutaneous dosing: Initial approval will be granted for 1 year for treatment of GPP when not experiencing a flare

RENEWALS

- ✓ IV dosing for treatment of GPP Flare may be renewed for one additional fill if the below criteria are met:
  - Patient has received on initial dose of Spevigo for current GPP flare AND
  - Documentation is provided that the patient requires a second dose of Spevigo in order to treat persistent GPP flare symptoms including one of the following:
    - GPPPGA pustulation subscore ≥ 2; OR

- Fever; OR
- Asthenia; OR
- Myalgia; OR
- Elevated C-reactive protein; OR
- Leukocytosis with peripheral blood neutrophilia [above the upper limit of normal (ULN)]

✓ Subcutaneous dosing
- Patient has positive response to therapy
- Approval will be granted for 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 9.22.2022	9.2022
Annual Review	Updated verbiage to include t/f of biologic, updated denial message, and updated format.	9.2023
Annual Review	Updated criteria to include expanded indication for treatment of GPP when not experiencing a flare; added criteria for severity requirements for IV dosing	4.2024

REFERENCE:

1. Anderson PO. Monoclonal antibodies during breastfeeding. Breastfeed Med. 2021;16(8):591-593. doi:10.1089/bfm.2021.0110[PubMed 33956488]
2. Bachelez H, Choon SE, Marrakchi S, et al. Trial of spesolimab for generalized pustular psoriasis. N Engl J Med. 2021;385(26):2431-2440. doi:10.1056/NEJMoa2111563[PubMed 34936739]
3. Clements T, Rice TF, Vamvakas G, et al. Update on transplacental transfer of IgG subclasses: impact of maternal and fetal factors. Front Immunol. 2020;11:1920. doi:10.3389/fimmu.2020.01920[PubMed 33013843]
4. Mirza HA, Badri T, Kwan E. Generalized Pustular Psoriasis. StatPearls. 2021 Sep 14. https://www.ncbi.nlm.nih.gov/books/NBK493189/
5. Palmeira P, Quinello C, Silveira-Lessa AL, Zago CA, Carneiro-Sampaio M. IgG placental transfer in healthy and pathological pregnancies. Clin Dev Immunol. 2012;2012:985646. doi:10.1155/2012/985646[PubMed 22235228]
6. Pentsuk N, van der Laan JW. An interspecies comparison of placental antibody transfer: new insights into developmental toxicity testing of monoclonal antibodies. Birth Defects Res B Dev Reprod Toxicol. 2009;86(4):328-344. doi:10.1002/bdrb.20201[PubMed 19626656]
7. Refer to manufacturer's labeling.
8. Spevigo (spesolimab) [prescribing information]. Ridgefield, Connecticut: Boehringer Ingelheim Pharmaceuticals Inc; September 2022.
9. Strober B, Kotowsky N, Medeiros R, et al. Unmet medical needs in the treatment and management of generalized pustular psoriasis flares: evidence from a survey of Corrona registry dermatologists. Dermatol Ther. 2021;11:529-541. doi:10.1007/s13555-021-00493-0
10. Robinson A, Van Voorhees AS, Hsu S, et al. Treatment of pustular psoriasis: from the Medical Board of the National Psoriasis Foundation. J Am Acad Dermatol. 2012 Aug;67(2):279-288. doi:10.1016/j.jaad.2011.01.032
11. Gooderham MJ, Van Voorhees AS, Lebwohl MG. An update on generalized pustular psoriasis. Expert Rev Clin Immunol. 2019;15(9):907-919. doi:10.1080/1744666X.2019.1648209
12. Krueger J, Puig L, Thaçi D. Treatment Options and Goals for Patients with Generalized Pustular Psoriasis. Am J Clin Dermatol. 2022 Jan;23(Suppl 1):51-64. doi: 10.1007/s40257-021-00658-9. Epub 2022 Jan 21. PMID: 35061230; PMCID: PMC8801408.
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Prior Authorization Criteria for SPRYCEL (dasatinib)

FDA-Approved Indications

- Adult Patients with:
  - Newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase.
  - chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib.
  - Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy.
- Pediatric patients 1 years of age and older with:
  - Ph+ CML in chronic phase
  - newly diagnosed Ph+ ALL in combination with chemotherapy.

1. Patient has an FDA approved diagnosis **AND**
2. Patient is
   a. 18 years of age or older for newly diagnosed Ph+ CML in chronic phase OR chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML OR Ph+ ALL with resistance to prior therapy **OR**
   b. 1-17 years of age for Ph+ CML in chronic phase or newly diagnosed PH+ ALL in combination with chemo **AND**
3. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
✓ Initial authorization will be granted for a period of 1 year

RENEWALS

✓ Documentation or claim data supports continuation of treatment
✓ Patient is responding positively to therapy and still requires the medication for induction of remission
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Annual Review	Updated approval duration to 1 year	5.2024

REFERENCE:

1. Sprycel [Prescribing Information] Princeton, NJ: Bristol Myers Squibb; February 2023.

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Prior Authorization Criteria for STELARA® (ustekinumab)

FDA-APPROVED INDICATIONS

- Psoriatic arthritis (PsA): Patients 6 years and older with active psoriatic arthritis
- Plaque psoriasis (PP): Patients 6 years and older with moderate to severe plaque psoriasis
- Crohn's disease (CD): Adults with moderately to severely active Crohn's disease (CD)
- Ulcerative Colitis: Adult patients with active moderate to severe ulcerative colitis

Diagnosis: for Psoriatic Arthritis (PsA)

1. Patient has diagnosis of psoriatic arthritis **AND**
2. Patient is 6 years of age or older **AND**
3. Dosage and direction of use:
    a. *Adults < 100kg & Pediatric Patients 60kg to 100kg*: 45 mg at 0 and 4 weeks, and then every 12 weeks thereafter
    b. *Pediatric Patients < 60kg:* 0.75 mg/kg administered subcutaneously at 0 and 4 weeks, then every 12 weeks thereafter
    c. *Adults & Pediatric Patients > 100kg with coexistent psoriatic arthritis and moderate to severe plaque psoriasis:* Initial and maintenance: 90 mg at 0 and 4 weeks, and then every 12 weeks **AND** thereafter
4. Quantity requested does not exceed: Initial dose: 1 injection/28 days; Maintenance dose: 1 injection/84 days **AND**
5. Patient has had an inadequate response or has labeled contraindications at least one non-biologic disease-modifying antirheumatic drug (DMARDs) (e.g., methotrexate, leflunomide) **AND**
6. Patient is not receiving Stelara in combination with other biologic DMARDs **AND**
7. The medication is prescribed by a rheumatologist

Diagnosis: for Plaque Psoriasis (PP)

1. Patient has diagnosis of moderate to severe chronic plaque psoriasis **AND**
2. PP is affecting more than 3% of body surface area (BSA) or affecting crucial body areas (e.g., hands, feet, face, or genitals) **AND**
3. Patient is 6 years of age or older **AND**
4. Dosage and direction of use:
    a. *Adults < 100kg & Pediatric Patients 60kg to 100kg:* 45 mg administered subcutaneously at 0 and 4 weeks, then every 12 weeks thereafter **AND**
    b. *Adults & Pediatric Patients > 100kg*: 90 mg administered subcutaneously at 0 and 4 weeks, then every 12 weeks thereafter **AND**
    c. *Pediatric Patients < 60kg:* 0.75 mg/kg administered subcutaneously at 0 and 4 weeks, then every 12 weeks thereafter **AND**
5. Quantity requested does not exceed: Initial dose: 1 injection/28 days; Maintenance dose: 1 injection/84 days **AND**
6. Patient has had an adequate trial and failure of UV or systemic therapy (i.e., methotrexate, acitretin, cyclosporine) **AND**
7. Patient has had an adequate trial and failure to topical therapy (i.e., corticosteroids, calcipotriene, calcitriol, tazarotene, tacrolimus) **AND**
8. Patient is not receiving Stelara in combination with other biologic DMARDs **AND**

9. The medication is prescribed by a dermatologist

Diagnosis: for Crohn's Disease (CD)

1. Patient has diagnosis of moderate to severe Crohn's disease **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: recommended dosage : A single IV infusion using a weight-based dosage regimen: 260 mg; 2 vials (weight ≤55 kg), 390 mg; 3 vials (weight >55 kg to 85 kg), 520 mg; 4 vials (weight >85 kg) followed by subcutaneous maintenance dose of 90 mg every 8 weeks; begin maintenance dosing 8 weeks after the IV induction dose **AND**
4. Quantity requested does not exceed: Maintenance (subcutaneous): 1 injection (90mg)/56 days
5. Patient has had an adequate trial and failure of at least one of the following: azathioprine, 6-mercaptopurine, methotrexate, glucocorticoids **AND**
6. Patient is not receiving Stelara in combination with other biologic DMARDs **AND**
7. Prescribed by or in consultation with a gastroenterologist

Diagnosis: for Ulcerative Colitis (UC)

1. Patient has diagnosis of moderately to severely active Ulcerative Colitis (UC) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: initial dose; A single IV infusion using a weight-based dosage regimen: 260 mg; 2 vials (weight ≤ 55 kg), 390 mg; 3 vials (weight >55 kg to 85 kg), 520 mg; 4 vials (weight >85 kg) followed by subcutaneous maintenance dose of 90 mg every 8 weeks; begin maintenance dosing 8 weeks after the IV induction dose **AND**
4. Quantity requested does not exceed: Maintenance dose; subcutaneous 90 mg administered 8 weeks after the initial intravenous dose, then every 8 weeks thereafter **AND**
5. Patient has had an adequate trial and failure of at least one of the following: topical or oral 5-ASA agents, glucocorticoids, azathioprine, 6-mercaptopurine **AND**
6. Patient is not receiving Stelara in combination with other biologic DMARDs **AND**
7. Prescribing provider is a gastroenterologist

INITIAL APPROVALS

- ✓ Prescriber attestation that labs/notes indicate patient has the disease or requires the medication
- ✓ Confirm weight is provided **AND**
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided (e.g., baseline decrease in number of plaques, improvement in skin appearance, etc.) **AND**
- ✓ Patient is not receiving medication in combination with other biologic DMARDs **AND**
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Revised	Created based on existing MaxorPlus approved criteria	7.2019
Update	Added default denial message	12.2019
Update	Now Non-Preferred Step-2 for UC (previously not an approved indication). The patient is now directed to try Humira prior to Stelara SC. Reviewed under Jan' 2020 CAB meeting.	1.2020
Update	Updated to Preferred Step 1 for UC and CD	12.2020
Update	Annual Review: Update approved age for plaque psoriasis and dosage.	2.2022
Update	Removed TB test exclusion criteria; Updated indication section with wording from FDA approved indications; Separated out denial message by indication; Updated references; removed PDE4-I exclusion criteria based on package insert PsA: Updated age range and dosing based on package insert; updated wording of t/f requirement for consistency Plaque psoriasis: Updated BSA to 3% per guidelines; separated out t/f criteria UC: Updated t/f options based on guidelines; removed induction language for consistency	6.2023
Updated	Updated format and removed "completed by" in history section.	8.2023
Updated	CD: Updated trial and failure requirement to one agent	3.2024

REFERENCE:

1. Stelara Prescribing Information. Horsham, PA: Janssen Biotech; June 2018. Available at: www.stelarainfo.com. Accessed March 1, 2019.
2. Stelara [package insert]. Horsham, PA: Janssen Biotech Inc.; December 2020. 2. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol 2008; 58(5):826-50.
3. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Psoriatic arthritis: Overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol 2008;58(5):851-64.
4. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. J Am Acad Dermatol 2009;60(4):643-59.
5. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the treatment of psoriasis with phototherapy and photochemotherapy. J Am Acad Dermatol 2010;62(1):114-35.
6. Coates, L.C., Soriano, E.R., Corp, N. et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. Nat Rev Rheumatol 18, 465–479 (2022). https://doi.org/10.1038/s41584-022-00798-0
7. Feuerstein JD, Ho EY, Shmidt E, et al; American Gastroenterological Association Institute Clinical Guidelines Committee. AGA clinical practice guidelines on the medical management of moderate to severe luminal and perianal fistulizing Crohn's disease. *Gastroenterology* 2021;160:2496-2508. (https://doi.org/10.1053/j.gastro.2021.04.022)
8. Nakase H, Uchino M, Shinzaki S, etc. Evidence-based clinical practice guidelines for inflammatory bowel disease 2020. J Gastroenterol. 2021 Jun;56(6):489-526. doi: 10.1007/s00535-021-01784-1. Epub 2021 Apr 22. PMID: 33885977; PMCID: PMC8137635.
9. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology. 2020 Apr;158(5):1450-1461. doi: 10.1053/j.gastro.2020.01.006. Epub 2020 Jan 13. PMID: 31945371; PMCID: PMC7175923.
10. Sandborn WJ, Feagan BG, Hanauer SB, Lichtenstein GR. The Guide to Guidelines in Ulcerative Colitis: Interpretation and Appropriate Use in Clinical Practice. Gastroenterol Hepatol (N Y). 2021 Apr;17(4 Suppl 4):3-13. PMID: 34135718; PMCID: PMC8191814.

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Prior Authorization Criteria for STIMATE® (desmopressin acetate) nasal spray

1. Patient has diagnosis of:
   - Hemophilia A with Factor VIII coagulant activity levels greater than 5% OR
   - Von Willebrand's disease (type I) **AND**
2. Patient is 11 months of age or older **AND**
3. Dosage and direction of use: 150 mcg spray once in each nostril (total dose of 300mcg) per day **AND**
4. Quantity requested does not exceed: 150 mcg spray once in each nostril (total dose of 300mcg) per day **AND**
5. Prescribed by or in consultation with a hematologist.

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 1 year

RENEWALS

✓ Documentation of positive clinical response to therapy has been proven
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	1.2021
Annual Review	No Changes	1.2022
Annual Review	No Changes	1.2023

REFERENCE:

1. Stimate (desmopressin acetate) nasal spray [prescribing information]. King of Prussia, PA: CSL Behring; June 2013.
2. Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. Haemophilia. Jan 2013; 19(1): e1-47.
3. Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF): Database of treatment guidelines. Available at https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-ScientificAdvisory-Council-MASAC/MASAC-Recommendations. Accessed November 29, 2017.

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Prior Authorization Criteria for STIVARGA (regorafenib)

FDA-Approved Indications

- Treatment of patients with metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type, an anti-EGFR therapy
- Treatment of patients with locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and sunitinib malate
- Treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib

1. Patient has an FDA approved diagnosis **AND**
2. Patient is 18 years of age or older **AND**
3. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated duration to 1 year	5.2024

REFERENCE:

1. STIVARGA. [Prescribing Information]. Whippany, NJ. Bayer HealthCare Pharmaceuticals Inc: December 2020.

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Prior Authorization Criteria for STRENSIQ® (asfotase alfa)

1. Patient has diagnosis of:
    a. Juvenile-onset hypophosphatasia **OR**
    b. Perinatal-onset hypophosphatasia **OR**
    c. Infantile-onset hypophosphatasia **AND**
2. Patient is ≤ 18 years of age at onset **AND**
3. Dosage and direction of use:
    a. Juvenile-onset hypophosphatasia: 2 mg/kg administered subcutaneously 3 times weekly or 1 mg/kg 6 times weekly.
    b. Perinatal or infantile-onset hypophosphatasia: 2 mg/kg administered subcutaneously 3 times weekly or 1 mg/kg 6 times weekly. The dose may be increased to 3 mg/kg three times per week for insufficient efficacy **AND**
4. Quantity requested does not exceed:
    a. Juvenile-onset hypophosphatasia: 6 mg/kg per week
    b. Perinatal/infantile-onset hypophosphatasia: 9 mg/kg per week **AND**
5. Patient has one of the following clinical signs and/or symptoms of hypophosphatasia:
    a. Vitamin B6-dependend seizures **OR**
    b. Failure to thrive or growth failure/short stature **OR**
    c. Nephrocalcinosis with hypercalcemia/hypercalciuria **OR**
    d. Skeletal abnormalities and associated impairments (any of the following):
        i. Craniosynostosis (premature fusion of one or more cranial sutures) with increased intracranial pressure **OR**
        ii. Rachitic chest deformity (costochonfral junction enlargement seen in advanced rickets) with associated respiratory compromise **OR**
        iii. Limb deformity with delayed walking or gait abnormality **OR**
        iv. Compromised exercise capacity due to rickets and muscle weakness **OR**
        v. Low bone mineral density for age with unexplained fractures **OR**
        vi. Alveolar bone loss with premature loss of deciduous (primary) teeth **AND**
6. Onset of the disease was perinatal/infantile or juvenile (18 years or younger) **AND**
7. Diagnosis was confirmed by the presence of mutation(s) in the ALPL gene as detected by ALPL molecular genetic testing for tissue non-specific alkaline phosphate (TNSALP) OR the diagnosis is supported by all of the following:
    a. Serum alkaline phosphatase level below the gender- and age-specific reference range of the laboratory performing the test **AND**
    b. Plasma pyridoxal 5'-phosphate (PLP; main circulating from of vitamin B6) above the upper limit of normal (ULN) OR urinary phosphoethanolamine (PEA) above the ULN **AND**
8. Prescribing physician is a specialist such as an Endocrinologist or specialist experienced in the treatment of metabolic bone disorders.

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 6 months.

RENEWALS

✓ Documentation of positive clinical response to therapy, as evidenced by improvement of any of the following on initial approval:

- Height velocity;
- Respiratory function;
- Skeletal manifestations (e.g. bone mineralization, bone formation and remodeling, fractures, deformities);
- Motor function, mobility, or gait **AND**

✓ Approval duration for renewal: 6 to 12 months

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created per request	3.2020
Updated	Added denial message; specified clinical symptoms and re-authorization criteria	12.2020
Annual Review	No Change	3.2021
Annual Review	Updated dose and format	3.2022
Annual Review	Updated format	3.2023
Annual Review	Updated reference; updated format	3.2024

REFERENCE:

1. Strensiq (asfotase alfa) [prescribing information]. Boston, MA: Alexion Pharmaceuticals Inc; March 2023.
2. Bianchi ML. Hypophosphatasia: an overview of the disease and its treatment. Osteoporos Int. 2015;26(12):2743-57.
3. Mornet E, Nunes ME. Hypophosphatasia. GeneReviews [Internet]. Available at https://www.ncbi.nlm.nih.gov/books/NBK1150/. Updated February 4, 2016. Accessed October 18, 2017.
4. Kishnani PS, Rush ET, Arundel P, et al. Monitoring guidance for patients with hypophosphatasia treated with asfotase alfa. Mol Genet Metab. 2017;122(1-2):4-17. doi:10.1016/j.ymgme.2017.07.010[PubMed 28888853]
5. Seefried L, Kishnani PS, Moseley S, et al. Pharmacodynamics of asfotase alfa in adults with pediatric-onset hypophosphatasia. Bone. 2021;142:115664. doi:10.1016/j.bone.2020.115664[PubMed 32987199]
6. Scott LJ. Asfotase alfa in perinatal/infantile-onset and juvenile-onset hypophosphatasia: A guide to its use in the USA. Bio Drugs. 2016; 30:41-48. DOI 10.1007/s40259-016-0161-x.
7. Bishop N. Clinical management of hypophosphatasia. Clin Cases miner Bone Metab. 2015;12(2): 170-173.

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Prior Authorization Criteria for SUCRAID® (sacrosidase solution)

1. Patient has diagnosis of congenital sucrase-isomaltase deficiency (CSID) **AND**
2. Dosage and direction of use:
    a. 15 kg and less: 1 mL (8,500 IU) orally with each meal and snack
    b. More than 15 kg: 2 mL (17,000 IU) orally with each meal and snack **AND**
3. Quantity requested does not exceed: 236 mL (2 bottles)/ 28 days or 1 box (150 single use 2 mL containers)/30 days **AND**
4. Diagnosis has been confirmed by one of the following:
    a. Small bowel biopsy **OR**
    b. Sucrose breath test **OR**
    c. Genetic test **AND**
5. Prescribed by or in consultation with a gastroenterologist or geneticist

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 12 months.

RENEWALS

✓ Documentation of positive clinical response to therapy has been provided
✓ Approval duration for renewal: 12 months.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Annual Review	Updated references	1.2024

REFERENCE:

1. Sucraid [Prescriber Information]. Vero Beach, FL: QOL Medical, LLC.; December 2023.

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Prior Authorization Criteria for SUNLENCA® (lenacapavir)

1. Patient has a diagnosis of HIV-1 infection **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use:

Initiation Option 1	
Day 1	927 mg by subcutaneous injection (2 x 1.5 mL injections) 600 mg orally (2 x 300 mg tablets)
Day 2	600 mg orally (2 x 300 mg tablets)
Initiation Option 2	
Day 1	600 mg orally (2 x 300 mg tablets)
Day 2	600 mg orally (2 x 300 mg tablets)
Day 8	300 mg orally (1 x 300 mg tablet)
Day 15	927 mg by subcutaneous injection (2 x 1.5 mL injections)
Maintenance: 927 mg by subcutaneous injection (2 x 1.5 mL injections) every 6 months (26 weeks) from the date of the last injection +/-2 weeks.	

4. Quantity requested does not exceed: initial dose is based on initiation schedule. Please verify dose. Maintenance dose: 3 ml (two – 1.5 ml/463.5 mg single-dose vial) every 6 months **AND**
5. Patient continues to have a detectable viremia (viral load > 400 copies/mL) **AND**
6. Patient has confirmed multi-drug resistance with an assay demonstrating lack of sufficient treatment options to construct a fully suppressive regimen **AND**
7. Patient has documented resistance to at least TWO antiretroviral medications from each of at least 3 of the 4 classes of antiretroviral medications (NRTI, NNRTI, PI and INSTI), and ≤ 2 fully active antiretroviral medications from the 4 classes of antiretroviral medications remaining at baseline due to resistance, intolerability, drug access, contraindication, or other safety concerns **AND**
8. Prescribed by or in consultation with an infectious disease specialist.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year.

RENEWALS

✓ Patient has positive response to treatment (i.e., decrease in viral load)
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 1.12.2023	1.2023

REFERENCE:

1. Sunlenca (lenacapavir) [prescribing information]. Foster City, CA: Gilead Sciences, Inc; December 2022.
2. Kozal M, Aberg J, Pialoux G, et al. Fostemsavir in adults with multidrug-resistant HIV-1 infection. N Engl J Med. 2020;382(13):1232-1243. doi:10.1056/NEJMoa1902493[PubMed 32212519]
3. US Department of Health and Human Services (HHS) Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available http://aidsinfo.nih.gov/contentfiles/lvguidelines/AdultandAdolescentGL.pdf. Updated December 18, 2019. Accessed January 6, 2023.
4. US Department of Health and Human Services (HHS) Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission. Recommendations for the use of antiretroviral drugs in pregnant women with HIV infection and interventions to reduce perinatal HIV transmission in the United States. https://aidsinfo.nih.gov/contentfiles/lvguidelines/perinatalgl.pdf. Updated April 14, 2020. Accessed January 6, 2023.
5. Stellbrink H, DeJesus E, Segal-Maurer S, et al. Subgroup efficacy analyses of long-acting subcutaneous lenacapavir in phase 2/3 heavily treatment-experienced people with HIV (CAPELLA study). Presented at: 18th European AIDS Conference; October 27-30, 2021; virtual meeting. Accessed January 6, 2023. https://eacs2021.abstractserver.com/program/#/details/presentations/465

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Prior Authorization Criteria for SUNOSI™ (solriamfetol)

FDA-APPROVED INDICATIONS

- Excessive daytime sleepiness associated with Narcolepsy
- Obstructive sleep apnea (OSA)

Diagnosis: Narcolepsy

1. Patient has diagnosis of excessive daytime sleepiness associated with narcolepsy **AND**
2. Patient is 18 years and older **AND**
3. Dosage and direction of use: initial dose of 75mg once daily. Dose may be increased every 3 days to a max dose of 150 mg once daily **AND**
4. Quantity requested does not exceed: 1 tablet/day (30/30 days) **AND**
5. Patient has daily periods of irrepressible need to sleep or daytime lapses into drowsiness or sleep occurring for at least three months **AND**
6. Narcolepsy is confirmed by an overnight polysomnogram followed the next day by an MSLT that demonstrates a mean sleep latency ≤8 minutes and at least two sleep-onset REM periods (SOREMPs). A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT **AND**
7. Patient has had an adequate trial and failure (at least 90 days) or contraindication to:
    - Modafinil or armodafinil **OR**
    - A central nervous system (CNS) stimulant [e.g., amphetamine, dextroamphetamine, methylphenidate **AND**
8. Prescribed by or in consultation with a neurologist, psychiatrist, pulmonologist, or sleep medicine specialist

Diagnosis: OSA

1. Patient has diagnosis of obstructive sleep apnea (OSA) **AND**
2. Patient is 18 years and older **AND**
3. Dosage and direction of use: initial dose of 37.5mg once daily. Dose may be increased every 3 days to a max dose of 150mg once daily **AND**
4. Quantity requested does not exceed: 1 tablet/day (30/30 days) **AND**
5. Patient has an adequate trial of BOTH of the following:
    - Continuous Positive Airway Pressure (CPAP)
    - Modafinil or armodafinil
6. Prescribed by or in consultation with a specialist such as a neurologist, psychiatrist, pulmonologist, or sleep specialist

INITIAL APPROVALS

✓ Initial approval will be for a period of 6 months

RENEWALS

✓ Documentation of positive clinical response to therapy has been provided
✓ Patient has disease stabilization or improvement in disease
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	11.2019
Update	Update Format & Denial Message	2.2020
Update	Added 90 day requirement to prerequisite therapy	4.2021
Update	Combined denial to one default message	4.2021
Annual review	No Change	4.2022
Update	updated t/f criteria to include only modafinil or armodafinil or another stimulant if modafinil or armodafinil is contraindicated for narcolepsy.	8.2022
Annual review	Updated format and references	4.2023
Updated	Updated criteria for Narcolepsy, added specialist requirement, updated approval duration to be consistent with the drug class, and created separate denial message for OSA	10.2023
Annual review	Updated diagnostic criteria for narcolepsy; updated trial and failure to include CNS stimulant or modfanil/armodafinil; updated prescriber requirements; removed combination restrictions per practice guidelines	7.2024

REFERENCE:

1. Baladi MG, Forster MJ, Gatch MB, et al. Characterization of the neurochemical and behavioral effects of solriamfetol (JZP-110), a selective dopamine and norepinephrine reuptake inhibitor. J Pharmacol Exp Ther. 2018;366(2):367-376. doi: 10.1124/jpet.118.248120.[PubMed 29891587]
2. American Psychiatric Association. Sleep-wake disorders. In: Diagnostic and Statistical Manual of Mental Disorders Fifth Edition (DSM-5). Arlington, VA: American Psychiatric Association; 2013:361-422.
3. American Academy of Sleep Medicine. Central disorders of hypersomnolence. In: The International Classification of Sleep Disorders – Third Edition (ICSD-3) Online Version. Darien, IL: American Academy of Sleep Medicine; 2014.
4. Morgenthaler, T. (2007). Practice Parameters for the Treatment of Narcolepsy and other Hypersomnias of Central Origin. [online] American Academy of Sleep.
5. Medicine. Available at: https://j2vjt3dnbra3ps7ll1clb4q2-wpengine.netdna-ssl.com/wp-content/uploads/2017/07/PP_Narcolepsy.pdf
6. Ruoff C, Swick TJ, Doekel R, Emsellem HA, Feldman NT, Rosenberg R, Bream G, Khayrallah MA, Lu Y, Black J. Effect of Oral JZP-110 (ADX-N05) on Wakefulness and Sleepiness in Adults with Narcolepsy: A Phase 2b Study. Sleep. 2016; 39(7):1379-87.
7. Scammell, T. (2019). Clinical Features and Diagnosis of Narcolepsy in Adults. [online] Www-uptodate-com.ezproxy.cnsu.edu. Available at: https://wwwuptodate-com.ezproxy.cnsu.edu/contents/clinical-features-and-diagnosis-of-narcolepsy-inadults?search=narcolepsy%20treatment&source=search_result&selectedTitle=3~125&usage_type=default&display_rank=3.
8. Sunosi (solriamfetol) [product monograph]. Oakville, Ontario, Canada: Innomar Strategies Inc; August 2022.
9. Maski K, Trotti LM, Kotagal S, Robert Auger R, Rowley JA, Hashmi SD, Watson NF. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2021 Sep 1;17(9):1881-1893. doi: 10.5664/jcsm.9328. PMID: 34743789; PMCID: PMC8636351.

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Prior Authorization Criteria for SUTENT (sunitinib)

FDA Indications

- Treatment of adult patients with gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate
- Treatment of adult patients with advanced renal cell carcinoma (RCC)
- Adjuvant treatment of adult patients at high risk of recurrent RCC following nephrectomy
- Treatment of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in adult patients with unresectable locally advanced or metastatic disease

1. Patient has an FDA approved diagnosis **AND**
2. Patient is 18 years of age or older **AND**
3. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated approval duration to 1 year	5.2024

REFERENCE:

1. SUTENT. [Prescribing Information]. New York, NY. Pfizer Laboratories: September 2021.

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Prior Authorization Criteria for SYPRINE® (trientine hydrochloride)

1. Patient has diagnosis of Wilson's disease **AND**
2. Patient is 6 years of age or older **AND**
3. Dosage and direction of use:
    a. Age > 12 years: 750-1250 mg/day up to 2000 mg orally daily
    b. Age < 12 years: 500-750 mg/day up to 1500mg orally daily **AND**
4. Quantity requested does not exceed:
    a. Age > 12 years: 8 capsules/day (240/30 days)
    b. Age < 12 years: 6 capsules/day (180/30 days) **AND**
5. Patient is intolerant to penicillamine **AND**
6. For brand requests: patient has had an adequate trial of generic trientine **AND**
7. Prescribed by or in consultation with a specialist

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 1 year.
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided **AND**
- ✓ Patient has not developed significant adverse effects or condition has not worsen while on therapy **AND**
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2019
Update	Add Denial Message	2.2020
Annual review	Added Additional Clinical Rules section; Updated denial message	7.2021
Annual review	No changes	7.2022
Update	Added Cuvrior from CAB 4.20.2023	4.2023
Annual review	Updated format	7.2023
Update	Separated from Cuvrior; clarified trial and failure criteria; added specialist requirement	9.2023

REFERENCE:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2016. Available at: http://www.clinicalpharmacology-ip.com/. Accessed August 30, 2019
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3. Cuvrior Prescribing Information. Chicago, IL: Orphalan; April 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215760s000lbl.pdf.

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6. Trientine hydrochloride capsules [prescribing information]. Princeton, NJ: Dr. Reddy's Laboratories; July 2019.
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8. Schilsky ML, Roberts EA, Bronstein JM, Dhawan A, Hamilton JP, Rivard AM, Washington MK, Weiss KH, Zimbrean PC. A multidisciplinary approach to the diagnosis and management of Wilson disease: Executive summary of the 2022 Practice Guidance on Wilson disease from the American Association for the Study of Liver Diseases. Hepatology. 2023 Apr 1;77(4):1428-1455. doi: 10.1002/hep.32805. Epub 2022 Dec 7. PMID: 36152019.

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Prior Authorization Criteria for TABLOID (thioguanine)

FDA-Approved Indications

- Remission induction and remission consolidation treatment of acute nonlymphocytic leukemias

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Added FDA approved dx and age	5.2024

REFERENCE:

1. TABLOID [Prescribing Information]. Mason, OH. Aspen Global Inc.: August 2022.

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Prior Authorization Criteria for TABRECTA™ (capmatinib)

1. Patient has diagnosis of metastatic non-small cell lung cancer (NSCLC) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Directions for Use: 400 mg orally twice daily **AND**
4. Quantity requested does not exceed: 112 tablets/28 days **AND**
5. Patient's disease has presence of mutation that leads to MET (mesenchymal-epithelial transition) exon 14 skipping (METex14) detected by an FDA-approved test, i.e. FoundationOne CDx **AND**
6. Requested medication follows appropriate sequence of therapy for the diagnosis **AND**
7. Prescribed by or in consultation with an oncologist.

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
- ✓ Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 5.21.2020	5.2020
Annual Review	No Changes	5.2021
Annual Review	No Changes	5.2022
Annual Review	No Changes	5.2023
Annual review	Updated approval to 1 year; added requested medication to follow appropriate sequence of therapy	5.2024

REFERENCE:

1. TABRECTA (capmatinib) East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; March 2024.
2. National Comprehensive Cancer Network. Multiple Myeloma (Version 3.2023). https://www.nccn.org/professionals/physician_gls/pdf/nscl_blocks.pdf. Accessed May 10, 2023.

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Prior Authorization Criteria for TAFINLAR (dabrafenib)

FDA Indications

- Treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test as a single agent
- Treatment, in combination with trametinib, of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test
- Adjuvant treatment, in combination with trametinib, of patients with melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection
- Treatment, in combination with trametinib, of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test
- Treatment, in combination with trametinib, of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options
- Treatment, in combination with trametinib, of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options
- Treatment, in combination with trametinib, of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy

1. Patient has an FDA approved diagnosis **AND**
2. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
3. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
✓ Initial authorization will be granted for a period of 6 months.

RENEWALS

✓ Documentation or claim data supports continuation of treatment
✓ Patient is responding positively to therapy and still requires the medication for induction of remission
✓ Approval duration for renewal: 6 months to 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023

REFERENCE:

1. Tafinlar [Prescribing Information] East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2023.

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Prior Authorization Criteria for TAGRISSO™ (osimertinib)

FDA Approved Indications

- As adjuvant therapy after tumor resection in adult patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test
- First-line treatment of adult patients with metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.
- Treatment of adult patients with metastatic EGFR T790M mutation positive NSCLC, as detected by an FDA-approved test, whose disease has progressed on or after EGFR TKI therapy
- First-line treatment of adult patients, in combination with pemetrexed and platinum-based chemotherapy, with locally advanced or metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist.

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on previously criteria	9.2019
Update	Add Denial Message; updated approval duration for renewal: 6 to 1 year based on jan2020 CAB decision	2.2020
Update	Update PA criteria based on updated NCCN guidelines	7.2021
Annual Review	No Changes	7.2022
Update	Update PA criteria to include expanded indication: As adjuvant therapy after tumor resection in adult patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations.	9.2022
Annual Review	No Changes	9.2023
Update	Updated to oncology template; updated approval duration; updated indications	5.2024
Annual Review	No Changes	9.2024

REFERENCE:

1. Mok TS, Wu Y-L, Ahn M-J, et al. Osimertinib or platinum-pemetrexed in EGFR T790M-positive lung cancer. *N Engl J Med.* 2017;376(7):629-640.[PubMed 27959700]

2. Noonan SA, Sachs PB, Camidge DR. Transient asymptomatic pulmonary opacities occurring during osimertinib treatment. *J Thorac Oncol*. 2016;11(12):2253-2258. doi: 10.1016/j.jtho.2016.08.144.[PubMed 27618759]
3. Remon J, Caramella C, Jovelet C, et al. Osimertinib benefit in EGFR-mutant NSCLC patients with T790M-mutation detected by circulating tumour DNA [published online January 18, 2017]. *Ann Oncol.* 2017. pii: mdx017. doi: 10.1093/annonc/mdx017.[PubMed 28104619]
4. Soria JC, Ramalingam SS. Osimertinib in EGFR mutation-positive advanced NSCLC. *N Engl J Med*. 2018;378(13):1262-1263. doi: 10.1056/NEJMc1801669.[PubMed 29590540]
5. Tagrisso (osimertinib) [product monograph]. Mississauga, Ontario, Canada: AstraZeneca Canada Inc; August 2019
6. National Comprehensive Cancer Network. Small Cell Lung Cancer (Version 3.2023). https://www.nccn.org/professionals/physician_gls/pdf/nscl_blocks.pdf. Accessed August 17, 2023.

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Prior Authorization Criteria for TALTZ™ (ixekizumab)

FDA-APPROVED INDICATIONS

- Psoriatic arthritis (PsA): Adults with active psoriatic arthritis
- Plaque psoriasis (PP): In patients ≥ 6 years of age with moderate-to-severe plaque psoriasis
- Ankylosing spondylitis (AS): Adult with active ankylosing spondylitis
- Non-Radiographic Axial Spondyloarthritis (nr-axSpA): Adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation

Diagnosis: for Psoriatic Arthritis (PsA)

1. Patient has diagnosis of psoriatic arthritis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: recommended dose is 160 mg by subcutaneous injection (two 80 mg injections) at Week 0, followed by 80 mg every 4 weeks **AND**
4. Quantity requested does not exceed: initial dose: 2 pens (80mg/mL per pen)/month; maintenance dose: 1 pen/month **AND**
5. Patient has had an inadequate response or has labeled contraindications to at least one non-biologic disease-modifying antirheumatic drug (DMARDs) (e.g., methotrexate, leflunomide) **AND**
6. Patient is not receiving Taltz in combination with other biologic DMARDs **AND**
7. Prescribed by or in consultation with a rheumatologist

Diagnosis: for Plaque Psoriasis (PP)

1. Patient has diagnosis of moderate to severe chronic plaque psoriasis
2. PP is affecting more than 3% of body surface area (BSA) or affecting crucial body areas (e.g., hands, feet, face, or genitals) **AND**
3. Patient is 6 years of age or older **AND**
4. Dosage and direction of use:
    a. ≥18 years of age recommended dose is 160 mg (two 80 mg injections) at Week 0, followed by 80 mg at Weeks 2, 4, 6, 8, 10, and 12, then 80 mg every 4 weeks
    b. <18 years of age: >50 kg: 160 mg at week 0, followed by 80 mg every 4 weeks; 25-50 kg: 80 mg at week 0, followed by 40 mg every 4 weeks; <25 kg: 40 mg at week 0, followed by 20 mg every 4 weeks **AND**
5. Quantity requested does not exceed: Initial dose 3 pens for 1st month, then 2 pens/month for 2 months; maintenance dose: 1 pen/month **AND**
6. Patient has had an adequate trial and failure of UV or systemic therapy (i.e., methotrexate, acitretin, cyclosporine) **AND**
7. Patient has had an adequate trial and failure to topical therapy (i.e., corticosteroids, calcipotriene, calcitriol, tazarotene, tacrolimus) **AND**
8. Patient is not receiving Taltz in combination with other biologic DMARDs **AND**
9. Prescribed by or in consultation with a dermatologist

Diagnosis: for Ankylosing Spondylitis (AS)

1. Patient has a documented diagnosis of ankylosing spondylitis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 160mg once, followed by 80mg every 4 weeks; **AND**
4. Quantity requested does not exceed: initial dose: 2 pens (80mg/mL per pen)/ month; maintenance dose: 1 pens/month **AND**

5. Patient has had trial and failure of TWO scheduled/maintenance NSAIDs, each used for a duration of at least four weeks **AND**
6. Patient will not receive Taltz in combination with other biologic DMARDs **AND**
7. Prescribed by or in consultation with a rheumatologist

Diagnosis: for Non-Radiographic axial spondyloarthritis (nr-axSpA)

1. Patient has diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 80 mg every 4 weeks **AND**
4. Quantity requested does not exceed: initial dose: 1 pen/month **AND**
5. Patient's non-radiographic axial spondyloarthritis presents with objective signs of inflammation (with one of the following):
    a. C-reactive protein (CRP) elevated beyond the upper limit of normal **OR**
    b. Sacroiliitis reported on magnetic resonance imaging (MRI) **AND**
6. Patient has had an adequate trial and failure of TWO scheduled/maintenance NSAIDs, each used for a duration of 4 weeks **AND**
7. Patient will not receive Taltz in combination with other biologic DMARDs **AND**
8. Prescribed by or in consultation with a rheumatologist

INITIAL APPROVALS

- ✓ Prescriber attestation that labs/notes indicate patient has the disease or requires the medication
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided **AND**
- ✓ Patient is not receiving medication in combination with other biologic DMARDs
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2019
Revised	Formatted to new template	8.2019
Update	Added criteria for new indication of AS	10.2019
Update	Added default denial message	12.2019
Reviewed	Under Jan' 2020 CAB meeting, no change.	1.2020
Updated	Added indication of nr-axSpA and updated criteria, removed step 1 requirement (Taltz has become step 1)	12.2020
Reviewed	Annual Review: No Changes	12.2021
Updated	Annual Review: for PsA and AS, update t/f criteria to include non-steroidal anti-inflammatory drugs (NSAIDs) or non-biologic disease-modifying antirheumatic drug (DMARDs) such as methotrexate or leflunomide. Update DMARDs abbreviation and also denial message.	2.2022
Updated	Removed TB test exclusion criteria; Separated out denial message by indication; Updated references; removed PDE4 exclusion based on package insert Plaque psoriasis: Updated BSA to 3% per guidelines; separated out t/f criteria PsA: Removed t/f of NSAID option per guidelines AS/nr-axSpA: Changed t/f requirements to trial of two NSAIDs per guidelines	6.2023
Updated	Updated format and removed "completed by" in history section.	8.2023
Annual Review	Updated pediatric dosing for plaque psoriasis	6.2024

REFERENCE:

1. Taltz (ixekizumab) [prescribing information]. Indianapolis, IN: Eli Lilly and Co; May 2020

2. Menter A, Korman NJ, Elmets CA, , et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 4. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol. 2009 Sep; 61(3):451-85.
3. Menter A, Gottlieb A, Feldman SR, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol 2008 May; 58(5):826-50
4. Hsu S, Papp KA, Lebwohl MG et al. Consensus guidelines for the management of plaque psoriasis. Arch Dermatol. 2012 Jan; 148(1):95-102
5. Pariser DM, Bagel J, Gelfand JM et al. National psoriasis foundation clinical consensus on disease severity. Arch Dermatol. 2007 Feb; 143: 239-242.
6. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. Ann Rheum Dis 2015;0:1-12. doi:10.1136/annrheumdis-2015-208337
7. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. American College of Rheumatology. 2019; 71(1):5-32. doi: 10.1002/art.40726
8. Coates, L.C., Soriano, E.R., Corp, N. et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. Nat Rev Rheumatol 18, 465–479 (2022). https://doi.org/10.1038/s41584-022-00798-0
9. Ward MM, Deodhar A, Gensler LS, Dubreuil M, Yu D, Khan MA, Haroon N, Borenstein D, Wang R, Biehl A, Fang MA, Louie G, Majithia V, Ng B, Bigham R, Pianin M, Shah AA, Sullivan N, Turgunbaev M, Oristaglio J, Turner A, Maksymowych WP, Caplan L. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Care Res (Hoboken). 2019 Oct;71(10):1285-1299. doi: 10.1002/acr.24025. Epub 2019 Aug 21. PMID: 31436026; PMCID: PMC6764857.

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Prior Authorization Criteria for TALZENNA (talazoparib)

FDA Indications

- Treatment as a single agent for adult patients with deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutated (gBRCAm) human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer
- Treatment in combination with enzalutamide of adult patients with homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC)

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated duration of approval; added FDA approved age	5.2024

REFERENCE:

1. TALZENNA. [Prescribing Information]. New York, NY. Pfizer Laboratories: June 2023.

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Prior Authorization Criteria for TARCEVA (erlotinib)

FDA Indications

- Treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen
- In combination with gemcitabine for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer

1. Patient has an FDA approved diagnosis **AND**
2. Patient is 18 years of age or older **AND**
3. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated approval duration to 1 year	5.2024

REFERENCE:

1. Tarceva. [Prescribing Information]. Northbrook, IL. Genentech, Inc: December 2016.

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Prior Authorization Criteria for TARGRETIN® (bexarotene) Capsules or Gel

FDA-Approved Indications

- TARGRETIN Capsules: Treatment of cutaneous manifestations of cutaneous T-cell lymphoma (CTCL) in patients who are refractory to at least one prior systemic therapy
- TARGRETIN Gel: topical treatment of cutaneous lesions in patients with cutaneous T-cell lymphoma (CTCL) (Stage IA and IB) who have refractory or persistent disease after other therapies or who have not tolerated other therapies.

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
- ✓ Initial approval will be granted for a period of 1 year
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewals: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	3.2017
Update	Update Format/Add Denial Message	3.2020
Annual Review	No Change	3.2021
Annual Review	No Change	3.2022
Annual Review	Updated criteria to include an adequate trial of the generic capsules or gel unless contraindicated.	3.2023
Annual Review	Updated criteria to include oncology verbiage based package insert and NCCN guidelines, and updated format	3.2024
Update	Updated oncology template	7.2024

REFERENCE:

1. Targretin Gel [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; February 2020
2. Targretin prescribing information. Bausch Health US, LLC. Bridgewater, NJ. April 2020.
3. Breneman D, Duvic M, Kuzel T, Yocum R, Truglia J, Stevens VJ. Phase 1 and 2 trial of bexarotene gel for skin-directed treatment of patients with cutaneous T-cell lymphoma [published correction appears in Arch Dermatol. 2002;138(10):1386]. Arch Dermatol. 2002;138(3):325-332. doi:10.1001/archderm.138.3.325.[PubMed 11902983]
4. National Comprehensive Cancer Network. Primary Cutaneous Lymphomas (Version 1.2024). https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous_blocks.pdf. Accessed February 12, 2024.

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Prior Authorization Criteria for TARPEYO™ (budesonide delayed release)

1. Patient has a diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by biopsy **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: 16 mg orally once daily for 9 months **AND**
4. Quantity requested does not exceed: 120/30 days or 16 mg (four-4mg capsules) orally once daily **AND**
5. Patient has risk of disease progression with **ONE** of the following:
    a. Patient has urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g **OR**
    b. Patient has proteinuria (defined as either ≥1 g/day or UPCR ≥0.8 g/g)
6. Patient has an estimated glomerular filtration rate (eGFR) ≥ 35 mL/min/1.73 m^2 **AND**
7. Patient has had an adequate trial of at least 90 days of an ACE inhibitor or ARB (stable dose of maximally-tolerated RAS inhibitor therapy) **AND**
8. Prescribed by or in consultation with a specialist such as a nephrologist

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 9 months

RENEWALS

✓ May not be renewed

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 1.13.22	1.2022
Annual Review	Updated criteria to include patient has proteinuria and an estimated glomerular filtration rate (eGFR) ≥ 35 mL/min/1.73 m^2	1.2023
Annual Review	Updated initial approval duration to 9 months and removed renewal; added additional requirement to confirm diagnosis by biopsy; added 90 day duration of ACE-I or ARB	12.2023

REFERENCE:

1. Tarpeyo (budesonide) [prescribing information]. Stockholm Sweden: Colliditas Therapeutics AB; December 2021.
2. Wyatt RJ, Julian BA. IgA nephropathy. New England Journal of Medicine. 2013;368(25):2402–2414.
3. IgA nephropathy. National Kidney Foundation website. https://www.niddk.nih.gov/health-information/kidney-disease/iga-nephropathy
4. Yuzawa Y, Yamamoto R, Takahashi K, Katafuchi R, Tomita M, Fujigaki Y, Kitamura H, Goto M, Yasuda T, Sato M, Urushihara M, Kondo S, Kagami S, Yasuda Y, Komatsu H, Takahara M, Harabuchi Y, Kimura K, Matsuo S. Evidence-based clinical practice guidelines for IgA nephropathy 2014. Clin Exp Nephrol. 2016 Aug;20(4):511-535. doi: 10.1007/s10157-015-1223-y. PMID: 27095365; PMCID: PMC4956709.
5. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. Kidney Int. 2021 Oct;100(4S):S1-S276. Available at: https://kdigo.org/wp-content/uploads/2017/02/KDIGO-GlomerularDiseases-Guideline-2021-English.pdf. Accessed January 5, 2022.
6. Fellström BC, Barratt J, Cook H, et al. NEFIGAN Trial Investigators. Targeted-release budesonide versus placebo in patients with IgA nephropathy (NEFIGAN): a double-blind, randomised, placebocontrolled phase 2b trial. Lancet. 2017 May 27;389(10084):2117-2127.

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Prior Authorization Criteria for TASIGNA (nilotinib)

FDA Indications

- Treatment of adult and pediatric patients greater than or equal to 1 year of age with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase
- Treatment of adult patients with chronic phase and accelerated phase Philadelphia chromosome positive chronic myelogenous leukemia (Ph+ CML) resistant or intolerant to prior therapy that included imatinib
- Treatment of pediatric patients greater than or equal to 1 year of age with chronic phase and accelerated phase Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) with resistance or intolerance to prior tyrosine-kinase inhibitor (TKI) therapy

1. Patient has an FDA approved diagnosis **AND**
2. Patient is 1 year of age or older **AND**
3. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Annual Review	Updated duration to 1 year	5.2024

REFERENCE:

1. Tasigna [Prescribing Information] East Hanover, NJ: Novartis; February 2024.

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Prior Authorization Criteria for TAVALISSE® (fostamatinib)

1. Patient has diagnosis of chronic immune thrombocytopenia **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 100 mg twice daily. Titrate based off platelet count. **AND**
4. Quantity requested does not exceed: 60 tablets/ 30 days **AND**
5. Patient had insufficient response to previous treatment (e.g., corticosteroids, immunoglobulins, thrombopoietin receptor agonists, or splenectomy) **AND**
6. Patient has low baseline platelet counts (e.g., < 30 x 10^9/L) **AND**
7. Prescribed by or in consultation with a hematologist

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 6 months.

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided (e.g., increase in platelet count from baseline to a level sufficient to avoid clinically important bleeding)
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated criteria verbiage and included requirement to for low baseline platelet count	7.2024

REFERENCE:

1. TAVALISSE. [Prescribing Information]. San Francisco, CA. Rigel Pharmaceuticals: November 2020.

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Prior Authorization Criteria for TAZVERIK™ (tazemetostat)

FDA-APPROVED INDICATIONS

- Adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection.
- Adult patients with relapsed or refractory follicular lymphoma whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies.
- Adult patients with relapsed or refractory follicular lymphoma who have no satisfactory alternative treatment options.

1. Patient has an FDA approved diagnosis **AND**
2. Patient is:
    a. 18 years of age or older for relapsed or refractory follicular lymphoma **OR**
    b. 16 years of age or older for metastatic or locally advanced epithelioid sarcoma **AND**
3. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA Criteria created based on CAB 2.13.2020	2.2020
Annual Review	No Changes	2.2021
Updated	Update max dose for advanced epithelioid sarcoma.	7.2021
Updated	Updated expanded indications for relapsed or refractory follicular lymphoma; update max dose for advanced epithelioid sarcoma.	7.2022
Annual review	Updated format	2.2023
Annual review	Updated criteria to include FDA approved indications with general oncology verbiage and updated denial message	2.2024

REFERENCE:

1. Italiano A, Soria JC, Toulmonde M, et al. Tazemetostat, an EZH2 inhibitor, in relapsed or refractory B-cell non-Hodgkin lymphoma and advanced solid tumours: a first-in-human, open-label, phase 1 study. Lancet Oncol. 2018;19(5):649-659. doi: 10.1016/S1470-2045(18)30145-1[PubMed 29650362]
2. Stacchiotti S, Schoffski P, Jones R, et al. Safety and efficacy of tazemetostat, a first-in-class EZH2 inhibitor, in patients (pts) with epithelioid sarcoma (ES) (NCT02601950). J Clin Oncol. 2019;37(15s: 11003) [abstract 11003 from 2019 ASCO Annual Meeting].
3. Tazverik (tazemetostat) [prescribing information]. Cambridge, MA: Epizyme Inc; January 2020.

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Prior Authorization Criteria for TEGSEDI (inotersen)

1. Patient has a diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR-PN) confirmed by genetic testing **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: 284 mg (1.5 ml) administered by subcutaneous injection once weekly **AND**
4. Quantity requested does not exceed: 6 ml (four-284 mg vials)/28 days **AND**
5. Patient is currently experiencing signs and symptoms of polyneuropathy including peripheral or autonomic caused by hATTR amyloidosis **AND**
6. Patient does **not** have any of the labeled contraindications:
    a. Platelet count less than 100 x 10^9 /L **OR**
    b. History of acute glomerulonephritis caused by TEGSEDI **AND**
7. Patient does not have severe renal impairment, end-stage renal disease, moderate or severe hepatic impairment, or prior liver transplant **AND**
8. Patient is not taking therapy concomitantly with a TTR-lowering agent (e.g., Amvuttra, Onpattro, or Wainua) or a TTR-stabilizing agent, including diflunisal, Vyndaqel, and Vyndamax **AND**
9. Prescribed by or in consultation with a specialist such as a neurologist.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Documentation of clinical response to therapy, such as an improvement, stabilization, or slowing of progression of hATTR-PN manifestations.
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated criteria verbiage to align with drug class, added labeled contraindications, and updated denial message	2.2024

REFERENCE:

1. Carroll A, Dyck PJ, de Carvalho M, et alNovel approaches to diagnosis and management of hereditary transthyretin amyloidosisJournal of Neurology, Neurosurgery & Psychiatry 2022;93:668-678.
2. Hawkins PN, et al. Evolving landscape in the management of transthyretin amyloidosis. Ann Med. 2015;47(8):625–638. doi:10.3109/07853890.2015.1068949
3. Adams D, et al. HELIOS-A: results from the Phase 3 study of vutrisiran in patients with hereditary transthyretin-mediated amyloidosis with polyneuropathy. Presented at: the 2022 AAN Annual Meeting; April 2–7, 2022; Seattle, Washington; April 24-26, 2022; Virtual Meeting. Abstract S8.003.
4. Alcantara M, Mezi MM, Baker SK, et al. Canadian guidelines for hereditary transthyretin amyloidosis polyneuropathy management. Can J Nero Sci. 2022;49:7-18
5. Berk JL, et al. Repurposing diflunisal for familial amyloid polyneuropathy: a randomized clinical trial. JAMA. 2013;310(24):2658–2667. doi:10.1001/jama.2013.283815
6. Dyck PJB, et al. Development of measures of polyneuropathy impairment in hATTR amyloidosis: From NIS to mNIS + 7. J Neurol Sci. 2019;405:116424. doi:10.1016/j.jns.2019.116424
7. Luigetti M, Romano A, Di Paolantonio A, Bisogni G, Sabatelli M. Diagnosis and Treatment of Hereditary Transthyretin Amyloidosis (hATTR) Polyneuropathy: Current Perspectives on Improving Patient Care. Ther Clin Risk Manag. 2020 Feb 21;16:109-123. doi: 10.2147/TCRM.S219979. PMID: 32110029; PMCID: PMC7041433.
8. Tegsedi (inotersen) [prescribing information]. Waltham, MA: Sobi Inc; June 2022.
9. Tegsedi (inotersen) [product monograph]. Newmarket, Ontario, Canada: Progress Therapeutics Inc; March 2022.

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Prior Authorization Criteria for TEMODAR (temozolomide oral)

FDA Indications

- Treatment of adult patients with newly diagnosed glioblastoma multiforme concomitantly with radiotherapy and then as maintenance treatment
- Adjuvant treatment of adult patients with newly diagnosed anaplastic astrocytoma
- Treatment of adult patients with refractory anaplastic astrocytoma, i.e., patients who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Update	Updated duration of approval; added FDA approved dx and age	5.2024
Annual Review	Updated indication of newly diagnosed anaplastic astrocytoma; Updated references	7.2024

REFERENCE:

1. Temozolomide. [Prescribing Information]. Durham, NC Accord Healthcare: September 2023.

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Prior Authorization Criteria for TEZSPIRE™ (tezepelumab-ekko)

1. Patient has a diagnosis of severe asthma **AND**
2. Patient is 12 years of age or older **AND**
3. Dosage and Direction for Use: 210 mg administered once every 4 weeks by subcutaneous injection by a healthcare provider **AND**
4. Quantity requested does not exceed: one pre-filled syringe or single-dose vial (210 mg)/28 days **AND**
5. Patient has been adherent to the use of controller therapy (i.e., medium- to high-dose inhaled corticosteroid (e.g. Flovent, Pulmicort, Qvar) plus either a long-acting beta2 agonist (e.g. Serevent) or leukotriene modifier (e.g. Singulair, Accolate) **AND**
6. Patient experienced ≥ 2 exacerbations within the last 12 months despite adherent use of optimized doses of therapy requiring any of the following:
    a. Oral/systemic corticosteroid treatment (or increase in dose if already on oral corticosteroid)
    b. Urgent care visit or hospital admission
    c. Intubation **AND**
7. Patient is not receiving Tezspire in combination with another biologic medication indicated for asthma treatment **AND**
8. Patient will continue to use maintenance asthma treatments **AND**
9. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Patient is responding positively to treatment
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 1.27.2022	1.2022
Annual review	No Changes	1.2023
Annual review	Added immunologist to provider type; updated wording to align with other biologic medications for severe asthma; added patient is responding positively to treatment to renewal criteria	1.2024

REFERENCE:

1. Tezspire (tezepelumab) [prescribing information]. Thousand Oaks, CA: Amgen, Inc; May 2023.
2. Asthma and Allergy Foundation of America. Asthma facts and figures. Updated April 2021. Accessed January 21, 2022. https://www.aafa.org/asthma-facts/
3. 2021 GINA Report, Global Strategy for Asthma Management and Prevention. Updated 2021, Acccessed 1/13/22
4. Mann,M, Meyer, RJ. Drug Development for Asthma and COPD: A Regulatory Perspective. Respiratory Care, Jun 2018, 63 (6) 797 – 817; DOI: 10.4187/respcare.06009
5. TEZSPIRE® (tezepelumab-ekko) [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2021. Accessed 1/13/22
6. West, Erin E et al. "TSLP: A Key Regulator of Asthma Pathogenesis." Drug discovery today. Disease mechanisms vol. 9,3-4 (2012): 10.1016/j.ddmec.2012.09.003. doi:10.1016/j.ddmec.2012.09.003
7. Menzies-Gow A, et al. Tezepelumab in adults and adolescents with severe, uncontrolled asthma. N Engl J Med. 2021;384(19):1800-1809. doi:10.1056/NEJMoa2034975
8. Tran TN, et al. Overlap of atopic, eosinophilic, and TH2-high asthma phenotypes in a general population with current asthma. Ann Allergy Asthma Immunol. 2016;116(1):37–42. doi:10.1016/j.anai.2015.10.027

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Prior Authorization Criteria for THALOMID (thalidomide)

FDA Indications

- Treatment of patients with newly diagnosed multiple myeloma (MM), in combination with dexamethasone
- Acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL)
- Maintenance treatment for prevention and suppression of the cutaneous manifestations of ENL recurrence

Diagnosis: Multiple Myeloma

1. Patient has a diagnosis of multiple myeloma **AND**
2. Patient is 18 years of age or older **AND**
3. Requested medication is being used in combination with dexamethasone **AND**
4. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
5. Prescribed by or in consultation with an oncologist

Diagnosis: Erythema nodosum leprosum

1. Patient has a diagnosis of moderate to severe erythema nodosum leprosum **AND**
2. Patient is 12 years of age or older **AND**
3. One of the following:
    a. Requested medication is being used for acute treatment **OR**
    b. Requested medication is being used as maintenance therapy for prevention and suppression of cutaneous manifestations of ENL recurrence **AND**
4. Prescribed by or in consultation with an infectious disease specialist

INITIAL APPROVALS

- ✓ For cancer diagnosis: confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year.

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated duration of approval to 1 year	4.2024

REFERENCE:

1. Thalomid (thalidomide). [Prescribing Information]. Princeton, NJ: Celgene Corporation. March 2023.

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Prior Authorization Criteria for THIOLA EC®, THIOLA® (tiopronin)

1. Patient has diagnosis of severe homozygous cystinuria **AND**
2. Dosage and direction of use:
    a. Adults: 800 mg/day in 3 divided doses
    b. Pediatrics: 15 mg/kg/day in 3 divided doses **AND**
3. Quantity requested does not exceed:
    a. Adults: max 1000 mg/day
    b. Pediatrics: 50 mg/kg/day **AND**
4. Patient weighs 20 kg or greater **AND**
5. Patient has had an inadequate response to high fluid intake, alkali, and diet modification **AND**
6. Prescribed by or in consultation with an nephrologist, urologist, or physician that specializes in the treatment of cystinuria

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 12 months.

RENEWALS

✓ Documentation of positive clinical response to therapy has been provided
✓ Approval duration for renewal: 12 months.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Annual Review	No changes	5.2024

REFERENCE:

1. Thiola EC (tiopronin DR) [prescribing information]. San Diego, CA: Mission Pharmacal Company; March 2021.
2. Thiola (tiopronin) [prescribing information]. San Diego, CA: Mission Pharmacal Company; June 2019.

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Prior Authorization Criteria for TIBSOVO (ivosidenib)

FDA-Approved Indications

- Treatment of newly-diagnosed acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test in adult patients who are ≥ 75 years old or who have comorbidities that preclude use of intensive induction chemotherapy
- Treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated duration of approval; added FDA approved dx and age	5.2024

REFERENCE:

1. TIBSOVO. [Prescribing Information]. Cambridge, MA. Agios Pharmaceuticals, Inc: May 2022.

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Prior Authorization Criteria for TREMFYA® (guselkumab)

FDA-APPROVED INDICATIONS

- Psoriatic arthritis (PsA): Adults with active psoriatic arthritis
- Plaque psoriasis (PP): Adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy

Diagnosis: Plaque Psoriasis

1. Patient has diagnosis of moderate to severe chronic plaque psoriasis (PP) **AND**
2. PP is affecting more than 3% of body surface area (BSA) or affecting crucial body areas (e.g., hands, feet, face, or genitals) **AND**
3. Patient is 18 years of age or older **AND**
4. Dosage and direction of use: administered 100 mg subcutaneously at Week 0, Week 4 and every 8 weeks thereafter **AND**
5. Quantity requested does not exceed: Initial dose: 1 injection (1 mL)/28 days (may vary depending on dosing schedule); maintenance dose: 1 injection (1 mL)/56 days **AND**
6. Patient has had an adequate trial and failure of UV or systemic therapy (i.e., methotrexate, acitretin, cyclosporine) **AND**
7. Patient has had an adequate trial and failure to topical therapy (i.e., corticosteroids, calcipotriene, calcitriol, tazarotene, tacrolimus) **AND**
8. Patient is not receiving requested medication in combination with other biologic DMARDs **AND**
9. Prescribed by or in consultation with a dermatologist

Diagnosis: Psoriatic Arthritis

1. Patient has diagnosis of psoriatic arthritis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: administered 100 mg subcutaneously at Week 0, Week 4 and every 8 weeks thereafter **AND**
4. Quantity requested does not exceed: Initial dose: 1 injection (1 mL)/28 days (may vary depending on dosing schedule); maintenance dose: 1 injection (1 mL)/56 days **AND**
5. Patient has had an inadequate response or has contraindications to at least one non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide) **AND**
6. Patient is not receiving requested medication in combination with other biologic **AND**
7. Prescribed by or in consultation with a rheumatologist

INITIAL APPROVALS

- ✓ Prescriber attestation that labs/notes indicate patient has the disease or requires the medication
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive clinical response to Tremfya therapy has been provided **AND**
- ✓ Patient is not receiving Tremfya in combination with other biologic DMARDs **AND**
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2018
Revised	Formatted to new template	9.2019
Updated	Added default denial message	12.2019
Reviewed	Under Jan' 2020 CAB meeting, no change	1.2020
Updated	Added indication for Psoriatic Arthritis and updated information based on CAB 11.2020	12.2020
Updated	Annual Review: No Change	12.2021
Updated	Annual Review: for PsA and AS, update t/f criteria to include non-steroidal anti-inflammatory drugs (NSAIDs) or non-biologic disease-modifying antirheumatic drug (DMARDs) such as methotrexate or leflunomide. Update DMARDs abbreviation and also denial message	3.2022
Updated	Removed TB test exclusion criteria; Updated references; Removed PDE4 exclusion based on package insert Plaque psoriasis: Updated BSA to 3% per guidelines; separated out t/f criteria PsA: Removed t/f of NSAID option based on guidelines	6.2023
Updated	Updated format and removed "completed by" in history section.	8.2023
Annual review	Updated quantity exceeds limits; updated references	6.2024/9.2024

REFERENCE:

1. Tremfya [package insert]. Horsham, PA: Janssen Biotech Inc.; November 2023.
2. Nakamura M, Lee K, Jeon C, et al. Guselkumab for the Treatment of Psoriasis: A Review of Phase III Trials. Dermatol Ther (Heidelb). 2017 Jun 21. Doi: 10.1007/s13555-017-0187-0.
3. Langley RG, Tsai TF, Flavin S, et al. Efficacy and safety of guselkumab in patients with psoriasis who have an inadequate response to ustekinumab: Results of the randomized, double-blind, Phase 3 NAVIGATE trial. Br J Dermatol. 2017 Jun 21. Doi: 10.1111/bjd.15750.
4. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol 2008; 58(5):826-50.
5. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Psoriatic arthritis: Overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol 2008;58(5):851-64.
6. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. J Am Acad Dermatol 2009;60(4):643-59.
7. American Academy of Dermatology Work Group, Menter A, Korman NJ, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol 2011; 65:137.

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Prior Authorization Criteria for tretinoin oral

FDA-Approved Indications

- Remission in patients with acute promyelocytic leukemia (APL), French-American-British (FAB) classification M3 (including the M3 variant), characterized by the presence of the t(15;17) translocation and/or the presence of the PML/RARα gene who are refractory to, or who have relapsed from, anthracycline chemotherapy, or for whom anthracycline-based chemotherapy is contraindicated. Tretinoin capsules are for the induction of remission only

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist.

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Annual Review	Updated to oncology drug format; updated duration of approval	5.2024

REFERENCE:

1. Tretinoin [Prescribing Information] Mahwah, NJ: Glenmark Pharmaceuticals Inc.; April 2023.

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Prior Authorization Criteria for TRUXIMA® (rituximab-abbs)

Indications:

- Rheumatoid Arthritis (RA)
  - In combination with methotrexate, is indicated for the treatment of adult patients with moderately- to severely-active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies
- Granulomatosis Polyangiitis (GPA) (Wegener's granulomatosis) or Microscopic Polyangiitis (MPA)
  - In combination with glucocorticoids, is indicated for the treatment of adult patients with Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA)
- Non-Hodgkin's Lymphomas (NHL)
  - Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL as a single agent.
  - Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy.
  - Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy.
  - Previously untreated diffuse large B-cell, CD20-positive NHL in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy regimens
- Chronic lymphocytic leukemia (CLL)
  - In combination with fludarabine and cyclophosphamide (FC), for the treatment of adult patients with previously untreated and previously treated CD20-positive CLL

Diagnosis: Rheumatoid Arthritis (RS)

1. Patient has diagnosis of moderate to severe rheumatoid arthritis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: Administered in combination with methotrexate is two-1000 mg intravenous infusions separated by 2 weeks (one course) every 24 weeks or based on clinical evaluation, but not sooner than every 16 weeks. **AND**
4. Quantity requested does not exceed: Dose is within the approved dose recommended by the FDA or dose is supported by compendia or medical literature **AND**
5. Patient has had an inadequate response or has contraindications to methotrexate or at least one conventional DMARD therapy **AND**
6. Patient has had an inadequate response or has contraindications to a preferred TNF antagonist agent **AND**
7. Rituxan will be administered in combination with methotrexate unless contraindicated or clinically significant adverse effects **AND**
8. Patient is not receiving medication in combination with other biologic DMARDs **AND**
9. Prescribed by or in consultation with a specialist such as a Rheumatologist.

Diagnosis: Granulomatosis Polyangiitis (GPA) (Wegener's granulomatosis) or Microscopic Polyangiitis (MPA)

1. Patient has diagnosis of Wegener's Granulomatosis or Microscopic Polyangiitis **AND**
2. Patients age is 18 years of age and older **AND**
3. Dosage and Direction for Use: The induction dose in combination with glucocorticoids is 375 mg/m2 once weekly for 4 weeks. The follow up dose for patients who have achieved disease control with induction treatment, in combination with glucocorticoids is two 500 mg intravenous infusions separated by two weeks, followed by a 500 mg intravenous infusion every 6 months thereafter based on clinical evaluation **AND**
4. Quantity requested does not exceed: Dose is within the approved dose recommended by the FDA or dose is supported by compendia or medical literature **AND**

5. Patient had an inadequate response, contraindication, or intolerance to glucocorticoids **AND**
6. Prescribed by a specialist such as a Dermatologist.

Diagnosis: Non-Hodgkin's Lymphoma (NHL)

1. Patient has diagnosis of any of the following Non-Hodgkin's lymphoma (NHL):
   a. Relapsed or refractory, low grade or follicular, CD20-positive B-cell as a single agent for adults
   b. Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy for adults.
   c. Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy.
   d. Previously untreated diffuse large B-cell, CD20-positive NHL in combination with (cyclophosphamide, doxorubicin, vincristine, and prednisone) (CHOP) or other anthracycline-based chemotherapy regimens for adults
2. Patient 18 years of age or older **AND**
3. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an Oncologist.

Diagnosis: Chronic lymphocytic leukemia (CLL)

1. Patient has diagnosis of Chronic Lymphocytic Leukemia **AND**
2. Age 18 years of age and older **AND**
3. Dosage and Direction for Use: 375 mg/m2 in the first cycle and 500 mg/m2 in cycles 2–6, in combination with FC, administered every 28 days **AND**
4. Quantity requested does not exceed: 500 mg/m2. Dose is within the approved dose recommended by the FDA or dose is supported by compendia or medical literature **AND**
5. Patient is taking drug regimen in combination with fludarabine and cyclophosphamide
6. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
7. Prescribed by or in consultation with a specialist such as an Oncologist.

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial approval will be granted for a period of 6 months

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ For oncology indications: Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	4.2019
Updated	Added Truxima to the Rituxan criteria Added Chronic lymphocytic leukemia diagnosis Added Default Denial Messages	2.2020
Updated	Added Riabni to criteria based off CAB 1.14.21	1.2021
Reviewed	Annual Review: No Change	4.2022
Updated	Update criteria to include: previously untreated, advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL) for patients 6 months and older for Rituxan. Updated indication for Ruxience and Riabni to include RA.	10.2022
Updated	Created separate criteria for all biosimilars; updated format; added no concomitant biologics for RA diagnosis; added renewal criteria	9.2023

REFERENCE:

1. Truxima (rituximab) [product monograph]. Toronto, Ontario, Canada: Teva Canada Limited; July 2019.
2. National Comprehensive Cancer Network. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed October 17, 2022.
3. Singh JA, Furst DE, Bharat A, et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. Arthritis Care Res. 2012; 64(5): 625-639.
4. National Comprehensive Cancer Network. B-Cell Lymphomas Version 5.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell_blocks.pdf. Accessed October 17, 2022.
5. Anderson J, Caplan L, Yazdany J, et al. Rheumatoid arthritis disease activity measures: American College of Rheumatology recommendations for use in clinical practice. Arthritis Care Res (Hoboken). 2012 May; 64(5): 640–647. doi:10.1002/acr.21649.
6. Neunert C, Lim W, Crowther M, et al. The American Society of Hematology 2011 evidencebased practice guideline for immune thrombocytopenia. Blood. April 2011; 117(16): 4190-4207.
7. Joly P, Maho-Vaillant M, Prost-Squarcioni C, et.al. First-line rituximab combined with shortterm prednisone versus prednisone alone for the treatment of pemphigus (Ritux 3): a prospective, multicenter, parallel-group, open-label randomized trial. Lancet. 2017; 389: 2031–40.

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Prior Authorization Criteria for TUKYSA® (tucatinib)

FDA-Approved Indications

- In combination with trastuzumab and capecitabine for treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting.
- In combination with trastuzumab for the treatment of adult patients with RAS wild-type HER2-positive unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.

1. Patient has an FDA approved diagnosis **AND**
2. Patient is 18 years of age or older **AND**
3. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
- ✓ Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided with current chart notes, and other pertinent information to demonstrate patient has experienced a positive response with therapy.
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 5.7.2020	5.2020
Annual Review	No change	5.2021
Annual Review	No change	5.2022
Annual Review	Added expanded indication of colorectal cancer; Updated denial message.	5.2023
Annual Review	Updated approval duration to 1 year; update to oncology drug format	4.2024

REFERENCE:

1. Murthy RK, Loi S, Okines A, et al. Tucatinib, trastuzumab, and capecitabine for HER2-positive metastatic breast cancer [published correction appears in N Engl J Med. 2020;382(6):586]. N Engl J Med. 2020;382(7):597-609. doi:10.1056/NEJMoa1914609[PubMed 31825569]
2. Tukysa (tucatinib) [prescribing information]. Bothell, WA: Seattle Genetics Inc; January 2023.
3. National Comprehensive Cancer Network. Breast Cancer (Version 4.2023). https://www.nccn.org/professionals/physician_gls/pdf/breast_blocks.pdf. Accessed June 28, 2023.
4. National Comprehensive Cancer Network. Colon Cancer (Version 2.2023). https://www.nccn.org/professionals/physician_gls/pdf/colon_blocks.pdf. Accessed June 28, 2023.

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Prior Authorization Criteria for TURALIO™ (pexidartinib)

1. Patient has diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) **AND**
2. Patient is 18 years and older **AND**
3. Dosage and direction of use: 500 mg (two-250mg capsules) orally twice daily **AND**
4. Quantity requested does not exceed: 4 capsules/day (112/28) **AND**
5. Confirm that the disease is associated with severe morbidity or functional limitations and not amenable to improvement with surgery **AND**
6. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
7. Prescribed by or in consultation with an oncologist.

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year.

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy documented by current chart notes
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2019
Update	Add Denial Message	2.2020
Annual Review	No Change	8.2020
Annual Review	No Change	8.2021
Annual Review	No Change	8.2022
Annual Review	Updated dosage recommendation and criteria; Updated denial message	8.2023
Annual Review	Updated approval duration; updated dosing instructions; added requirement to follow appropriate sequence of therapy	2.2024

REFERENCE:

1. Turalio (pexidartinib) [prescribing information]. Basking Ridge, NJ: Daiichi Sankyo Inc; November 2023..
2. National Comprehensive Cancer Network. Soft Tissue Sarcoma (Version 2.2023). https://www.nccn.org/professionals/physician_gls/pdf/sarcoma_blocks.pdf. Accessed August 8, 2023.

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Prior Authorization Criteria for TYENNE® SC (tocilizumab-aazg)

FDA-APPROVED INDICATIONS

- Rheumatoid arthritis (RA): Treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs)
- Giant cell arteritis (GCA): Treatment of giant cell arteritis in adult patients
- Polyarticular juvenile idiopathic arthritis (pJIA): Treatment of active polyarticular juvenile idiopathic arthritis in patients ≥2 years of age
- Systemic juvenile idiopathic arthritis (SJIA): Treatment of active systemic juvenile idiopathic arthritis in patients ≥2 years of age

Diagnosis: for Rheumatoid Arthritis (RA)

1. Patient has diagnosis of moderate to severe Rheumatoid Arthritis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use:
    - <100 kg: 162 mg once every other week; increase to 162 mg once every week based on clinical response
    - ≥100 kg: 162 mg once every week **AND**
4. Quantity requested does not exceed: 4 injections (162mg per pen or syringe)/month **AND**
5. Patient has had an inadequate response or has contraindications to at least one non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide) **AND**
6. Patient's weight is provided **AND**
7. Patient has failed to achieve symptom control after adequate therapy with, or has labeled contraindications to Adalimumab* (documentation required) **AND**
8. Patient is not receiving Tyenne in combination with other biologic DMARDs **AND**
9. For non-preferred tocilizumab formulations, patient has had an adequate trial of ALL preferred tocilizumab formulations **AND**
10. Prescribed by or in consultation with a rheumatologist.

Diagnosis: for Polyarticular Juvenile Idiopathic Arthritis (pJIA)

1. Patient has diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis **AND**
2. Patient is 2 years of age or older **AND**
3. Dosage and direction of use:
    - <30 kg: 162 mg/dose once every 3 weeks
    - ≥30 kg: 162 mg/dose once every 2 weeks **AND**
4. Quantity requested does not exceed: 2 injections (162mg per pen or syringe)/month (may vary depending on dosing schedule) **AND**
5. Patient's weight is provided **AND**
6. Patient has had an inadequate response or has labeled contraindications to non-biologic DMARDs (e.g., methotrexate, leflunomide)
7. Patient has failed to achieve symptom control after adequate treatment with, or has labeled contraindications to Adalimumab* (documentation required) **AND**
8. Patients is not receiving Tyenne in combination with other biologic DMARDs **AND**
9. For non-preferred tocilizumab formulations, patient has had an adequate trial of ALL preferred tocilizumab formulations **AND**
10. Prescribed by or in consultation with a rheumatologist

Diagnosis: for Systemic Juvenile Idiopathic Arthritis (sJIA)

1. Patient has diagnosis of systemic juvenile idiopathic arthritis **AND**
2. Patient is 2 years of age or older **AND**
3. Dosage and direction of use:
    - <30 kg: 162 mg/dose once every 2 weeks
    - ≥30 kg: 162 mg/dose once every week **AND**
4. Quantity requested does not exceed: Optimize dose based on weight **AND**
5. Patient's weight is provided **AND**
6. Patient has failed to achieve symptom control after adequate treatment with, or has labeled contraindications to Adalimumab* (documentation required) **AND**
7. Patients is not receiving Tyenne in combination with other biologic DMARDs **AND**
8. For non-preferred tocilizumab formulations, patient has had an adequate trial of ALL preferred tocilizumab formulations **AND**

9. Prescribed by or in consultation with a rheumatologist

Diagnosis: for Giant Cell Arteritis

1. Patient has diagnosis of Giant Cell Arteritis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 162 mg subcutaneously every week
4. Quantity requested does not exceed: 4 injections (162mg per pen or syringe)/month **AND**
5. Patient has had an adequate trial and failure of or contraindication to a systemic glucocorticoid **AND**
6. Patients is not receiving Tyenne in combination with other biologic DMARDs **AND**
7. For non-preferred tocilizumab formulations, patient has had an adequate trial of ALL preferred tocilizumab formulations **AND**
8. Prescribed by or in consultation with a rheumatologist.

INITIAL APPROVALS

- ✓ *Please review formulary for current preferred adalimumab products. The trial of more than one preferred adalimumab product counts as one preferred product
- ✓ Prescriber attestation that labs/notes indicate patient has the disease or requires the medication
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided (e.g., improvement in symptoms, decrease in joint swelling and tenderness, etc.) **AND**
- ✓ Patient is not receiving medication in combination with other biologic DMARDs **AND**
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 7.11.24	7.2024

REFERENCE:

1. Tyenne (tocilizumab) [prescribing information]. Lake Zurich, IL: Kabi USA, LLC; March 2024.
2. Singh JA, Saag KG, Bridges SL, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Rheumatology 2016. 68(1):1-26.
3. Quartier P. Systemic Juvenile Idiopathic Arthritis/Pediatric Still's Disease, a Syndrome but Several Clinical Forms: Recent Therapeutic Approaches. J Clin Med. 2022 Mar 1;11(5):1357. doi: 10.3390/jcm11051357. PMID: 35268449; PMCID: PMC8911482.
4. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Recommendations for Nonpharmacologic Therapies, Medication Monitoring, Immunizations, and Imaging. Arthritis Care Res (Hoboken). 2022 Apr;74(4):505-520. doi: 10.1002/acr.24839. Epub 2022 Mar 1. PMID: 35233989; PMCID: PMC10231687.
5. Maz M, Chung SA, Abril A, Langford CA, Gorelik M, Guyatt G, Archer AM, Conn DL, Full KA, Grayson PC, Ibarra MF, Imundo LF, Kim S, Merkel PA, Rhee RL, Seo P, Stone JH, Sule S, Sundel RP, Vitobaldi OI, Warner A, Byram K, Dua AB, Husainat N, James KE, Kalot MA, Lin YC, Springer JM, Turgunbaev M, Villa-Forte A, Turner AS, Mustafa RA. 2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Giant Cell Arteritis and Takayasu Arteritis. Arthritis Rheumatol. 2021 Aug;73(8):1349-1365. doi: 10.1002/art.41774. Epub 2021 Jul 8. PMID: 34235884.

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Prior Authorization Criteria for TYKERB® (lapatinib ditosylate)

INDICATIONS

- Indicated in combination with capecitabine for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress human epidermal growth factor receptor 2 (HER2) and who have received prior therapy including an anthracycline, a taxane, and trastuzumab.
- Indicated in combination with letrozole for the treatment of postmenopausal women with hormone (HR) receptor positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated.

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist.

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
- ✓ Initial approval will be granted for a period of 1 year
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created from CAB 10.22.2020	10.2020
Annual Review	No change	10.2021
Annual Review	No change	10.2022
Annual Review	Added brand name may be subject to formulary exclusions; added renewal criteria	10.2023
Update	Updated to oncology drug format; updated duration of approval	5.2024
Annual Review	No Change	9.2024

REFERENCE:

1. Tykerb (lapatinib) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2022.
2. Baselga J, Bradbury I, Eidtmann H, et al, "Lapatinib With Trastuzumab for HER2-Positive Early Breast Cancer (NeoALTTO): A Randomised, Open-Label, Multicentre, Phase 3 Trial," Lancet, 2012, 379(9816):633-40.
3. Giordano SH, Temin S, Chandarlapaty S, et al. Systemic therapy for patients with advanced human epidermal growth factor receptor 2-positive breast cancer: ASCO clinical practice guideline update. J Clin Oncol. 2018;36(26):2736-2740. doi:10.1200/JCO.2018.79.2697[PubMed 29939838]
4. National Comprehensive Cancer Network. Brest Cancer (Version 4.2022). https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf Accessed October 12, 2022.

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Prior Authorization Criteria for TYMLOS® (abaloparatide)

FDA-APPROVED INDICATIONS

- Treatment of postmenopausal women with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy
- Treatment to increase bone density in men with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy

1. Patient has diagnosis of osteoporosis **AND**
2. Patient is:
    a. Postmenopausal Women: 49 years of age or older
    b. Men: 42 years of age or older
3. Dosage and direction of use: 80 mcg subcutaneously once daily **AND**
4. Quantity requested does not exceed: 1 pen (3,120 mcg/1.56mL) per 30 days (max 2 years per lifetime) **AND**
5. Patient is postmenopausal if female **AND**
6. Patient has one of the following:
    a. A BMD t-score <-2.5 (DXA) at the hip, lumbar spine, femoral neck, or distal third of radius **OR**
    b. History of fragility fracture, including incidental or asymptomatic vertebral fracture **OR**
    c. A BMD t-score between -1.0 and -2.5 at the lumbar spine, femoral neck, total hip AND physician attestation that the patient is at high risk for fracture **AND**
7. Patient has tried and failed, is intolerant of, or has a medical contraindication to bisphosphonates (i.e., alendronate, ibandronate) **AND**
8. Patient has not received a cumulative therapy on PTH analogs (i.e., Tymlos, Forteo) that exceeds 2 years **AND**
9. Patient does not have pre-existing hypercalcemia or have underlying hypercalcemic disorders such as primary hyperparathyroidism **AND**
10. Patient does not have risk for osteosarcoma

INITIAL APPROVALS

✓ Initial authorization will be for a period of 1 year

RENEWALS

✓ The renewal period will be for a period of up to 1 year
✓ No more than 2 years of therapy per lifetime will be approved

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	3.2018
Annual review	Update Format/Add Denial Message	3.2020
Annual review	Update formatting: correct spelling	3.2021
Annual review	No Change	3.2022
Annual review	Updated criteria to include new indication: Osteoporosis treatment to increase bone density in men, updated diagnosis criteria, removed t/f option for Evista, HRT or miacalcin, and updated denial message	3.2023
Update	Updated format	9.2023
Annual Review	No Changes	9.2024

REFERENCE:

1. Miller PD, Hattersley G, Riis BJ et al. Effect of abaloparatide vs placebo on new vertebral fractures in postmenopausal women with osteoporosis. JAMA 2016: 316 (7):722-733.
2. Rosen CJ. Clinical practice. Postmenopausal osteoporosis. N Engl J Med 2005; 353:595.
3. Eastell R, Rosen CJ, Black DM, Cheung AM, Murad MH, Shoback D. Pharmacological management of osteoporosis in postmenopausal women: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2019;104(5):1595-1622. doi: 10.1210/jc.2019-00221Tymlos (abaloparatide) [prescribing information]. Waltham, MA: Radius Health; October 2018.
4. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis–2016: executive summary [published correction appears in Endocr Pract. 2017;23(3):383]. Endocr Pract. 2016;22(9):1111-1118. doi: 10.4158/EP161435.ESGL.
5. Rosen HN, Drezner MK. Overview of the management of osteoporosis in postmenopausal women. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed November 4, 2021.
6. Tymlos (abaloparatide) [prescribing information]. Boston, MA: Radius Health Inc; December 2022.
7. ACOG Committee on Clinical Practice Guidelines–Gynecology. Management of Postmenopausal Osteoporosis: ACOG Clinical Practice Guideline No. 2. Obstet Gynecol. 2022 Apr 1;139(4):698-717. doi: 10.1097/AOG.0000000000004730. Erratum in: Obstet Gynecol. 2022 Jul 1;140(1):138. PMID: 35594133.
8. Qaseem A, Hicks LA, Etxeandia-Ikobaltzeta I, Shamliyan T, Cooney TG; Clinical Guidelines Committee of the American College of Physicians; Cross JT Jr, Fitterman N, Lin JS, Maroto M, Obley AJ, Tice JA, Tufte JE. Pharmacologic Treatment of Primary Osteoporosis or Low Bone Mass to Prevent Fractures in Adults: A Living Clinical Guideline From the American College of Physicians. Ann Intern Med. 2023 Feb;176(2):224-238. doi: 10.7326/M22-1034. Epub 2023 Jan 3. Erratum in: Ann Intern Med. 2023 Jun;176(6):882-884. PMID: 36592456.

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Prior Authorization Criteria for UKONIQ® (umbralisib tosylate)

FDA-Approved Indications

- Treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen (i.e., ritxuximab)
- Treatment of adult patients with relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of systemic therapy (i.e., CHOP + rituximab, ritxuximab, Gazyva)

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist.

INITIAL APPROVAL

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
- ✓ Initial approval duration will be granted for a period of 1 year

RENEWAL

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 2.25.2021	3.2021
Annual Review	No change	3.2022
Annual Review	No change	3.2023
Annual Review	Updated criteria to include FDA-approved indications based on package insert, updated denial message, and updated format.	2.2024
Update	Updated oncology template verbiage	8.2024

REFERENCE:

1. Hwang JP, Feld JJ, Hammond SP, et al. Hepatitis B virus screening and management for patients with cancer prior to therapy: ASCO provisional clinical opinion update. *J Clin Oncol*. 2020;38(31):3698-3715. doi:10.1200/JCO.20.01757[PubMed 32716741]
2. Ukoniq (umbralisib) [prescribing information]. Edison, NJ: TG Therapeutics Inc; February 2021.
3. US Department of Health and Human Services; Centers for Disease Control and Prevention; National Institute for Occupational Safety and Health. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings 2016. https://www.cdc.gov/niosh/docs/2016-161/. Updated September 2016. Accessed February 6, 2021.
4. Zinzani PL, Samaniego F, Jurczak W, et al. Umbralisib, the once daily dual inhibitor of PI3Kδ and casein kinase-1ε demonstrates clinical activity in patients with relapsed or refractory indolent non-Hodgkin lymphoma: results from the phase 2 global unity-NHL trial. https://ash.confex.com/ash/2020/webprogram/Paper134851.html. Updated December 7, 2020. Accessed February 6, 2020.
5. National Comprehensive Cancer Network. B-Cell Lymphomas (Version 1.2024). https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed February 5, 2024.

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Prior Authorization Criteria for VALCHLOR (mechlorethamine hcl)

FDA-Approved Indications

- Topical treatment of Stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma in patients who have received prior skin-directed therapy

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist.

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year.

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated to oncology template; updated duration of approval	7.2024

REFERENCE:

1. VALCHLOR. [Prescribing Information]. Iselin, NJ. Helsinn Therapeutics, Inc: January 2020.

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Prior Authorization Criteria for VARUBI® (rolapitant)

1. Patient has symptoms of nausea and vomiting associated with chemotherapy **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 180 mg within 2 hours prior to initiation of chemotherapy **AND**
4. Quantity requested does not exceed: 2 tablets per chemotherapy treatment **AND**
5. Patient is undergoing highly emetogenic chemotherapy for cancer **AND**
6. Patient is using Varubi in combination with a 5-HT3 receptor agonist (e.g., ondansetron, granisetron, palonosetron) and a corticosteroid (dexamethasone) **AND**
7. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 12 months.

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided
- ✓ Approval duration for renewal: 12 months.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Annual Review	Added 5-HT3 receptor agonist examples	7.2024

REFERENCE:

1. Varubi (rolapitant) [prescribing information]. Deerfield, IL: TerSera; December 2020.

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Prior Authorization Criteria for VELTASSA® (patiromer powder)

1. Patient has diagnosis of hyperkalemia **AND**
2. Patient is 12 years of age or older **AND**
3. Dosage and direction of use:
    - Recommended dose for age 18 years or older: 8.4 grams once daily; may be titrated to reach desired serum potassium concentration
    - Recommended dose for 12 to 17 years old: 4 grams once daily; may be titrated to reach desired serum potassium concentration **AND**
4. Quantity requested does not exceed: maximum of 25.2 grams once daily **AND**
5. Requested medication is not being used as emergency treatment for life-threatening hyperkalemia **AND**
6. Patient follows a low potassium diet (<3 gm/day) **AND**
7. Patient has had a trial and failure to a loop or thiazide diuretic, unless clinically inappropriate **AND**
8. Prescribed by or in consultation with a nephrologist or cardiologist

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 6 months.

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided
- ✓ Approval duration for renewal: 6 months.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Annual Review	Updated FDA approved age and dosing	6.2024

REFERENCE:

1. Veltassa [package insert]. Redwood City, CA; Relypsa, Inc.: March 2023.
2. Mount, David B. Treatment and prevention of hyperkalemia in adults. UpToDate. August 2022.

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Prior Authorization Criteria for VEMLIDY® (tenofovir alafenamide)

1. Patient has diagnosis of chronic hepatitis B virus infection with compensated liver disease **AND**
2. Patient is 6 years of age or older and weighs at least 25 kg **AND**
3. Dosage and direction of use: 25 mg (one tablet) taken orally once daily with food **AND**
4. Quantity requested does not exceed: 30 tablets/30 days
5. Patient has tried and failed tenofovir disoproxil fumarate or entecavir unless clinically significant adverse effects are experienced or both are contraindicated **AND**
6. Patient does not have HIV-1 infection and is not using this medication as a single agent for HIV treatment **AND**
7. Patient's creatinine clearance is >15mL/min **AND**
8. Patient does not have decompensated (ChildPugh B or C) hepatic impairment **AND**
9. Prescribed by or in consultation with a specialist such as a gastroenterologist, hepatologist, or infectious disease specialist.

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 1 year

RENEWALS

✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Revised	Created	3.2017
Update	Update Format / Add Denial Message	2.2020
Annual Review	No Changes	3.2021
Annual Review	No Changes	3.2022
Update	Added expanded indication to include patient age 12 year old and older	12.2022
Annual Review	No Changes	3.2023
Annual Review	No Changes	3.2024
Update	Updated criteria to include expanded indication for patient age 6 year old and older weighs at least 25 kg	4.2024

REFERENCE:

1. Agarwal K, Fung SK, Nguyen TT, et al. Twenty-eight day safety, antiviral activity, and pharmacokinetics of tenofovir alafenamide for treatment of chronic hepatitis B infection. *J Hepatol*. 2015;62(3):533-540.[PubMed 25450717]
2. Ray AS, Fordyce MW, Hitchcock MJ. Tenofovir alafenamide: A novel prodrug of tenofovir for the treatment of Human Immunodeficiency Virus. *Antiviral Res*. 2016;125:63-70.[PubMed 26640223]
3. Terrault NA, Bzowej NH, Chang KM, Hwang JP, Jonas MM, Murad MH; American Association for the Study of Liver Diseases (AASLD). AASLD guidelines for treatment of chronic hepatitis B. *Hepatology*. 2016;63(1):261-283.[PubMed 26566064]
4. Tran TT, Ahn J, Reau NS. ACG Clinical Guideline: Liver Disease and Pregnancy. *Am J Gastroenterol*. 2016;111(2):176-194. doi: 10.1038/ajg.2015.430.[PubMed 26832651]
5. Vemlidy (tenofovir alafenamide) [prescribing information]. Foster City, CA: Gilead Sciences Inc; October 2022.

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Prior Authorization Criteria for VENCLEXTA® (venetoclax tablets)

FDA- APPROVED INDICATIONS

- For the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
- In combination with azacitidine, or decitabine, or low-dose cytarabine for the treatment of newly diagnosed acute myeloid leukemia (AML) in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist.

INITIAL APPROVAL

✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
✓ Initial approval duration will be 1 year

RENEWAL

✓ Documentation or claim data supports continuation of treatment
✓ Patient is responding positively to therapy
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based PA Criteria Review	7.2021
Annual Review	No Changes	7.2022
Annual Review	Updated wording; removed criteria for monotherapy or combination therapy for CLL/SLL dx for clarity	7.2023
Annual Review	Updated to oncology drug format; updated approval duration; updated renewal section	5.2024

REFERENCE:

1. Venclexta Prescribing Information. North Chicago, IL: AbbVie Inc.; May 2020. Available at: https://www.venclexta.com.
2. National Comprehensive Cancer Network. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Version 3.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cll_blocks.pdf. Accessed July 20, 2022.
3. National Comprehensive Cancer Network. Acute Myeloid Leukemia Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/aml_blocks.pdf. Accessed July 20, 2022.
4. National Comprehensive Cancer Network. B-Cell Lymphomas (Version 5.2022). https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed July 23, 2022.
5. Eyre TA, Walter HS, Iyengar S, et al. Efficacy of venetoclax monotherapy in patients with relapsed, refractory mantle cell lymphoma after Bruton tyrosine kinase inhibitor therapy. Haematologica. 2019;104(2):e68-e71. doi: 10.3324/haematol.2018.198812.[PubMed 30190341]
6. Roberts AW, Davids MS, Pagel JM, et al. Targeting BCL2 with Venetoclax in Relapsed Chronic Lymphocytic Leukemia. N Engl J Med. 2016;374(4):311-22.[PubMed 26639348]

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Prior Authorization Criteria for VERZENIO (abemaciclib)

FDA-APPROVED INDICATIONS

- Early breast cancer
  - In combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence
- Advanced or recurrent breast cancer
  - In combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer
  - In combination with fulvestrant for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy.
  - As monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.

1. Patient has an FDA approved diagnosis **AND**
2. Patient is 18 years of age or older **AND**
3. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year.

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Annual Review	Updated duration to 1 year	5.2024

REFERENCE:

1. Verzenio [Prescribing Information] Indianapolis, IN: Lilly; January 2024.

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Prior Authorization Criteria for VIBERZI® (eluxadoline)

1. Patient has diagnosis of irritable bowel syndrome with diarrhea (IBS-D) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 100 mg tablet twice daily with food **AND**
4. Quantity requested does not exceed: 2 tablets/day (60/30) **AND**
5. Patient has tried and failed or was intolerant to two of the following medications or has a contraindication to all of the following medications:
    a. Anti-diarrheal agent (ex. loperamide, diphenoxylate-atropine)
    b. Antispasmodic agent (ex. dicyclomine, hyoscyamine)
    c. Bile acid sequestrants (ex. cholestyramine, colestipol)
    d. Tricyclic antidepressants (ex. amitriptyline).

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 1 year

RENEWALS

✓ Documentation of positive clinical response to therapy
✓ May renew in up to 1 year intervals

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	3.2017
Update	Update Format/Add Denial Message	2.2020
Annual Review	No Change	3.2021
Annual Review	No Change	3.2022
Annual Review	No Change; Update format	3.2023
Annual Review	Added documentation of positive clinical response to renewal	2.2024

REFERENCE:

1. Viberzi (eluxadoline) [prescribing information]. Madison, NJ: Allergan USA Inc; June 2020.
2. Treatment of irritable bowel syndrome in adults. UpToDate (database online). St. Louis, MO: Wolters Kluwer Health, Inc 2016. Updated periodically. Literature review current through: Jun 2016. | This topic last updated: Jan 28, 2016.
3. Weinberg DS, Smalley W, Heidelbaugh JJ, Sultan S. American Gastroenterological Association Institute guideline on the pharmacological management of irritable bowel syndrome. Gastroenterology. 2014; 147(5): 1146-1148.
4. Barshop K, Staller K. Eluxadoline in irritable bowel syndrome with diarrhea: rationale, evidence and place in therapy. Ther Adv Chronic Dis. 2017;8(11):153-160. doi:10.1177/2040622317714389[PubMed 29090081]
5. Wald A. Treatment of irritable bowel syndrome in adults. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com. Accessed February 8, 2023.

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Prior Authorization Criteria for VIDAZA (azacitidine for injection)

FDA Indications

- Myelodysplastic syndromes (MDS)
  - Treatment of adult patients with the following French-American-British (FAB) myelodysplastic syndrome subtypes: refractory anemia (RA) or refractory anemia with ringed sideroblasts (if accompanied by neutropenia or thrombocytopenia or requiring transfusions), refractory anemia with excess blasts (RAEB), refractory anemia with excess blasts in transformation (RAEB-T), and chronic myelomonocytic leukemia (CMMoL)
- Juvenile myelomonocytic leukemia (JMML)
  - Treatment of pediatric patients aged one month and older with newly diagnosed JMML

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Update	Updated duration of approval; added FDA approved age	5.2024
Annual Review	Updated reference	7.2024

REFERENCE:

1. Vidaza (azacitidine). [Prescribing Information]. Princeton, NJ: Celgene Corporation. January 2024.

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Prior Authorization Criteria for VIGADRONE (vigabatrin)

FDA-Approved Indications

- Refractory Complex Partial Seizures
- Infantile Spasms

Diagnosis: Refractory Complex Partial Seizures

1. Patient has diagnosis of refractory complex partial seizures **AND**
2. Patient is 2 years of age or older **AND**
3. Quantity requested does not exceed: 3000 mg/day **AND**
4. Patient has had an inadequate response to two formulary anticonvulsants **AND**
5. Requested medication will be used as an adjunctive therapy **AND**
6. Prescribed by or in consultation with a neurologist

Diagnosis: Infantile Spasms

1. Patient has diagnosis of infantile spasms **AND**
2. Patient is between 1 month to 2 years of age **AND**
3. Quantity requested does not exceed: 150 mg/kg/day **AND**
4. Requested medication will be used as an monotherapy **AND**
5. Prescribed by or in consultation with a neurologist

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 12 months.
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided
- ✓ Approval duration for renewal: 12 months.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023

REFERENCE:

1. VIGADRONE. [Prescribing Information]. Maple Grove, MN. Upsher-Smith Laboratories, LLC: March 2023.

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Prior Authorization Criteria for VIJOICE® (alpelisib)

1. Patient has diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS) assessed as severe or life threatening **AND**
2. Patient must be 2 years of age or older **AND**
3. Dosage and direction for use:
    a. Pediatric patients 2 to less than 18 years of age: 50 mg once daily with food. Dose can be increased to 125 mg once daily in patients ≥ 6 years old for response optimization ONLY after 24 weeks of treatment with 50 mg dose once daily **OR**
    b. Patients ≥18 years old: 250 mg taken orally once daily with food; **AND**
4. Quantity requested does not exceed 28 caps/28 days for 50 mg & 125 mg or 56 caps/28 days for 250 mg pack (200 mg & 50 mg tabs) **AND**
5. Confirm patient has a documented evidence of a mutation in the PIK3CA gene confirmed by genetic testing **AND**
6. Patient has severe clinical manifestations of PROS as determined by the prescriber (e.g., excessive tissue growth, blood vessel malformations, scoliosis, vascular tumors, cardiac or renal manifestations, and those that require systemic treatment) **AND**
7. Confirm patient has a negative pregnancy test or is not breastfeeding **AND**
8. Prescribed by or in consultation with a specialist such as a clinical geneticist or a physician that specializes in the management of PROS manifestations.

INITIAL APPROVALS

✓ Initial Approval will be granted for a period of 24 weeks (6 months)

RENEWALS

✓ Patient had achieved one of the following:
- ≥ 20% reduction from baseline in the sum of measurable target lesion volume (1-3 lesions) confirmed by at least one subsequent imaging assessment
- Absence of a ≥ 20% increase from baseline in any target lesion or progression of non-target lesions
- No appearance of a new lesion

✓ Approval will be granted for an additional period of 24 weeks (6 months)

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB Meeting 04.21.2022	4.2022
Annual Review	Updated formatting, diagnosis verbiage, diagnosis criteria, and specialist requirement.	4.2023
Annual Review	No changes	4.2024

REFERENCES:

1. Canaud G, et al. EPIK-P1: Retrospective Chart Review Study of Patients With PIK3CA-Related Overgrowth Spectrum Who Have Received Alpelisib as Part of a Compassionate Use Programme. Presented at the 2021 ESMO Congress; September 17-21, 2021.
2. Keppler-Noreuil KM, Sapp JC, Lindhurst MJ, et al. Clinical delineation and natural history of the PIK3CA-related overgrowth spectrum. Am J Med Genet A. 2014;164A(7):1713-1733.
3. PIK3CA-related overgrowth spectrum. Genetic and Rare Disease Information Center, Accessed 4/12/22. https://rarediseases.info.nih.gov/diseases/12182/pik3ca-related-overgrowth-spectrum
4. Vijoice: Prescribing Information. East Hanover, New Jersey, USA: Novartis Pharmaceuticals Corporation; April 2022. Accessed 3.27.23
5. Mirzaa G, Graham JM Jr, Keppler-Noreuil K. PIK3CA-related overgrowth spectrum. 2013 Aug 15 [Updated 2021 Dec 23]. In: Adam MP, Ardinger HH, Pagon RA, et al., editors. Gene Reviews [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2022
6. Keppler-Noreuil K, Rios JJ, Parker V, et al. PIK3CA-related overgrowth spectrum (PROS): diagnostic and testing eligibility criteria, differential diagnosis, and evaluation. Am J Med Genet A. 2015;0(2):287-295.

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Prior Authorization Criteria for VIRAZOLE (ribavirin inhalation solution)

1. Patient has diagnosis of severe lower respiratory tract infection due to RSV **AND**
2. Patient is less than 3 years of age **AND**
3. Dosage and direction of use: 20 mg/mL solution aerosolized over 12-18 hours once daily for 3-7 days **AND**
4. Quantity requested does not exceed: 1 vial/ day **AND**
5. Patient is hospitalized and will be receiving requested medication in inpatient setting **AND**
6. Prescribed by or in consultation with an infectious disease specialist

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 7 days
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ May not be renewed

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	No change	2.2024

REFERENCE:

1. Virazole (ribavirin). [Prescribing information]. Bridgewater, NJ: Bausch Health US. May 2019.

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Prior Authorization Criteria for VISTOGARD® (uridine triacetate)

FDA Indications

- Indicated for the emergency treatment of adult and pediatric patient:
  - Following a fluorouracil or capecitabine overdose regardless of the presence of symptoms
  - Who exhibit early-onset, severe or life-threatening toxicity affecting the cardiac or central nervous system, and/or early onset, unusually severe adverse reactions (e.g., gastrointestinal toxicity and/or neutropenia) within 96 hours following the end of fluorouracil or capecitabine administration.

1. Patient has an FDA approved diagnosis where the medication is prescribed for the management of overdose or toxicity due to fluorouracil or capecitabine administration **AND**
2. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
3. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 month (up to 20 doses).

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Removed renewal section	2.2024

REFERENCE:

1. Vistogard oral granules [prescribing information]. Rockville, MD: Wellstat Therapeutics; February 2017.
2. Jacob A, Sekkath Veedu J, Selene I, et al. Case report: uridine triacetate in the management of delayed onset 5-fluorouracil toxicity: a case report and review of literature. Front Pharmacol. 2022;13:977734. doi:10.3389/fphar.2022.977734[PubMed 36160401]
3. Ma WW, Saif MW, El-Rayes BF, et al. Emergency use of uridine triacetate for the prevention and treatment of life-threatening 5-fluorouracil and capecitabine toxicity. Cancer. 2017;123(2):345-356. doi:10.1002/cncr.30321[PubMed 27622829]

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Prior Authorization Criteria for VITRAKVI (larotrectinib)

FDA Indications

- Treatment of adult and pediatric patients with solid tumors that:
  - have a neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion without a known acquired resistance mutation
  - are metastatic or where surgical resection is likely to result in severe morbidity
  - have no satisfactory alternative treatments or that have progressed following treatment

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated duration of approval; added FDA approved age	5.2024

REFERENCE:

1. Vitrakvi (larotrectinib). [Prescribing Information]. Whippany, NJ: Bayer Pharmaceuticals, Inc. December 2022.

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Prior Authorization Criteria for VIVJOA™ (oteseconazole)

1. Patient has a diagnosis of recurrent vulvovaginal candidiasis (VVC) **AND**
2. Patient is 12 years of age and older **AND**
3. Patient is one of the following:
    a. Not of reproductive potential (i.e., hysterectomy, history of tubal ligation, salpingo-oophorectomy) **OR**
    b. Postmenopausal **AND**
4. Dosage and Direction for Use:
   For the Vivjoa - only Dosage Regimen:
    - On Day 1: Vivjoa 600 mg (as a single dose) orally, then
    - On Day 2: Vivjoa 450 mg (as a single dose) orally, then
    - Beginning on Day 14: Vivjoa 150 mg once a week (every 7 days) orally for 11 weeks (Weeks 2 through 12).

   For the fluconazole/VIVJOA Dosage Regimen, prescribe fluconazole:
    - On Day 1, Day 4, and Day 7: fluconazole 150 mg orally, then
    - On Days 14 through 20: Vivjoa 150 mg once daily orally for 7 days, then
    - Beginning on Day 28: Vivjoa 150 mg once a week (every 7 days) orally for 11 weeks (Weeks 4 through 14) **AND**
5. Quantity requested does not exceed: the dosing schedule 18 capsules/treatment course (84 to 98 days) **AND**
6. Patient has history of RVVC with 3 or more acute VVC episodes within the past 12 months **AND**
7. Patient has had a trial and failure of a maintenance course of oral fluconazole

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 4 months

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 7.28.2022	7.2022
Annual Review	No Change	7.2023
Annual Review	Removed t/f requirement of topical azoles based on treatment recommendations; updated approval duration to 4 months	1.2024

REFERENCE:

1. Vivjoa (oteseconazole) [prescribing information]. Durham, NC: Mycovia Pharmaceuticals Inc; April 2022.
2. Chew SY, et al. Vulvovaginal candidosis: contemporary challenges and the future of prophylactic and therapeutic approaches. Mycoses. 2016;59(5):262-273. doi: 10.1111/myc.12455
3. Denning DW, et al. Global burden of recurrent vulvovaginal candidiasis: a systematic review. Lancet Infect Dis. 2018;18(11):e339-e347. doi:10.1016/S1473-3099(18)30103-8
4. Pappas PG, et al. Clinical Practice Guideline for the Management of Candidiasis: 2016 Update by the Infectious Diseases Society of America. Clin Inf Dis. 2016;62(4):e1-e50. https://doi.org/10.1093/cid/civ933
5. Sobel JD. Recurrent vulvovaginal candidiasis. Am J Obstet Gynecol. 2016;214(1):15-21. doi: 10.1016/j.ajog.2015.06.067
6. Sobel JD, et al. Oteseconazole: an advance in treatment of recurrent vulvovaginal candidiasis. Future Microbiol. 2021;16(18):1453-1461. doi.org/10.2217/fmb-2021-0173
7. Vulvovaginal Candidiasis (VVC). Sexually Transmitted Infections Treatment Guidelines, 2021. Centers for Disease Control and Prevention. Updated July 22, 2021. Accessed July 22, 2022. https://www.cdc.gov/std/treatment-guidelines

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Prior Authorization Criteria for VIZIMPRO (dacomitinib)

1. Patient has a diagnosis of metastatic non-small cell lung cancer **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and directions: 45 mg orally once daily **AND**
4. Quantity does not exceed: 30 tablets/30 days **AND**
5. Patient has an epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test **AND**
6. Requested medication is being used as first line treatment **AND**
7. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
8. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated duration of approval to 1 year	2.2024

REFERENCE:

1. Vizimpro (dacomitinib). [Prescribing Information]. New York, NY: Pfizer Labs. December 2020.

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Prior Authorization Criteria for VONJO™ (pacritinib)

FDA-Approved Indication

- Treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 × 10^9 /L (1).

1. Patient has an FDA approved diagnosis **AND**
2. Patient is 18 years of age or older **AND**
3. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial Approval will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval will be granted for an additional period of 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 3.24.2022	3.2022
Annual Review	No Changes	3.2023
Annual Review	Updated initial approval duration, updated criteria to general oncology verbiage based on NCCN guidelines and package insert and updated references.	3.2024

REFERENCES

1. Al-Ali HK, et al. Managing patients with myelofibrosis and low platelet counts. *Ann Hematol*. 2017;96(4):537–548. doi:10.1007/s00277-016-2697-8
2. Gerds AT, et al. Determining the recommended dose of pacritinib: results from the PAC203 dose-finding trial in advanced myelofibrosis. *Blood Adv*. 2020;4(22):5825–5835. doi:10.1182/bloodadvances.2020003314.
3. Leukemia & Lymphoma Society. Myeloproliferative neoplasms: polycythemia vera, essential thrombocytopenia and myelofibrosis. Revised 2021. Accessed March 16, 2022. https://www.lls.org/sites/default/files/2021-10/PS81_MPN_Booklet_2021.pdf
4. Mauro G. FDA approves pacritinib for intermediate- or high-risk myelofibrosis with severe thrombocytopenia. OncLive. February 28, 2022. Accessed March 16, 2022. https://www.onclive.com/view/fda-approves-pacritinib-for-intermediate-or-high-risk myelofibrosis
5. Vonjo (pacritinib) [prescribing information]. Seattle, WA: CTI BioPharma Corp; August 2023.
6. National Comprehensive Cancer Network. Myeloproliferative Neoplasms (Version 1.2024). https://www.nccn.org/professionals/physician_gls/pdf/mpn_blocks.pdf. Accessed February 22, 2024.

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Prior Authorization Criteria for VOQUEZNA® (vonoprazan), VOQUEZNA DUAL PAK®, VOQUEZNA TRIPLE PAK ®

FDA-Approved Indications

- For healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults.
- To maintain healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults.
- For the relief of heartburn associated with non-erosive gastroesophageal reflux disease in adults.
- In combination with amoxicillin and clarithromycin for the treatment of *Helicobacter pylori* (*H. pylori*) infection in adults.
- In combination with amoxicillin for the treatment of *H. pylori* infection in adults.

Diagnosis: Erosive Esophagitis (Voquezna tablet only)

1. Patient has a diagnosis of erosive esophagitis **AND**
2. Patient is 18 years and older **AND**
3. Dosage and Direction for Use:
    a. Healing of erosive esophagitis: 20 mg once daily for 8 weeks
    b. Maintenance of healing: 10 mg once daily for up to 6 months **AND**
4. Quantity requested does not exceed: 30 tabs/30 days **AND**
5. Patient has had trial and failure to two generic proton pump inhibitors

Diagnosis: Relief of heartburn associated with GERD (Voquezna tablet only)

1. Patient has a diagnosis of heartburn associated with non-erosive gastroesophageal reflux disease **AND**
2. Patient is 18 years and older **AND**
3. Dosage and Direction for Use: 10 mg once daily for 4 weeks **AND**
4. Quantity requested does not exceed: 28 tabs/28 days **AND**
5. Patient has had trial and failure to two generic proton pump inhibitors

Diagnosis: H. Pylori (Voquezna tablet or Voquezna Paks)

1. Patient has a diagnosis of Heliobacter pylori **AND**
2. Patient is 18 years and older **AND**
3. Dosage and Direction for Use:
    a. Triple therapy: 20 mg Voquezna plus 1000 mg amoxicillin plus 500 mg clarithromycin twice daily for 14 days
    b. Dual therapy: 20 mg Voquezna twice daily plus 1000 mg amoxicillin three times daily for 14 days **AND**
4. Quantity requested does not exceed:
    a. Voquezna tablets: 28 tablets/14 days
    b. Voquezna Triple Pak: 112/14 days
    c. Voquezna Dual Pak: 112/14 days
5. Patient has had a trial and failure of one of the following:
    a. Bismuth quadruple therapy (bismuth, metronidazole, tetracycline, and a proton pump inhibitor) **OR**
    b. Clarithromycin-based therapy (clarithromycin, proton pump inhibitor, amoxicillin, and/or metronidazole)

INITIAL APPROVALS

- ✓ For erosive esophagitis and GERD indication: Initial approval will be granted for a period of 6 months
- ✓ For H. pylori indication: Initial approval will be granted for a one time fill of 14 days

RENEWALS

- ✓ For erosive esophagitis and GERD indications:
  - Patient is responding positively to therapy
  - Prescriber confirms patient continues to require maintenance therapy
  - Approval duration for renewal: 1 year
- ✓ For H pylori indication: Not eligible for renewal. Patient must meet initial criteria.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 11.30.23	11.2023
Annual Review	Added expanded indication of heartburn associated with GERD for Voquezna	8.2024

REFERENCE:

1. Voquezna (vonoprazan) [prescribing information]. Buffalo Grove, IL: Phathom Pharmaceuticals Inc; November 2023.
2. Voquenzna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) [prescribing information]. Buffalo Grove, IL: Phathom Pharmaceuticals; August 2023.
3. Voquezna Dual Pak (vonoprazan and amoxicillin) [prescribing information]. Buffalo Grove, IL: Phathom Pharmaceuticals; May 2022.

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Prior Authorization Criteria for VOTRIENT (pazopanib hcl)

FDA Indications

- Treatment of adults with advanced renal cell carcinoma
- Treatment of adults with advanced soft tissue sarcoma who have received prior chemotherapy

1. Patient has an FDA approved diagnosis **AND**
2. Patient is 18 years of age or older **AND**
3. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year
- ✓

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Annual Review	Updated duration of approval to 1 year	5.2024

REFERENCE:

1. VOTRIENT [Prescribing Information]. East Hanover, NJ. Novartis Pharmaceuticals Corporation: January 2024.

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Prior Authorization Criteria for VOWST™ (fecal microbiota spores, live-brpk)

1. Patient has a diagnosis of at least two recurrent Clostridioides Difficile Infection episodes (≥3 total CDI episodes. A CDI episode is defined as ≥3 unformed/loose stools/day for 2 consecutive days) **AND**
2. Patient is 18 years of age and older **AND**
3. Dosage and Direction for Use: 4 capsules orally once daily for 3 days **AND**
4. Quantity requested does not exceed: 12 capsules/3 days **AND**
5. Patient has completed at least 10 days of antibiotic therapy (vancomycin or Dificid) for recurrent C. difficile 2-4 days before initiating treatment with Vowst **AND**
6. Patient's current episode of CDI must be controlled (<3 unformed/loose stools/day for 2 consecutive days) **AND**
7. Patient has a positive stool test for C. difficile within 30 days before prior authorization request **AND**
8. Patient has not received a prior course of Vowst **AND**
9. Prescribed by or in consultation with an infectious disease specialist.

INITIAL APPROVALS

✓ Initial approval will be granted for one- time treatment.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 5.18.2023	5.2023
Annual Review	Removed trial and failure of alternative therapy; added separate requirement for antibiotic therapy	5.2024

REFERENCE:

1. Vowst (fecal microbiota) [prescribing information]. Brisbane, CA: Aimmune Therapeutics, Inc; April 2023.
2. Johnson S, Lavergne V, Skinner AM, Gonzales-Luna AJ, Garey KW, Kelly CP, Wilcox MH. Clinical Practice Guideline by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 Focused Update Guidelines on Management of Clostridioides difficile Infection in Adults. Clin Infect Dis. 2021 Sep 7;73(5):e1029-e1044. doi: 10.1093/cid/ciab549. PMID: 34164674.
3. Feuerstadt P, et al. SER-109, an oral microbiome therapy for recurrent Clostridioides difficile infection. N Engl J Med. 2022;386(3):220–229. doi:10.1056/NEJMoa2106516
4. Guh AY, et al. Trends in U.S. burden of Clostridioides difficile infection and outcomes. New Engl J Med. 2020;382:1320–1330. doi:10.1056/NEJMoa1910215.
5. Gough E, et al. Systematic review of intestinal microbiota transplantation (fecal bacteriotherapy) for recurrent Clostridium difficile infection. Clin Infect Dis. 2011;53(10):994– 1002. doi:10.1093/cid/cir632
6. Song JH, et al. Recurrent Clostridium difficile infection: risk factors, treatment, and prevention. Gut Liver. 2019;13(1):16–24. doi: 10.5009/gnl18071

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Prior Authorization Criteria for VOXZOGO® (vosoritide)

1. Patient has a diagnosis of achondroplasia confirmed through genetic testing **AND**
2. Patient is 17 years of age or younger **AND**
3. Dosage and direction for use: recommended dosage is based on patient's weight and is administered subcutaneously once daily **AND**
4. Quantity requested does not exceed: dosed by weight, please optimize quantity based on prescribed dosing scheduling to ensure appropriate quantity is dispensed **AND**
5. Documentation of recent growth velocity **AND**
6. Patient has a current growth velocity 1.5 centimeters/year or greater **AND**
7. Patient has recent imaging with evidence of open epiphyses **AND**
8. Patient has not had limb-lengthening surgery in the previous 18 months and does not plan to have limb-lengthening surgery while on Voxzogo **AND**
9. Patient has not received previous treatment with growth hormone, insulin-like growth factor 1, or anabolic steroids in the previous 6 months **AND**
10. Prescribed by or in consultation with a specialist such as an endocrinologist or neonatologist

INITIAL APPROVALS

- ✓ Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of a clinically meaningful improvement increase in growth velocity over baseline **AND**
- ✓ Patient continues to have recent evidence of open epiphyses **AND**
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 12.21.2021	12.2021
Updated	Updated ages to 5-17	12.2021
Annual Review	No Changes	12.2022
Annual Review	Updated age to 17 years or younger; Removed Tanner score requirement and added open epiphyses requirement to initial and renewal criteria; Add requirement for patient to not have had limb-lengthening surgery; Updated format	12.2023

REFERENCE:

1. A Alade SL, Brown RE, Paquet A. Polysorbate 80 and E-Ferol toxicity. Pediatrics. 1986;77(4):593-597.[PubMed 3960626]
2. Centers for Disease Control (CDC). Unusual syndrome with fatalities among premature infants: association with a new intravenous vitamin E product. MMWRm Morb Mortal Wkly Rep. 1984;33(14):198-199. http://www.cdc.gov/mmwr/preview/mmwrhtml/00000319.htm[PubMed 6423951]
3. Lucente P, Iorizzo M, Pazzaglia M. Contact sensitivity to Tween 80 in a child. Contact Dermatitis. 2000;43(3):172.[PubMed 10985636]
4. Savarirayan R, Irving M, Bacino CA, et al. C-type natriuretic peptide analogue therapy in children with achondroplasia. N Engl J Med. 2019;381(1):25-35. doi:10.1056/NEJMoa1813446[PubMed 31269546]
5. Savarirayan R, et al. Once-daily, subcutaneous vosoritide therapy in children with achondroplasia: a randomised, double-blind, phase 3, placebo-controlled, multicentre trial [published correction appears in Lancet. 2020 Oct 10;396(10257):1070]. Lancet. 2020;396(10252):684–692. doi:10.1016/S0140- 6736(20)31541-5.
6. Stratbucker WB. In brief: Achondroplasia. Pediatr Rev. 2009;30(3):114-115. doi:10.1542/pir.30-3-114
7. Shelley WB, Talanin N, Shelley ED. Polysorbate 80 hypersensitivity. Lancet. 1995;345(8980):1312-1313.[PubMed 7746084]
8. Voxzogo (vosoritide) [prescribing information]. Novato, CA: BioMarin Pharmaceutical Inc; November 2023

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Prior Authorization Criteria for VOYDEYA™ (danicopan)

1. Patient has diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) **AND**
2. Patient is 18 years of age and older **AND**
3. Dosage and direction of use: 150 mg three times a day administered orally. Depending on clinical response, can increase to 200 mg three times a day **AND**
4. Quantity requested does not exceed: 180/30 days **AND**
5. Patient has signs and symptoms attributed to PNH (e.g., abdominal pain, anemia, dyspnea, extreme fatigue, smooth muscle dystonia, unexplained/unusual thrombosis, hemolysis/hemoglobinuria, kidney disease, pulmonary hypertension) **AND**
6. Therapy is being used as add-on-therapy to Ultomiris or Soliris **AND**
7. Patient must have received vaccinations against encapsulated bacteria, including Streptococcus pneumoniae, Neisseria meningitidis (serogroups A, C, W, Y and B), and Haemophilus influenzae type B, according to current ACIP recommendations at least 2 weeks prior to initiation of therapy **AND**
8. Prescribed by or in consultation with a specialist such as hematologist, oncologist, or immunologist.

INITIAL APPROVALS

- ✓ Initial approval will be granted for a period of 6 months

RENEWALS

- ✓ Documentation of positive clinical response to therapy is provided
- ✓ Approval duration for renewal: 6 months – 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created from CAB 4.18.24	4.2024

REFERENCE:

1. Voydeya (danicopan) [prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc; March 2024.
2. Oliver M, Patriquin CJ. Paroxysmal Nocturnal Hemoglobinuria: Current Management, Unmet Needs, and Recommendations. J Blood Med. 2023 Dec 6;14:613-628. doi: 10.2147/JBM.S431493. PMID: 38084255; PMCID: PMC10710797.
3. Cançado RD, Araújo ADS, Sandes AF, Arrais C, Lobo CLC, Figueiredo MS, Gualandro SFM, Saad STO, Costa FF. Consensus statement for diagnosis and treatment of paroxysmal nocturnal haemoglobinuria. Hematol Transfus Cell Ther. 2021 Jul-Sep;43(3):341-348. doi: 10.1016/j.htct.2020.06.006. Epub 2020 Jul 6. PMID: 32713742; PMCID: PMC8446255.
4. Parker C, Omine M, Richards S, et al. Diagnosis and management of paroxysmal nocturnal hemoglobinuria. Blood 2005; 106(12):3699-3709. doi:10.1182/blood-2005-04-1717.
5. Kulasekararaj AG, Hill A, Rottinghaus ST, et al. Ravulizumab (ALXN1210) vs eculizumab in C5-inhibitor-experienced adult patients with PNH: the 302 study. Blood. 2019;133(6):540-549. doi: 10.1182/blood-2018-09-876805.[PubMed 30510079]
6. Röth A, Rottinghaus ST, Hill A, et al. Ravulizumab (ALXN1210) in patients with paroxysmal nocturnal hemoglobinuria: results of 2 phase 1b/2 studies. Blood Adv. 2018;2(17):2176-2185. doi: 10.1182/bloodadvances.2018020644.[PubMed 30171081]

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Prior Authorization Criteria for VTAMA®(tapinarof) cream

1. Patient has diagnosis of plaque psoriasis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and directions of use: Apply a thin layer to affected area once daily **AND**
4. Quantity requested does not exceed: 60 g (1 tube)/30 days **AND**
5. Patient has BSA involvement ≥3% and ≤20% **AND**
6. Patient has had a minimum of a 4 week trial and failure of at least two topical therapies from different therapy classes (i.e., corticosteroids, calcipotriene, calcitriol, tazarotene, tacrolimus) **AND**
7. Prescribed by or in consultation with a specialist such as a dermatologist.

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 6 months

RENEWALS

✓ Approval duration for renewal: period of one year if clinically appropriate

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 6.16.2022	6.2022
Updated	Added trial duration of 4 weeks; updated references	6.2023
Annual Review	Updated denial message.	4.2024

REFERENCE:

1. Lebwohl MG, Stein Gold L, Strober B, et al. Phase 3 trials of tapinarof cream for plaque psoriasis. N Engl J Med. 2021;385(24):2219-2229. doi:10.1056/NEJMoa2103629[PubMed 34879448]
2. Vtama (tapinarof) [prescribing information]. Long Beach, CA: Dermavant Sciences Inc; May 2022.
3. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.

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Prior Authorization Criteria for VYNDAQEL® (tafamidis meglumine)/VYNDAMAX ® (tafamidis)

1. Patient has diagnosis of cardiomyopathy caused by transthyretin-mediated amyloidosis (ATTR-CM), either wild-type transthyretin amyloidosis or hereditary transthyretin amyloidosis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use:
   - Vyndaqel: 80 mg once daily (4 capsules/day)
   - Vyndamax: 61mg once daily (1 capsule/day) **AND**
4. Quantity limit does not exceed:
   - Vyndaqel: 4 capsules/day (112/28 days)
   - Vyndamax: 1 capsule/day (28/28 days) **AND**
5. Confirm presence of amyloid deposit via biopsy (cardiac and noncardiac sites) **AND**
6. Confirm presence of a variant TTR genotype (TTR mutation) by genetic testing and/or TTR precursor protein identified by immunohistochemistry, scintigraphy or mass spectrometry **AND**
7. Prescriber attestation that chart notes or other documentation provided for evidence of heart failure (one of the following):
   a) A history of heart failure with at least one prior hospitalization for heart failure OR
   b) Clinical evidence of heart failure (without hospitalization) manifested in signs or symptoms of volume overload or elevated intracardiac pressures requiring treatment with a diuretic for improvement **AND**
8. Patient has cardiac involvement confirmed by means of echocardiography, with an end-diastolic interventricular septal wall thickness >12 mm **AND**
9. Patient does not have history of heart or liver transplant and does not have implanted cardiac device **AND**
10. Patient does not have New York Heart Association class IV heart failure **AND**
11. Patient does not have presence of primary light-chain amyloidosis **AND**
12. Patient is not receiving Onpattro or Tegsedi **AND**
13. Prescribed by or in consultation with a cardiologist.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 6 months

RENEWALS

✓ Patient must show evidence of slowing of clinical decline to demonstrate patient has experienced a positive response to therapy (i.e., walking ability, nutrition, cardiac related hospitalization, cardiac procedures or laboratory tests)

✓ Approval duration: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Revised	Created	8.2019
Update	Update Format/Denial Message; No Change	2.2020/8.2020
Annual Review	No Change	8.2021
Annual Review	No Change	8.2022
Annual Review	Updated format and added “prescriber attestation” verbiage	8.2023
Annual Review	Added requirement to not use in patients receiving Onpattro or Tegsedi	2.2024

REFERENCE:

1. Ando Y, Coelho T, Berk JL, Cruz MW, Ericzon BG, Ikeda S, et al. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet J Rare Dis. 2013; 8: 31.
2. Vyndaqel and Vyndamax [package insert]. Pfizer, Inc: New York, NY; October 2023.

3. Mauer MS, Schwartz JH, Gundapeneni B, et al. Tafamidis treatment for patients with transthyretin amyloid cardiomyopathy. N Engl J Med. 2018; 379:1007-16.
4. Gillmore JD, Maurer MS, Falk RH, et al. Nonbiopsy diagnosis of cardiac transthyretin amyloidosis. Circulation. 2016; 133:2404-12.
5. Mckenna WJ. Treatment of amyloid cardiomyopathy. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com (Accessed on December 16, 2020.)
6. Mckenna WJ. Clinical manifestations and diagnosis of amyloid cardiomyopathy. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com (Accessed on December 16, 2020.)
7. Falk RH. Diagnosis and management of the cardiac amyloidoses. Circulation 2005; 112:2047.
8. William J McKenna, MD. Clinical manifestations and diagnosis of amyloid cardiomyopathy. UpToDate: April 2019.

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Prior Authorization Criteria for WELIREG™ (belzutifan)

FDA-Approved Indications

- Treatment of adult patients with von Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery
- Treatment of adult patients with advanced renal cell carcinoma (RCC) following a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI)

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Documentation or claim data supports continuation of treatment
✓ Patient is responding positively to therapy
✓ Approval duration for renewal: 1 year

DEFAULT DENIAL MESSAGE

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 9.23.2021	9.2021
Annual Review	No Change	9.2022
Annual Review	Updated format	9.2023
Annual Review	Updated to oncology drug format; added indication for RCC	8.2024

REFERENCE:

1. Srinivasan R, Donskov F, Iliopoulos O, et al. Phase 2 study of belzutifan (MK-6482), an oral hypoxia-inducible factor 2α (HIF-2α) inhibitor, for Von Hippel-Lindau (VHL) disease-associated clear cell renal cell carcinoma (ccRCC). J Clin Oncol. 2021;39(suppl 15; abstr 4555). doi:10.1200/JCO.2021.39.15_suppl.4555
2. Welireg (belzutifan) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; January 2024.
3. National Comprehensive Cancer Network. Kidney Cancer (Version 2.2022). https://www.nccn.org/professionals/physician_gls/pdf/kidney_blocks.pdf. Accessed September 21, 2021.
4. National Organization for Rare Disorders. Von Hippel-Lindau disease. Accessed September 21, 2021. https://rarediseases.org/rare-diseases/von-hippel-lindau-disease/
5. National Institutes of Health, Genetic and Rare Diseases Information Center. Von Hippel-Lindau disease. Updated February 2, 2016. Accessed September 21, 2021. https://rarediseases.info.nih.gov/diseases/7855/von-hippel-lindau-disease

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Prior Authorization Criteria for XALKORI (crizotinib)

FDA-APPROVED INDICATIONS

- Treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK) or ROS1-positive as detected by an FDA-approved test
- Treatment of pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK-positive
- Treatment of adult and pediatric patients 1 year of age and older with unresectable, recurrent, or refractory inflammatory myofibroblastic tumor (IMT) that is ALK-positive

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Update	Update initial approval duration and age range	12.2023
Annual Review	Updated wording to age is appropriate based on FDA labeling; updated wording to requested medication follows appropriate therapy for diagnosis	6.2024

REFERENCE:

1. XALKORI. [Prescribing information]. New York, NY. Pfizer Labs: September 2023.

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Prior Authorization Criteria for XELJANZ®/XELJANZ XR® (tofacitinib)

FDA-APPROVED INDICATIONS

- Rheumatoid arthritis (RA): Adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers
- Psoriatic arthritis (PsA): Adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers
- Ulcerative colitis (UC): Adult patients with moderately to severely active ulcerative colitis (UC), who have had an inadequate response or who are intolerant to TNF blockers
- Juvenile Idiopathic Arthritis (JIA): Patients 2 years of age and older with active polyarticular juvenile arthritis (XELJANZ only)
- Ankylosing Spondylitis: Adult patients with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers

Diagnosis: for Rheumatoid Arthritis (RA)

1. Patient has diagnosis of moderate to severe rheumatoid arthritis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use:
    a. Immediate release: 5 mg twice daily
    b. Extended release: 11 mg once daily **AND**
4. Quantity requested does not exceed: for immediate release: 60 tablets/30 days; for extended release: 30 tablet/30 days **AND**
5. Patient had inadequate response or has contraindications to at least one non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide) **AND**
6. Patient has failed to achieve symptom control after adequate therapy with, or has labeled contraindications to at least one of the following: Enbrel or Adalimumab* **AND**
7. Patient is not receiving Xeljanz/XR in combination with other biologic DMARDs **AND**
8. Prescribed by or in consultation with a rheumatologist

Diagnosis: for Psoriatic Arthritis (PsA)

1. Patient has diagnosis of psoriatic arthritis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: **AND**
    a. Immediate release: 5 mg twice daily
    b. Extended release: 11 mg once daily **AND**
4. Quantity requested does not exceed: for immediate release: 60 tablets/30 days; for extended release: 30 tablet/30 days **AND**
5. Patient has had an inadequate response or has contraindications to at least one non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide) **AND**
6. Patient has failed to achieve symptom control after adequate therapy with, or has labeled contraindications to at least one of the following: Enbrel or Adalimumab* **AND**
7. Patient is not receiving Xeljanz/XR in combination with other biologic DMARDs **AND**
8. Prescribed by or in consultation with a rheumatologist or dermatologist

Diagnosis: for Ulcerative Colitis (UC)

1. Patient has a diagnosis of moderately to severely active ulcerative colitis (UC) **AND**
2. Patient is 18 years of age or older **AND**

3. Dosage and direction of use:
    a. Immediate release:
        i. Induction period: 10 mg twice daily for at least 8 weeks; based on therapeutic response, may continue 10 mg twice daily for a maximum of 16 weeks or transition to maintenance dose. Discontinue therapy if inadequate response achieved after 16 weeks using 10 mg twice daily
        ii. Maintenance dose: 5 mg twice daily; if patient experiences loss of response on 5 mg twice daily, then use 10 mg twice daily after assessing the benefits and risks, and use for the shortest duration; use lowest effective dose to maintain response
    b. Extended release:
        i. Induction period: 22 mg once daily for at least 8 weeks; evaluate patients and transition to maintenance therapy depending on therapeutic response. If needed continue 22 mg once daily for a maximum of 16 weeks. Discontinue 22 mg once daily after 16 weeks if adequate therapeutic response is not achieved
        ii. Maintenance: 11 mg once daily. if patient experiences loss of response on 11 mg once daily, then use 22 mg once daily after assessing the benefits and risks and use for the shortest duration; use lowest effective dose to maintain response **AND**
4. Quantity requested does not exceed:
    a. Immediate release:
        i. Induction period: 60 tablets (10mg)/30 days up to 4 months (16 weeks)
        ii. Maintenance period: 60 tablets (5 mg)/30 days
    b. Extended release:
        i. Induction period: 30 tablets (22mg tablet)/30 days up to 4 months (16 weeks)
        ii. Maintenance period: 30 tablets (11mg tablet)/30 days **AND**
5. Patient has the patient had an adequate trial and failure of at least ONE oral systemic agent (e.g., 6-mercaptopurine, azathioprine, methotrexate, cyclosporine, tacrolimus, corticosteroid (e.g., prednisone). A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis **AND**
6. Patient has failed to achieve symptom control after adequate therapy with, or has labeled contraindications to Adalimumab* **AND**
7. Patient is not receiving Xeljanz/XR in combination with other biologic therapies **AND**
8. Prescribed by or in consultation with a gastroenterologist

Diagnosis: for Juvenile Idiopathic Arthritis (Xeljanz immediate-release only or Xeljanz Oral Solution)

1. Patient has diagnosis of active polyarticular juvenile arthritis (JIA) **AND**
2. Patient is 2 years of age or older **AND**
3. Dosage and direction of use: 5 mg twice daily or 5 mL (oral solution) twice daily or weight-based equivalent twice daily **AND**
4. Quantity requested does not exceed: 60 tablets/30 days or 300 mL oral solution/30 days **AND**
5. Patient has had an inadequate response or has contraindications to at least one non-biologic disease modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide) **AND**
6. Patient has failed to achieve symptom control after adequate therapy with, or has labeled contraindications to at least one of the following: Enbrel or Adalimumab* **AND**
7. Patient is not receiving Xeljanz/XR tablets or oral solution in combination with other biologic DMARDs **AND**
8. Prescribed by or in consultation with a rheumatologist

Diagnosis: for Ankylosing Spondylitis (AS)

1. Patient has diagnosis of Ankylosing Spondylitis **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use:
    a. Immediate release: 5 mg twice daily
    b. Extended release: 11 mg once daily **AND**
4. Quantity requested does not exceed: for immediate release: 60 tablets/30 days; for extended release: 30 tablet/30 days **AND**

5. Patient has had an adequate trial and failure of at least TWO NSAIDs (non-steroidal anti-inflammatory drug) each used for a duration of at least four weeks **AND**
6. Patient has failed to achieve symptom control after adequate therapy with, or has labeled contraindications to at least one of the following: Enbrel or Adalimumab* **AND**
7. Patient is not receiving Xeljanz/XR in combination with other biologic DMARDs **AND**
8. Prescribed by or in consultation with a rheumatologist

INITIAL APPROVALS

- ✓ * Please review formulary for current preferred adalimumab products. The trial of more than one preferred adalimumab product counts as one preferred product
- ✓ Prescriber attestation that labs/notes indicate patient has the disease or requires the medication
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided
- ✓ Patient is not receiving Xeljanz in combination with other biologic DMARDs
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Revised	Created based on previous MaxorPlus approved criteria, added to new template	7.2019
Update	Added preferred alternatives for UC	10.2019
Update	Added default denial message	12.2019
Update	Due to approval of Xeljanz XR in UC (previously only Xeljanz was approved for UC), Xeljanz XR has been added to Non-Preferred Step-2 for UC. Criteria are the same as for Xeljanz and direct the patient to the Preferred Product Step-1 product for UC (Humira). Xeljanz XR dose and direction has been updated. Reviewed under Jan' 2020 CAB meeting.	1.2020
Update	Added indication for JIA for Xeljanz immediate release (add to step 1)	12.2020
Update	Added indication for JIA for Xeljanz oral solution. Xeljanz oral solution dose and direction has been updated. Added default denial message.	3.2021
Annual Review	Update expanded indication; Added new diagnosis requirement to the criteria sections: Ankylosing Spondylitis.	1.2022
Update	Updated format/references	1.2023
Annual Review	Updated criteria for RA and PsA to include: patient has had an inadequate response or has labeled contraindications to at least one of the following non-biologic disease modifying anti-rheumatic drugs non-biologic (DMARDs): methotrexate or leflunomide; For AS: removed DMARDs requirement and updated criteria at least two NSAIDS based on guidelines; Removed negative TB test requirement; Updated denial message.	6.2023
Updated	UC: updated to trial of at least one agent, removed JAK/potent immunosuppressants, updated criteria to include trial of adalimumab, updated initial approval verbiage, created separate denial messages, and removed "completed by" in history section.	8.2023
Annual Review	Updated trial and failure wording; updated renewal section	6.2024

REFERENCE:

1. Xeljanz/Xeljanz XR (tofacitinib) [product monograph]. Kirkland, Quebec, Canada: Pfizer Canada ULC; May 2022.
2. Ringold S, Weiss PF, Beukelman T, et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. Arthritis Rheum. 2013;65(10):2499-2512.
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10. Ward MM, Deodhar A, Gensler LS, Dubreuil M, Yu D, Khan MA, Haroon N, Borenstein D, Wang R, Biehl A, Fang MA, Louie G, Majithia V, Ng B, Bigham R, Pianin M, Shah AA, Sullivan N, Turgunbaev M, Oristaglio J, Turner A, Maksymowych WP, Caplan L. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Care Res (Hoboken). 2019 Oct;71(10):1285-1299. doi: 10.1002/acr.24025. Epub 2019 Aug 21. PMID: 31436026; PMCID: PMC6764857.
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Prior Authorization Criteria for XELODA (capecitabine)

FDA-APPROVED INDICATIONS

- Colorectal cancer
  - Adjuvant treatment of patients with Stage III colon cancer as a single agent or as a component of a combination chemotherapy regimen.
  - Perioperative treatment of adults with locally advanced rectal cancer as a component of chemoradiotherapy.
  - Treatment of patients with unresectable or metastatic colorectal cancer as a single agent or as a component of a combination chemotherapy regimen.
- Breast cancer
  - Treatment of patients with advanced or metastatic breast cancer as a single agent if an anthracycline- or taxane-containing chemotherapy is not indicated.
  - Treatment of patients with advanced or metastatic breast cancer in combination with docetaxel after disease progression on prior anthracycline-containing chemotherapy.
- Gastric, Esophageal, or Gastroesophageal Junction cancer
  - Treatment of adults with unresectable or metastatic gastric, esophageal, or gastroesophageal junction cancer as a component of a combination chemotherapy regimen.
  - Treatment of adults with HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease as a component of a combination regimen.
- Pancreatic Cancer
  - Adjuvant treatment of adults with pancreatic adenocarcinoma as a component of a combination chemotherapy regimen.

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist.

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Annual Review	Updated duration to 1 year; updated criteria verbiage	5.2024

REFERENCE:

1. Xeloda [Prescribing Information] San Francisco, CA: Genentech, Inc; December 2022.

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Prior Authorization Criteria for XENAZINE® (tetrabenazine)

1. Patient has a diagnosis of chorea associated with Huntington's Disease **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: starting dose of 12.5 mg/day in the morning. After 1 week, the dose should be increased to 25 mg/day given as 12.5 mg twice a day. Then the dose should be slowly titrated at weekly intervals by 12.5 mg to a tolerated dose that reduces chorea. If a dose of 37.5 to 50 mg per day is needed, it should be given in a three times a day regimen **AND**
4. Quantity requested does not exceed: 50 mg/day (60 tablets/30 days) with a maximum single dose of 25mg **AND**
5. Patient does not have <u>any</u> of the labeled contraindications:
    a. Taking monoamine oxidase inhibitor (MAOI) or reserpine **OR**
    b. Taking deutetrabenazine or valbenazine **OR**
    c. Hepatic impairment **OR**
    d. Actively suicidal, or who have depression which is untreated or undertreated **AND**
6. For brand medication: patient has had an adequate trial of generic tetrabenazine **AND**
7. Prescribing physician is a Neurologist and is enrolled in the REMS program.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 12 weeks

RENEWALS

✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Reviewed	Reviewed	3.2017
Reviewed	Reviewed	3.2018
Updated	Removed an indication and updated renewal Updated to new format	2.2020
Annual review	No Change	2.2021
Annual review	No Change	2.2022
Annual review	Updated dosage and criteria requirement if request is for brand medication.	2.2023
Annual Review	Updated criteria to include "patient does not have any of the labeled contraindications" and updated format.	2.024

REFERENCE:

1. Melissa J. Armstrong, MD, MSc and Janis M. Miyasaki, MD, MEd, FAAN. *American Academy of Neurology. Evidence-based guideline: Pharmacologic treatment of chorea in Huntingon Disease. Neurology. 2012;89(5):597-603*
2. Godwin-Austen RB, Clark T. Persistent phenothiazine dyskinesia treated with tetrabenazine. *Br Med J.* 1971;4(5778):25-26.[PubMed 4938245]
3. Kazamatsuri H, Chien C, Cole JO. Treatment of tardive dyskinesia. I. Clinical efficacy of a dopamine-depleting agent, tetrabenazine. *Arch Gen Psychiatry.* 1972;27(1):95-99.[PubMed 4555831]
4. Lubbe WF and Walker EB, "Chorea Gravidarum Associated With Circulating Lupus Anticoagulant Successful Outcome of Pregnancy With Prednisone and Aspirin Therapy. Case Report," *Br J Obstet Gynaecol*, 1983, 90(5):487-90.[PubMed 6405781]
5. Nitoman (tetrabenazine) [product monograph]. Laval, Quebec, Canada: Valeant Canada LP; March 2011.
6. Ondo WG, Hanna PA, and Jankovic J, "Tetrabenazine Treatment for Tardive Dyskinesia: Assessment by Randomized Videotape Protocol," *Am J Psychiatry*, 1999, 156(8):1279-81.[PubMed 10450276]
7. Xenazine (tetrabenazine) tablets [prescribing information]. Deerfield, IL: Lundbeck; June 2022.

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Prior Authorization Criteria for XENLETA™ (lefamulin)

1. Patient has diagnosis of community-acquired bacterial pneumonia (CABP) caused by susceptible microorganisms **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 150 mg every 12 hours by intravenous infusion over 60 minutes for 5 to 7 days or 600 mg orally every 12 hours for 5 days **AND**
4. Quantity requested does not exceed:
    a. Injections: 14 vials/7 days;
    b. Tablets: 10 tablets/5 days **AND**
5. Confirm diagnosis of CABP via chest x-ray/radiograph **AND**
6. Bacteria culture and sensitivity tests are provided to show infection is caused by any of the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible isolates), Haemophilus influenzae, Legionella pneumoniae, Mycoplasma pneumoniae,* or *Chlamydophila pneumonia* **AND**
7. Patient has tried and failed at least two generic antibiotics for CABP such as azithromycin, moxifloxacin, etc. **AND**
8. Patient does not have any of the following:
    a. Patient is not concomitantly using any other CYP3A substrates that prolong the QT interval (contraindication) **OR**
    b. Patient must not be pregnant or breastfeeding **AND**
9. Prescribed by or in consultation with an Infectious Disease (ID) specialist.

INITIAL APPROVALS

- ✓ Chest X-ray, bacteria culture, and susceptibility test result confirms diagnosis
- ✓ Initial authorization will be granted for one-time approval.

RENEWALS

- ✓ Renewal authorization will be granted for one-time approval for oral if IV therapy was initiated in the hospital.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2018
Annual Review	No Change	8.2019
Update	Add Denial Message/Update Criteria	2.2020
Annual Review	No Change	8.2021
Annual Review	No Change	8.2022
Annual Review	Added to criteria: Patient is not concomitantly using any other CYP3A and patient is not pregnant or breast-feeding.	8.2023
Annual Review	No Change	2.2024

REFERENCE:

1. Xenleta (lefamulin) [prescribing information]. King of Prussia, PA: Nabriva Therapeutics US, Inc; June 2021
2. File TM. Treatment of community-acquired pneumonia in adults who require hospitalization. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed August 21, 2019.
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Prior Authorization Criteria for XERMELO (telotristat ethyl)

1. Patient has diagnosis of carcinoid syndrome diarrhea **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 250 mg three times daily **AND**
4. Quantity requested does not exceed: 90 tablets/30 days **AND**
5. Patient's diarrhea is inadequately controlled by somatostatin analog therapy **AND**
6. Requested medication is being used in combination with somatostatin analog therapy **AND**
7. Prescribed by or in consultation with an oncologist or gastroenterologist

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 12 months.

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided
- ✓ Approval duration for renewal: 12 months.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual review	Updated initial approval duration to 12 months	2.2024

REFERENCE:

1. Xermelo (telotristat ethyl). [Prescribing Information}. The Woodlands, TX: Lexicon Pharmaceuticals, Inc. March 2017.

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Prior Authorization Criteria for XIFAXAN® (rifaximin)

INDICATIONS

- Travelers' Diarrhea
- Hepatic Encephalopathy (HE)
- Irritable Bowel Syndrome with Diarrhea (IBS-D)
- **Small Intestinal Bacterial Overgrowth (SIBO) – *off label*

Diagnosis: for Travelers' Diarrhea

1. Patient has diagnosis of Travelers' Diarrhea caused by non-invasive strains of *Escherichia coli* **AND**
2. Patient is 12 years of age or older **AND**
3. Dosage and direction of use: 200 mg 3 times daily for 3 days **AND**
4. Quantity requested does not exceed: max dose of 9 tablets/3 days
5. Patient has tried and failed or has a contraindication to fluoroquinolones OR azithromycin **AND**
6. Strength requested is 200mg tablet (Only 200mg Xifaxan is indicated for travelers' diarrhea)

Diagnosis: for Hepatic Encephalopathy (HE)

1. Patient has a diagnosis of Hepatic Encephalopathy (HE) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 550 mg tablet 2 times a day **AND**
4. Quantity requested does not exceed: max dose of 2 tablets/day **AND**
5. Patient had a second HE episode despite receiving lactulose therapy **OR** patient was intolerant to or has a contraindication to lactulose **AND**
6. Strength requested is 550mg tablet

Diagnosis: for Irritable Bowel Syndrome with Diarrhea (IBS-D)

1. Patient has diagnosis of Irritable Bowel Syndrome with Diarrhea (IBS-D) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 550 mg tablet 3 times a day for 14 days (patients who experience recurrence can be retreated up to two times with the same regimen) **AND**
4. Quantity requested does not exceed: max dose: 42 tablets/14 days **AND**
5. Patient has tried and failed/was intolerant to two of the following medications or has a contraindication to all of the following medications:
    a. Anti-diarrheal agent (e.g., loperamide, diphenoxylate-atropine)
    b. Antispasmodic agent (e.g., dicyclomine, hyoscyamine)
    c. Bile acid sequestrants (e.g., cholestyramine, colestipol)
    d. Tricyclic antidepressants (e.g., amitriptyline)
6. Strength requested is 550mg tablet

**Diagnosis: Small Intestinal Bacterial Overgrowth (SIBO) *(Off-label)*

1. Patient has diagnosis Small Intestinal Bacterial Overgrowth (SIBO) confirmed by positive breath testing (glucose hydrogen or lactulose hydrogen) **AND**
2. Patient is 3 years of age or older **AND**
3. Dosage and direction of use:
    a. Children <u>3 years old to less than 8 years old</u>: 200 mg tablet 3 times a day for 7-14 days
    b. Children <u>8 years old and adolescents</u>: 200 to 550 mg 3 times daily for 7 to 14 days
    c. Adult patients (≥ 18 years and older): 550 mg tablet 3 times a day for 14 days
    d. Patients who experience recurrence can be retreated up to two times with the same regimen **AND**
4. Quantity requested does not exceed: max dose: 42 tablets/14 days **AND**

5. Patient has tried and failed/was intolerant to or has a contraindication to any of the following:
    a. Dietary change (i.e., low FODMAP, gluten-free diets)
    b. Antibiotics (e.g., ciprofloxacin, metronidazole, trimethoprim-sulfamethoxazole, amoxicillin/clavulanic acid)

INITIAL APPROVALS

Diagnosis: for Travelers' Diarrhea

- ✓ Initial authorization will be granted for one-time approval
- ✓ Quantity Limit: 9 tabs/3 days

Diagnosis: for Hepatic Encephalopathy (HE)

- ✓ Initial authorization will be granted for a period of 1 year
- ✓ Quantity Limit: 2 tabs/day

Diagnosis: for Irritable Bowel Syndrome with Diarrhea (IBS-D)

- ✓ Initial authorization will be granted one time approval. Patients who experience recurrence can be retreated up to two times with the same regimen
- ✓ Quantity Limit: 3 tabs/day

Diagnosis: Small intestinal bacterial overgrowth (SIBO)

- ✓ Initial authorization will be granted one time approval. Patients who experience recurrence can be retreated up to two times with the same regimen
- ✓ Quantity Limit: 3 tabs/day

RENEWALS

Diagnosis: for Travelers' Diarrhea

- ✓ Renewals for same episode of traveler's diarrhea are not allowed. Review initial criteria for new cases of traveler's diarrhea.

Diagnosis: for Hepatic Encephalopathy (HE)

- ✓ Renewal authorization will be granted for a period of 1 year

Diagnosis: for Irritable Bowel Syndrome with Diarrhea (IBS-D)

- ✓ Renewal authorization will be granted one-time approval. Patients who experience recurrence can be retreated up to two times with the same regimen.
- ✓ Quantity Limit: 3 tabs/day

Diagnosis: Small intestinal bacterial overgrowth (SIBO)

- ✓ Renewal authorization will be granted one time approval. Patients who experience recurrence can be retreated up to two times with the same regimen
- ✓ Quantity Limit: 3 tabs/day

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	3.2017
Updated	Update to new format; Update References	9.2019
Updated	Added default denial messages; Updated approval quantity limit	2.2020
Annual Review	No change	2.2021

Annual Review	No change	2.2022
Reviewed	Updated: include Small intestinal bacterial overgrowth (SIBO)	4.2022
Annual Review	Updated criteria for HE section to include: patient had a second HE episode despite receiving lactulose therapy.	5.2023
Annual Review	Updated traveler's diarrhea requirement to t/f of azithromycin or fluoroquinolone due to antibiotic resistance; updated renewal criteria for traveler's diarrhea	1.2024

REFERENCE:

1. Xifaxan (rifaximin) [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals Inc; October 2020.
2. Zar T, Graeber C, Perazella MA. Recognition, treatment, and prevention of propylene glycol toxicity. Semin Dial. 2007;20(3):217-219.[PubMed 17555487]
3. Pimentel M, Morales W, Chua K, et al. Effects of rifaximin treatment and retreatment in nonconstipated IBS subjects. Dig Dis Sci. 2011;56(7):2067-2072. doi: 10.1007/s10620-011-1728-5.[PubMed 2155974
4. Phongsamran PV, Kim JW, Cupo Abbott J, et al, "Pharmacotherapy for Hepatic Encephalopathy," Drugs, 2010, 70(9):1131-48.[PubMed 20518580]
5. Scarpellini E, Giorgio V et al. Rifaxamin Treatment for Small Intestinal Bacterial Overgrowth in Children with Irritable bowel Syndrome: A Preliminary Study. European Review for Medical and Pharmacological Sciences, 2013; 17: 1314 – 1320.
6. Shah SC et al. Meta-analysis: Antibiotic Therapy for Small Intestinal bacterial Overgrowth. Aliment Pharmacol Ther. 2013 October; 38(8): . doi:10.1111/apt.12479
7. Chang L, Sultan S, Lembo A, Verne GN, Smalley W, Heidelbaugh JJ. AGA Clinical Practice Guideline on the Pharmacological Management of Irritable Bowel Syndrome With Constipation. Gastroenterology. 2022;163(1):118-136. doi:10.1053/j.gastro.2022.04.016
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9. Vilstrup H, Amodio P, Bajaj J, et al. Hepatic encephalopathy in chronic liver disease: 2014 Practice Guideline by the American Association for the Study of Liver Diseases and the European Association for the Study of the Liver. Hepatology. 2014;60(2):715-735. doi:10.1002/hep.27210
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11. Hudson M, Schuchmann M. Long-term management of hepatic encephalopathy with lactulose and/or rifaximin: a review of the evidence. Eur J Gastroenterol Hepatol. 2019 Apr;31(4):434-450. doi: 10.1097/MEG.0000000000001311. PMID: 30444745; PMCID: PMC6416096.
12. Fallahzadeh MA, Rahimi RS. Hepatic Encephalopathy: Current and Emerging Treatment Modalities. Clin Gastroenterol Hepatol. 2022 Aug;20(8S):S9-S19. doi: 10.1016/j.cgh.2022.04.034. PMID: 35940731.

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Prior Authorization Criteria for XOLAIR® (omalizumab)

FDA-APPROVED INDICATIONS

- Moderate to severe persistent asthma in patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids
- Chronic idiopathic urticaria in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment
- Nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment
- Reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy.

Diagnosis: moderate to severe persistent asthma

1. Patient has diagnosis of moderate to persistent asthma **AND**
2. Patient is 6 years of age and older **AND**
3. Dosage and direction of use: for both adult and pediatric patient: 75 to 375 mg Subcutaneously every 2 or 4 weeks (dose and dosing frequency is determined by pre-treatment serum total IgE level and body weight); **AND**
4. Quantity requested does not exceed: 375mg every 2 weeks (may vary depending on package) **AND**
5. Patient has documentation that demonstrates moderate to severe persistent asthma defined by:
    - Hospitalization or emergency visit for asthma;
    - Requirement of systemic corticosteroids to control asthma exacerbation(s)
    - Increase need (more than 4 times a day) for short-acting beta-2 agonists for symptoms (not used for prevention of exercised-induced asthma)
6. Documentation of positive skin test or in vitro reactivity to a perennial aeroallergen (e.g. house dust mite, animal dander, cockroach, feathers, mold spores) **AND**
7. Patient's asthma is inadequately controlled after 3 months of treatment with optimized doses of BOTH of the following:
    - Medium to high dose inhaled corticosteroids (e.g. QVAR, Pulmicort, Flovent, Arnuity Ellipta,)
    - A long-acting beta-agonist (e.g. Serevent), or leukotriene modifiers (e.g. Singulair, Zyflo) if LABA is contraindicated
8. Patient's pre-treatment serum IgE level (provide labs):
    - ≥12 years of age: between 30IU/mL to 700IU/mL
    - 6 to 12 years of age: between 30IU/mL to 1300IU/mL
9. Patient's current weight (kg) is provided **AND**
10. Patient will continue to use maintenance asthma treatments **AND**
11. Xolair is not prescribed concurrently with Cinqair, Fasenra, Nucala, Tezspire, or Dupixent **AND**
12. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist

Diagnosis: Chronic idiopathic urticaria (CIU)

1. Patient has a diagnosis of chronic idiopathic urticaria **AND**
2. Patient is 12 years of age or older **AND**
3. Dosage and direction of use: 150 or 300 mg subcutaneously every 4 weeks **AND**
4. Quantity requested does not exceed: 2 syringes (150mg/mL per syringe)/28 days **AND**
5. Patient has hives on most days of the week, for a duration of longer than 6 weeks **AND**
6. The requesting physician has documented that the patient remains symptomatic despite at least 2 weeks of treatment with a trial of each of the following regimens or documented history of contraindication or intolerance to:
    a. Second generation H1-antihistamine (e.g. loratadine, fexofenadine, cetirizine, levocetirizine, etc);
    b. Second generation H1-antihistamine plus a leukotriene receptor antagonist (e.g. Singulair, Zyflo) or H2-antihistamine (famotidine, ranitidine and cimetidine) or 1st generation antihistamine

(e.g.hydroxyzine, chlorpheniramine) **AND**

7. Prescribed by or in consultation with a dermatologist, immunologist, or allergist.

Diagnosis: Nasal Polyps

1. Patient has a diagnosis of nasal polyps **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: 75 to 600 mg subcutaneously every 2 or 4 weeks based on serum total IgE level (IU/mL) before the start of treatment and by body weight **AND**
4. Quantity requested does not exceed: 4 syringes (150mg/mL per syringe)/28 days **AND**
5. Patient has bilateral polyps as determined by a nasal polyp score (NPS) ≥ 5 with NPS ≥ 2 in each nostril **AND**
6. Patient has two or more of the following symptoms for 12 weeks or more:
    a. Nasal blockage/congestion
    b. Nasal discharge
    c. Facial pain/pressure
    d. Reduction of smell **AND**
7. Patient remains symptomatic despite a 2 month trial of nasal corticosteroids (i.e., fluticasone, mometasone) AND nasal saline irrigation **AND**
8. Patient is currently on and will continue current maintenance therapy with intranasal corticosteroids, unless contraindicated **AND**
9. Xolair is not prescribed concurrently with Cinqair, Fasenra, Nucala, Tezspire, or Dupixent **AND**
10. Prescribed by or in consultation with an immunologist, otolaryngologist, or allergist

Diagnosis: Food Allergies

1. Patient has a diagnosis of IgE-mediated food allergy **AND**
2. Patient is 1 year of age or older **AND**
3. Dosage and direction of use: 75 mg to 600 mg subcutaneously every 2 or 4 weeks based on serum total IgE level before the start of treatment and by body weight **AND**
4. Quantity requested does not exceed: 4 syringes (150mg/mL per syringe)/28 days **AND**
5. Patient has one or more demonstrated food allergies through positive skin prick test or positive serum IgE **AND**
6. Requested medication is being used in conjunction to a diet that avoids food allergens **AND**
7. Requested medication is not being used concomitantly with Palforzia **AND**
8. Prescribed by or in consultation with an allergist or immunologist

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 1 year

RENEWALS

✓ Documentation of positive clinical response to therapy has been provided **AND**
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Reviewed	Reviewed	3.2017
Reviewed	Reviewed	3.2018
Revised	Included definition of moderate to severe persistent asthma; recommended dosing; added examples for formulary alternatives & specialist requirement	8.2019
Update	Add Denial Message	1.2020
Update	Updated PA criteria	7.2021
Update	Updated clinical criteria for severe persistent asthma to include: Xolair is not prescribed concurrently with Cinqair, Fasenra, Nucala, or Dupixent	5.2022

Annual Review	Asthma: Added trial and failure duration and dosing requirements; added requirement to continue maintenance therapy Nasal polyps: added trial duration, diagnosis requirements, specialist, and not prescribed concurrently with other biologics	5.2023
Annual Review	Added new indication of food allergies; updated initial approval duration to 1 year for chronic sinusitis and CIU	4.2024

REFERENCE:

1. Buhl R, Soler M, Matz J, et al. Omalizumab provides long-term control in patients with moderate-to-severe allergic asthma. Eur Respir J 2002;20:73-78.
2. Busse W, Corren J, Lanier BQ, et al. Omalizumab, anti-IgE recombinant humanized monoclonal antibody, for the treatment of severe allergic asthma. J Allergy Clin Immunol 2001;108:184-90.
3. Maurer M, Magrel M, Metz M, et al. Revision to the international guidelines on the diagnosis and therapy of chronic urticarial. JDDG: Journal der Deutschen Dermatologischen Gesellschaft 2013;11:971-978
4. National Heart, Lung and Blood Institute, National Asthma Education and Prevention Program: Expert Panel Report 3. Guidelines for the Diagnosis and Management of Asthma.
5. Xolair (omalizumab) [prescribing information]. San Francisco, CA: Genentech Inc; September 2018.
6. Bhattacharyya N, Villeneuve S, Joish VN, et al. Cost burden and resource utilization in patients with chronic rhinosinusitis and nasal polyps. Laryngoscope. 2019;129(9):1969–1975. doi:10.1002/lary.27852
7. Hamilos DL, Holbrook EH. Chronic rhinosinusitis: clinical manifestations, pathophysiology, and diagnosis. In: Peters AT, Deschler DG, Feldweg AM, eds. UptoDate. Waltham, MA: UpToDate. Updated November 30, 2020. Accessed July 7, 2021. https://www.uptodate.com/contents/chronic-rhinosinusitis-clinical-manifestations-pathophysiology-anddiagnosis
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9. Orlandi RR, Kingdom TT, et al. International consensus statement on allergy and rhinology: rhinosinusitis 2021. Int Forum Allergy Rhinol. 2021 Mar;11(3):213-739.
10. Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et al. Clinical practice guideline (update): adult sinusitis. Otolaryngol Head Neck Surg. 2015;152(2 Suppl):S1–S39. doi:10.1177/0194599815572097
11. Global Initiative for Asthma: Global strategy for asthma management and prevention (2023 update). Available at: https://ginasthma.org/wp-content/uploads/2023/05/GINA-2023-Full-Report-2023-WMS.pdf/. Accessed May 24, 2023.

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Prior Authorization Criteria for XOLREMDI™ (mavorixafor)

1. Patient has a diagnosis of WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis) confirmed by genotype variant of CXCR4 and ANC < 400 cells/µL **AND**
2. Patient is 12 years of age or older **AND**
3. Dosage and Direction for Use:
    a. Weight > 50 kg: 400 mg orally once daily **OR**
    b. Weight ≤ 50 kg: 300 mg orally once daily **AND**
4. Quantity requested does not exceed: 4 capsules/day for wt > 50kg and 3 capsules/day for wt < 50kg **AND**
5. Confirm the patient is not pregnant **AND**
6. Confirm the patient is not concurrently using a CXCR4 antagonist (Mozobil (plerixafor)) **AND**
7. Prescribed by or in consultation with a specialist such as an immunologist or hematologist.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Documentation or claim data supports continuation of treatment
✓ Patient is responding positively to therapy
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 5.30.2024	5.2024

REFERENCE:

1. Xolremdi (mavorixafor) [prescribing information]. Boston, MA: X4 Pharmaceuticals, Inc.; April 2024.

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Prior Authorization Criteria for XOSPATA (gilteritinib)

FDA-Approved Indications

- Treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated duration of approval; added FDA approved dx and age; added indication section	5.2024

REFERENCE:

1. XOSPATA [Prescribing Information]. Northbrook, IL. Astellas Pharma US, Inc: January 2022.

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Prior Authorization Criteria for XTANDI® (enzalutamide)

FDA-Approved Indications

- Treatment of patients with castration-resistant prostate cancer
- Treatment of patients with metastatic castration-sensitive prostate cancer
- Treatment of patients with non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis

1. Patient has an FDA approved diagnosis **AND**
2. Patient is 18 years of age or older **AND**
3. Requested medication follows appropriate sequence of therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
- ✓ Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy")
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 3.25.21	3.2021
Annual Review	No Changes	3.2022
Annual Review	No Changes	3.2023
Annual Review	Updated criteria verbiage based on package insert and NCCN guidelines and format	3.2023
Annual Review	Updated criteria based on package insert and NCCN guidelines, and updated initial and renewal duration of therapy	3.2024

REFERENCE:

1. Armstrong AJ, Szmulewitz RZ, Petrylak DP, et al. ARCHES: a randomized, phase III study of androgen deprivation therapy with enzalutamide or placebo in men with metastatic hormone-sensitive prostate cancer. *J Clin Oncol.* 2019;37(32):2974-2986. doi: 10.1200/JCO.19.00799.[PubMed 31329516]
2. Basch E, Loblaw DA, Oliver TK, et al. Systemic Therapy in Men With Metastatic Castration-Resistant Prostate Cancer: American Society of Clinical Oncology and Cancer Care Ontario Clinical Practice Guideline. *J Clin Oncol*. 2014;32(30):3436-3448. doi: JCO.2013.54.8404[PubMed 25199761]
3. Beer TM, Armstrong AJ, Rathkopf DE, et al; PREVAIL Investigators. Enzalutamide in metastatic prostate cancer before chemotherapy. *N Engl J Med*. 2014;371(5):424-433. doi:10.1056/NEJMoa1405095.[PubMed 24881730]
4. Hussain M, Fizazi K, Saad F, et al. Enzalutamide in men with nonmetastatic, castration-resistant prostate cancer. *N Engl J Med*. 2018;378(26):2465-2474. doi:10.1056/NEJMoa1800536.[PubMed 29949494]
5. Kalra D, Tesfazghi M. Falsely elevated digoxin levels in patients on enzalutamide. *Circ Heart Fail*. 2020;13(7):e007008. doi:10.1161/CIRCHEARTFAILURE.120.007008[PubMed 32527146]
6. Levine GN, D'Amico AV, Berger P, et al. Androgen-deprivation therapy in prostate cancer and cardiovascular risk: a science advisory from the American Heart Association, American Cancer Society, and American Urological Association: endorsed by the American Society for Radiation Oncology. *Circulation.* 2010;121(6):833-840.[PubMed 20124128]
7. Scher HI, Fizazi K, Saad F, et al. Increased survival with enzalutamide in prostate cancer after chemotherapy. *N Engl J Med.* 2012;367(13):1187-1977.[PubMed 22894553]

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9. National Comprehensive Cancer Network. Prostate Cancer (Version 4.2024). https://www.nccn.org/professionals/physician_gls/pdf/prostate_blocks.pdf Accessed February 29, 2024
10. Xtandi (enzalutamide) [prescribing information]. Northbrook, IL: Astellas Pharma US Inc; October 2020.
11. Xtandi (enzalutamide) [product monograph]. Markham, Ontario, Canada: Astellas Pharma Canada, Inc; June 2020.

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Prior Authorization Criteria for XURIDEN® (uridine triacetate)

1. Patient has a diagnosis of hereditary orotic aciduria **AND**
2. Dosage and direction of use: 60 mg/kg once daily. Dose may be increased based on efficacy **AND**
3. Quantity requested does not exceed: 8 gm/day **AND**
4. Prescribed by or in consultation with a metabolic disease specialist or geneticist

INITIAL APPROVALS

- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated approval duration to 1 year	2.2024

REFERENCE:

1. Xuriden (uridine tiracetate). [Prescribing information]. San Diego, CA: Travere Therapeutics. May 2021.

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Prior Authorization Criteria for YARGESA, ZAVESCA® (miglustat)

1. Patient has a diagnosis of mild to moderate type 1 Gaucher Disease **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: 100 mg orally three times a day at regular intervals. May reduce dosage to 100 mg once or twice a day in some patients due to tremor or diarrhea **AND**
4. Quantity requested does not exceed: 90/30 days **AND**
5. Disease is confirmed by enzyme assay demonstrating a deficiency of beta- glucocerebrosidase (glucosidase) enzyme activity OR by genetic testing **AND**
6. Patient is symptomatic (e.g., anemia, thrombocytopenia, bone disease, hepatomegaly, splenomegaly) **AND**
7. Patient has a documented inadequate response or a clinical reason where enzyme replacement therapy is not a therapeutic option (e.g., allergy, hypersensitivity, poor venous access) **AND**
8. Requested medication is being used as monotherapy **AND**
9. Prescribed by or in consultation with a specialist such as an endocrinologist or a physician that specializes in the treatment of Gaucher disease.

INITIAL APPROVALS

- ✓ Initial approval will be granted for a period of 1 year
- ✓ Brand name may be subject to formulary exclusions

RENEWALS

- ✓ Documentation of clinical response to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Added requested medications is being used as monotherapy	3.2024

REFERENCE:

1. Charrow J, Andersson HC, Kaplan P. Enzyme replacement therapy and monitoring for children with type 1 Gaucher disease: consensus recommendations. J Pediatr. 2004; 144: 112-20.
2. Gary SE, Ryan E, Steward AM, Sidransky E. Recent advances in the diagnosis and management of Gaucher disease. Expert Rev Endocrinol Metab. 2018 Mar;13(2):107-118. doi: 10.1080/17446651.2018.1445524. Epub 2018 Mar 12. PMID: 30058864; PMCID: PMC6129380.
3. Hollak, CEM, Weinreb NJ. The attenuated/late onset lysosomal storage disorders: therapeutic goals and indications for enzyme replacement treatment in Gaucher and Fabry disease. Best Pract Res Clin Endocrinol Metab. 2015; 29: 205-218.
4. M.Á. Torralba-Cabeza, M. Morado-Arias, A. Pijierro-Amador, M.C. Fernández-Canal, J. Villarrubia-Espinosa, Recommendations for oral treatment for adult patients with type 1 Gaucher disease, Revista Clínica Española (English Edition), Volume 222, Issue 9, 2022, Pages 529-542.
5. Andersson HC, Charrow J, Kaplan P, et al. Individualization of long-term enzyme replacement therapy for Gaucher disease. Genet Med. 2005; 7(2): 105-110.
6. Zavesca (miglustat) [prescribing information]. Titusville, NJ: Actelion Pharmaceuticals US Inc; August 2022.

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Prior Authorization Criteria for YCANTH™ (cantharidin)

1. Patient has a diagnosis of molluscum contagiosum **AND**
2. Patient is 2 years and older **AND**
3. Dosage and Direction for Use: Apply a single application directly to each lesion every 3 weeks as needed **AND**
4. Quantity requested does not exceed: Do not use more than two applicators during a single treatment session **AND**
5. Patient has had an adequate trial of an alternative therapy (e.g., salicylic acid, hydrogen peroxide, retinoids, potassium hydroxide, silver nitrate, imiquimod, and cantharidin) **AND**
6. Prescribed by or in consultation with a specialist such as a dermatologist.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 8.24.2023	8.2023
Annual review	No changes	2.2024

REFERENCE:

1. Ycanth (cantharidin) [prescribing information]. West Chester, PA: Verrica Pharmaceuticals Inc; July 2023.
2. Vakharia PP, Chopra R, Silverberg NB, Silverberg JI. Efficacy and Safety of Topical Cantharidin Treatment for Molluscum Contagiosum and Warts: A Systematic Review. Am J Clin Dermatol. 2018 Dec;19(6):791-803. [PubMed]
3. Leslie KS, Dootson G, Sterling JC. Topical salicylic acid gel as a treatment for molluscum contagiosum in children. J Dermatolog Treat. 2005;16(5-6):336-40. doi: 10.1080/09546630500430521. PMID: 16428156.
4. Badri T, Gandhi GR. Molluscum Contagiosum. [Updated 2023 Mar 27]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK441898/

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Prior Authorization Criteria for YUPELRI® (revefenacin)

1. Patient has a diagnosis for chronic obstructive pulmonary disease (COPD) **AND**
2. Patient must be 18 years of age or older **AND**
3. Dosage and direction of use: one 175 mcg vial (3ml) once daily with a standard jet nebulizer with a mouthpiece connected to an air compressor **AND**
4. Quantity requested does not exceed: 30 doses (90ml)/month **AND**
5. Patient has tried and failed two handheld LAMAS (i.e., Spiriva, Incruse, Tudorza, or Seebri)

INITIAL APPROVALS

✓ Initial approval will be for a period of 1 year.

RENEWALS

✓ May renew in up to 1 year intervals when the current chart notes, and other pertinent information demonstrate patient has experienced a positive response.

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Revised	Created	7.2019
Update	Update Format/Add Denial Message	7.2020
Annual Review	No change	7.2021
Annual Review	No change	7.2022
Annual Review	Updated reference	7.2023
Annual Review	Updated diagnosis wording	1.2024

REFERENCE:

1. Pudi KK, Barnes CN, Moran EJ, Haumann B, Kerwin E. A 28-day, randomized, double-blind, placebo-controlled, parallel group study of nebulized revefenacin in patients with chronic obstructive pulmonary disease. Respir Res. 2017;18(1):182. doi: 10.1186/s12931-017-0647-1.[PubMed 29096627]
2. Quinn D, Barnes CN, Yates W, et al. Pharmacodynamics, pharmacokinetics and safety of revefenacin (TD-4208), a long-acting muscarinic antagonist, in patients with chronic obstructive pulmonary disease (COPD): Results of two randomized, double-blind, phase 2 studies. Pulm Pharmacol Ther. 2018;48:71-79. doi: 10.1016/j.pupt.2017.10.003.[PubMed 28987804]
3. Yupelri (revefenacin) [prescribing information]. Morgantown, WV: Mylan Specialty L.P; May 2022.

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Prior Authorization Criteria for ZEJULA (niraparib)

FDA Indications

- Maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy
- Maintenance treatment of adult patients with deleterious or suspected deleterious germline *BRCA*-mutated (g*BRCA*mut) recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	7.2023
Annual Review	Updated duration of approval; added FDA approved age	5.2024

REFERENCE:

1. ZEJULA [Prescribing Information]. Durham, NC. GlaxoSmithKline: April 2023.

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Prior Authorization Criteria for ZELBORAF (vemurafenib)

FDA Indications

- Treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test
- Treatment of patients with Erdheim-Chester Disease (ECD) with BRAF V600 mutation

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate for diagnosis **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year.

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated duration and criteria.	5.2024

REFERENCE:

1. Zelboraf. [Prescribing Information]. San Francisco, CA. Genentech: May 2020.

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Prior Authorization Criteria for ZEPOSIA® (ozanimod)

FDA-APPROVED INDICATIONS

- Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults
- Moderately to severely active ulcerative colitis (UC) in adults.

Diagnosis: Multiple Sclerosis

1. Patient has diagnosis of relapsing forms of multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use: initial dose (a 7-day titration): days 1-4: 0.23 mg (one capsule) once daily, days 5-7: 0.46 mg (one capsule) once daily. Maintenance dose: after 7 days: 0.92 mg once daily
   Dose Titration Regimen:

Days	Recommended Dose
Days 1-4	0.23 mg once daily
Days 5-7	0.46 mg once daily
Day 8 and thereafter	0.92 mg once daily

4. Quantity requested does not exceed: 0.92 mg (one capsule/ day) **AND**
5. Confirm patient is not currently pregnant **AND**
6. Zeposia will not be used in combination with any other disease-modifying therapy for MS **AND**
7. Physician attestation that patient does **not** have any of the following contraindications to treatment:
   - MI, unstable angina, stroke, TIA, decompensated heart failure that required hospitalization, or Class III or IV heart failure within the last 6 months **OR**
   - Presence of Mobitz type II second-degree or third degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker **OR**
   - Severe untreated sleep apnea **OR**
   - Concomitant use of a monoamine oxidase inhibitor **AND**
8. Prescribed by or in consultation with a specialist such as a neurologist.

Diagnosis: Moderately to severely active ulcerative colitis (UC)

1. Patient has diagnosis of moderately to severely active ulcerative colitis (UC) **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and direction of use:
   a. Initiate ZEPOSIA with a 7-day titration with the following schedule
      i. Days 1-4: 0.23 mg once daily
      ii. Days 5-7: 0.46 mg once daily
      iii. Day 8 and after: 0.92 mg once daily **AND**
   b. Note: If a dose is missed during the first 2 weeks of treatment, reinitiate treatment using the titration regimen.
4. Quantity requested does not exceed:
   a. 37 capsules/37 days with starter pack
   b. 0.92mg/daily (30 capsules/30 days for 0.92mg) **AND**
5. Patient has had an adequate trial and failure of at least ONE oral systemic agent (e.g., 6-mercaptopurine, azathioprine, methotrexate, cyclosporine, tacrolimus, corticosteroid (e.g., prednisone). A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis **AND**
6. Patient has failed to achieve symptom control after adequate treatment with, or has labeled contraindications to two of the following agents: Adalimumab *, Skyrizi SC, Stelara SC, and Zymfentra **AND**

7. Patient is not receiving requested medication in combination with other biologic DMARDs **AND**
8. Prescribed by or in consultation with a gastroenterologist.

INITIAL APPROVALS

- ✓ * For UC: Please review formulary for current preferred adalimumab products. The trial of more than one preferred adalimumab product counts as one preferred product.
- ✓ Initial authorization will be granted for a period of 1 year.

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided
- ✓ MS: Confirm patient is not on other disease modifying therapies for MS
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created from CAB 6.18.2020	6.2020
Update	Added Additional Criteria - Moderately to severely active ulcerative colitis; Updated Default Denial Message.	7.2021
Reviewed	Annual review: no change	8.2022
Update	Criteria update for ulcerative colitis (UC): Zeposia will be moving from Step 3B (requiring trial/failure of two Step 1 products) to Step 2 (requiring trial/failure of only one Step 1 product Humira OR Stelara).	1.2023
Update	Criteria update: for ulcerative colitis (UC), Zeposia will be moving from Step 2 (requiring trial/failure of one Step 1 product) to Step 3B (requiring trial/failure of two Step 1 products Humira AND Stelara); updated denial message.	6.2023
Update	Create one policy for UC and MS indications	6.2023
Update	Updated criteria for MS, removed ST requirement; For UC: updated verbiage to include “preferred Adalimumab medications” and updated denial message.	8.2023
Annual Review	UC indication: Added Zymfentra as trial and failure option; updated wording	5.2024
Update	UC indication: Added Skyrizi SC as trial and failure option	7.2024

REFERENCE:

1. Hatcher SE, Waubant E, Nourbakhsh B, Crabtree-Hartman E, Graves JS. Rebound syndrome in patients with multiple sclerosis after cessation of fingolimod treatment. JAMA Neurol. 2016;73(7):790-794. doi:10.1001/jamaneurol.2016.0826[PubMed 27135594]
2. Jamilloux Y, Néel A, Lecouffe-Desprets M, et al. Progressive multifocal leukoencephalopathy in patients with sarcoidosis. Neurology. 2014;82(15):1307-1313. doi:10.1212/WNL.0000000000000318[PubMed 24610328]
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7. Zeposia (ozanimod) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; November 2022.
8. Cohan S, Lucassen E, Smoot K, Brink J, Chen C. Sphingosine-1-phosphate: its pharmacological regulation and the treatment of multiple sclerosis: a review article. Biomedicines. 2020;8(7):227. doi:10.3390/biomedicines8070227[PubMed 32708516]
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10. Farez MF, Correale J, Armstrong MJ, et al. Practice guideline update summary: vaccine-preventable infections and immunization in multiple sclerosis: report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. 2019;93(13):584-594. doi:10.1212/WNL.0000000000008157[PubMed 31462584].
11. Tice JA, Chapman R, Kumar V, et al. Disease-Modifying Therapies for Relapse-Remitting and Primary-Progressive Multiple Sclerosis: Effectiveness and Value. Institute for Clinical and Economic Review, 2017.

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Prior Authorization Criteria for ZIEXTENZO® (pegfilgrastim-bmez)

FDA-Approved Indications:

- Prevention of Chemotherapy-Induced Neutropenia

Diagnosis: Prevention of Chemotherapy-Induced Neutropenia

1. Patient diagnosis of prophylaxis or treatment for chemotherapy induced febrile neutropenia **AND**
2. Dosage and Direction for Use:
   a. **Adults:** 6 mg SubQ once per chemotherapy cycle, beginning at least 24 hours after completion of chemotherapy. **Note:** Do not administer in the period between 14 days before and 24 hours after administration of cytotoxic chemotherapy.
   b. **Infants, Children, and Adolescents**: Weight based dosing is used for pediatric patients <45kg. Administer once per chemotherapy cycle, beginning at least 24 hours after completion of chemotherapy. Do not administer in the period between 14 days before and 24 hours after administration of cytotoxic chemotherapy.
      a. <10 kg: SubQ: 0.1 mg/kg (0.01 mL/kg)
      b. 10 to 20 kg: SubQ: 1.5 mg (0.15 mL)
      c. 21 to 30 kg: SubQ: 2.5 mg (0.25 mL)
      d. 31 to <45 kg: SubQ: 4 mg (0.4 mL)
      e. ≥45 kg: SubQ: 6 mg (0.6 mL) **AND**
3. Quantity requested does not exceed: Weight based dosage and direction **AND**
4. Confirm that plan covers MD administered medications. This is administered SubQ by a healthcare provider, but can be given at home with proper training **AND**
5. Patient is currently receiving or will be receiving myelosuppressive chemotherapy **AND**
6. Patient has a non-myeloid malignancy **AND**
7. Patient is not using in combination with another granulocyte colony-stimulating factor (G-CSF) **AND**
8. Prescribing provider is specialist such as an Oncologist.

INITIAL APPROVALS

- ✓ The dose is within FDA recommended dosing or dose is supported by compendia or medical literature.
- ✓ Initial approval will be granted for a period of 6 months

RENEWALS

- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created Criteria to combine all pegfilgrastim medications	2.2020
Updated	Updated Criteria to include new ST edits	12.2020
Updated	Updated Criteria based on ST edits	10.2021

Annual Review	updated NCCN guideline reference	10.2022
Updated	Updated criteria to include Stimufend, biosimilar to Neulasta, for Prevention of Chemotherapy-Induced Neutropenia; Combined Flynetra criteria to biosimilar document; Udenyca was added to diagnosis Hematopoietic Radiation Injury Syndrome per FDA package insert.	2.2023
Updated	Created separate criteria for Ziextenzo and Fulphila	8.2023
Annual Review	Updated NCCN guideline reference	10.2023

REFERENCE:

1. Fulphila (pegfilgrastim-jmdb) [prescribing information]. Rockford, IL: Mylan Institutional LLC; May 2021.
2. Fylnetra (pegfilgrastim-pbbk) [prescribing information]. Bridgewater, NJ: Amneal Pharmaceuticals Inc; May 2022.
3. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors. Version 1.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf
4. Neulasta (pegfilgrastim) [prescribing information]. Thousand Oaks, CA: Amgen Inc; March 2021.
5. Nyvepria (pegfilgrastim) [prescribing information]. Thousand Oaks, CA: Amgen Inc; June 2020.
6. Smith TJ, Bohlke K, Lyman GH, Carson KR, et al. Recommendations for the use of WBC growth factors: American Society of Clinical Oncology Clinical Practice Guideline Update. J Clin Oncol. 2015;33(28):3199- 3212
7. Stimufend (pegfilgrastim-fpgk) [prescribing information]. Lake Zurich, IL: Fresenius Kabi USA LLC; September 2022.
8. Udenyca (pegfilgrastim-cbqv) [prescribing information]. Redwood City, CA: Coherus BioSciences, Inc; June 2021.
9. Ziextenzo (pegfilgrastim-bmez) [prescribing information]. Princeton, NJ: Sandoz Inc; March 2021.

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Prior Authorization Criteria for ZOKINVY® (lonafarnib)

1. Patient has diagnosis of:
    - Hutchinson-Gilford progeria syndrome (HGPS) OR
    - Processing-deficient progeroid laminopathy (PL) with either:
        - Heterozygous LMNA mutation with progerin-like protein accumulation OR
        - Homozygous or compound heterozygous ZMPSTE24 mutations **AND**
2. Patient is 12 months of age or older **AND**
3. Dosage and direction of use: initial dose of 115 mg/m^2 twice daily with morning and evening meals. After 4 months, increase to 150 mg/m^2 twice daily **AND**
4. Quantity requested does not exceed: dose based on BSA (m^2) **AND**
5. For Hutchinson-Gilford progeria syndrome (HGPS): patient has documentation of genetic mutation in the *LMNA* gene as confirmed by a generic test **AND**
6. Patient has a BSA of at least 0.39 m^2 **AND**
7. Patient does not have overt renal, hepatic, or pulmonary disease or immune dysfunction **AND**
8. Requested dose is appropriate for patient's BSA **AND**
9. Prescribed by or in consultation with a specialist in progeria, genetics, or metabolic disorders

INITIAL APPROVALS

✓ Initial authorization will be granted for a period of 6 months

RENEWALS

✓ Documentation of positive clinical response to therapy has been provided (reduction in urine oxalate concentration) **AND**

✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 1.14.2020	1.2021
Annual Review	No Change	1.2022
Annual Review	Updated criteria to include patient has documentation of genetic mutation in the LMNA gene as confirmed by a generic test for Hutchinson-Gilford progeria syndrome (HGPS)	1.2023

REFERENCE:

1. Zokinvy (lonafarnib) [prescribing information]. Palo Alto, CA: Eiger BioPharmaceuticals Inc; November 2020.
2. Progeria Research Foundation. PRF by the numbers. Published September 30, 2020. Accessed November 24, 2020. https://www.progeriaresearch.org/wp content/uploads/2020/10/PRF-By-the-Numbers_-FINAL-October2020.pdf.
3. Gordon LB, Kleinman ME, Miller DT, et al. Clinical trial of a farnesyltransferase inhibitor in children with Hutchinson-Gilford progeria syndrome. Proc Natl Acad Sci U S A. 2012;109(41):16666-16671. doi:10.1073/pnas.1202529109.
4. Leuty R. Approval of pricey rare disease drug by Peninsula company has side benefit: Voucher it sells for $95 million. The Business Journals. Published November 23, 2020. Accessed December 1, 2020. https://www.bizjournals.com/sanfrancisco/news/2020/11/23/abbvie-abbv-eiger eigr-progeria-zokinvy-voucher.html
5. Gonzalo S, Kreienkamp R, Askjaer P. Hutchinson-Gilford Progeria Syndrome: a premature aging disease caused by LMNA gene mutations. Ageing Res Rev. 2017;33:18-29.
6. Harhouri K, Frankel D, Bartoli C, et al. An overview of treatment strategies for HutchinsonGilford Progeria syndrome. Nucleus 2018; 9(1):246-257. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5973194/pdf/kncl-09-01-1460045.pdf. Accessed December 22, 2022.

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Prior Authorization Criteria for ZOLINZA (vorinostat)

FDA-Approved Indications

- Treatment of cutaneous manifestations in patients with cutaneous T-cell lymphoma (CTCL) who have progressive, persistent or recurrent disease on or following two systemic therapies

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated to oncology template; updated duration to 1 year	5.2024

REFERENCE:

1. Zolinza (vorinostat). [Prescribing Information]. Rahway, NJ: Merck & Co., Inc. July 2022.

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Prior Authorization Criteria for ZORYVE® 0.3% foam (roflumilast)

1. Patient has a diagnosis of seborrheic dermatitis **AND**
2. Patient is 9 years and older **AND**
3. Dosage and Direction for Use: Apply a thin layer once daily to affected areas on skin and/or scalp **AND**
4. Quantity requested does not exceed: 60 gm/30 days **AND**
5. Patient has had an inadequate response to both of the following:
    a. Topical antifungal **AND**
    b. Topical corticosteroid or topical calcineurin inhibitor **AND**
6. Prescribed by or in consultation with a specialist such as a dermatologist.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Approval duration for renewal: 1 year
✓ Patient has a positive response to therapy (documentation provided)

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 1.11.2024	1.2024

REFERENCE:

1. Zoryve foam (roflumilast) [prescribing information]. Westlake Village, CA: Arcutis Biotherapeutics Inc; December 2023.

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Prior Authorization Criteria for ZORYVE CREAM™ (roflumilast)

FDA-Approved Indications

- ZORYVE 0.3% CREAM: topical treatment of plaque psoriasis, including intertriginous areas, in adult and pediatric patients 6 years of age and older
- ZORYVE 0.15% CREAM: Topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older.

Diagnosis: Plaque psoriasis (Zoryve 0.3% Cream only)

1. Patient has a diagnosis of plaque psoriasis **AND**
2. Patient is 6 years of age or older **AND**
3. Dosage and Direction for Use: Apply topically once daily to affected areas **AND**
4. Quantity requested does not exceed: 60 grams/30 days (the quantity will depend on the location of the affected area) **AND**
5. Patient has had an adequate trial of at least two topical therapies from different therapy classes (i.e., corticosteroids, calcipotriene, calcitriol, tazarotene, tacrolimus) for at least four weeks each **AND**
6. Prescribed by or in consultation with specialist such as a dermatologist.

Diagnosis: Atopic Dermatitis (Zoryve 0.15% Cream only)

1. Patient has a diagnosis of atopic dermatitis **AND**
2. Patient is 6 years of age or older **AND**
3. Dosage and Direction for Use: Apply topically once daily to affected areas **AND**
4. Quantity requested does not exceed: 60 grams/30 days (the quantity will depend on the location of the affected area) **AND**
5. Patient has had an adequate trial and failure of at least one topical calcineurin inhibitor or topical corticosteroid for at least 4 weeks **AND**
6. Prescribed by or in consultation with specialist such as a dermatologist.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Patient has a positive response to therapy (documentation provided)
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 8.25.2022	8.2022
Annual Review	Added t/f duration of therapy; Updated denial message	8.2023
Annual Review	Update age range to 6 years and older	11.2023
Annual Review	Added atopic dermatitis indication for Zoryve 0.15%; removed concomitant med requirements	7.2024

REFERENCE:

1. Zoryve (roflumilast) [prescribing information]. Westlake Village, CA: Arcutis Biotherapeutics Inc; July 2024.
2. Rachakonda TD, Schupp CW, Armstrong AW. Psoriasis prevalence among adults in the United States. J Am Acad Dermatol. 2014;70(3):512-516. doi:10.1016/j.jaad.2013.11.013

3. Ayala-Fontánez N, Soler DC, McCormick TS. Current knowledge on psoriasis and autoimmune diseases. Psoriasis (Auckl). 2016;(6):7-32. doi:10.2147/PTT.S64950
4. Elements CA, Korman NJ, Farley EF, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol. 2020;84(2):432-470. doi:10.1016/j.jaad.2020.07.087
5. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020;82(6):1445-1486. doi:10.1016/j.jaad.2020.02.044
6. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80(4):1029-1072. doi:10.1016/j.jaad.2018.11.057
7. Elmets C, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol. 2021;84:432-470.

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Prior Authorization Criteria for ZTALMY® (ganaxolone)

1. Patient has diagnosis of seizures **AND**
2. Patient is 2 years of age and older **AND**
3. Dosage and direction of use: Ztalmy should be gradually titrated according to the recommended schedules.
    a. **Dosage for patients weighing 28 kg or less:** the starting dosage is 6 mg/kg three times daily (18 mg/kg/day) up to a maximum dosage of 21 mg/kg three times daily (63 mg/kg/daily).

Titration schedule for patients weighing 28 kg or less

Dosage	Total Daily Dosage	Days
6 mg/kg three times daily	18 mg/kg/day	1 to 7
11 mg/kg three times daily	33 mg/kg/day	8 to 14
16 mg/kg three times daily	48 mg/kg/day	15 to 21
21 mg/kg three times daily	63 mg/kg/day	22 to ongoing

    b. **Dosage for patients weighing over 28 kg:** the starting dosage is 150 mg three times daily (450 mg daily) up to a maximum dosage of 600 mg three times daily (1,800 mg daily)

Titration schedule for patients weighing more than 28 kg

Dosage	mL per dose	Total daily dosage/Days
150 mg three times daily	3	450 mg for 1 to 7 days
300 mg three times daily	6	900 mg for 8 to 14 days
450 mg three times daily	9	1,350 mg for 15 to 21
600 mg three times daily	12	1,800 mg for 22 to ongoing

4. Quantity requested does not exceed: dose based on weight above. For patients weighing more than 28kg, the dose should not exceed 600 mg three times daily (1,800mg daily) or 1,080ml (~10 bottles)/30 days **AND**
5. Patient has confirmed CDKL5 deficiency based on genetic testing **AND**
6. Patient has tried at least two previous antiepileptic therapies (i.e., lamotrigine, levetiracetam, valproate, vigabatrin) **AND**
7. Prescribed by or in consultation with a specialist such as a neurologist.

INITIAL APPROVALS

✓ Initial approval will be granted for a period of 1 year

RENEWALS

✓ Documentation of positive clinical response to therapy has been proven such as confirmed sustained reduction in monthly seizure frequency compared to baseline
✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	PA criteria created based on CAB 6.30.2022	6.2022
Annual Review	No changes	6.2023
Annual Review	Updated initial approval duration and references	5.2024

REFERENCE:

1. Ztalmy prescribing information. Radnor, PA: Marinus Pharmaceuticals, Inc.; June 2023.
2. Marinus Pharmaceuticals, Inc. About ganaxolone. Accessed May 20, 2024. https://marinuspharma.com/science-pipeline/about-ganaxolone/
3. Symonds JD, Zuberi SM, Steward K, et al. Incidence and phenotypes of childhood-onset genetic epilepsies: a prospective population-based national cohort. Brain. 2019;142(8):2303-2318. doi:10.1093/brain/awz195
4. Jakimiec M, Paprocka J, Smigiel R. CDKL5 deficiency disorder—a complex epileptic encephalopathy. Brain Sci. 2020;10(2):107. doi:10.3390/brainsci10020107
5. National Organization for Rare Disorders. CDKL5 deficiency disorder. Accessed May 20, 2024. https://rarediseases.org/rare-diseases/cdkl5/
6. CDKL5 deficiency disorder. US National Library of Medicine: MedlinePlus. Accessed May 20,2024. https://medlineplus.gov/genetics/condition/cdkl5-deficiency-disorder/#frequency
7. Marinus Pharmaceuticals, Inc. Study of adjunctive ganaxolone treatment in children and young adults with CDKL5 deficiency disorder (Marigold). NLM identifier: NCT03572933. Accessed May 20, 2024. https://clinicaltrials.gov/ct2/show/NCT03572933

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Prior Authorization Criteria for ZURZUVAE® (zuranolone)

1. Patient has a diagnosis of moderate to severe postpartum depression **AND**
2. Patient is 18 years of age or older **AND**
3. Dosage and Direction for Use: 50 mg (two 25 mg capsules) orally once daily in the evening for 14 days **AND**
4. Quantity requested does not exceed: 28 capsules/14 day **AND**
5. Patient is less than 12 months postpartum **AND**
6. Prescribed by or in consultation with a psychiatrist or OB/GYN

INITIAL APPROVALS

✓ Initial approval will be granted for 1 fill for 14 days

RENEWALS

✓ May not be renewed

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 11.30.2023	12.2023

REFERENCE:

1. Zurzuvae (zuranolone) [prescribing information]. Cambridge, MA: Biogen Inc; August 2023.

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Prior Authorization Criteria for ZYDELIG (idelalisib)

FDA-Approved Indications

- Treatment of patients with relapsed chronic lymphocytic leukemia (CLL), in combination with rituximab, in patients for whom rituximab alone would be considered appropriate therapy due to other co-morbidities

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated to oncology template; updated duration to 1 year	5.2024

REFERENCE:

1. Zydelig (idelalisib). [Prescribing information]. Foster City, CA: Gilead Sciences, Inc. February 2022.

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Prior Authorization Criteria for ZYKADIA (ceritinib)

FDA-Approved Indications

- Treatment of adults with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient is responding positively to therapy and still requires the medication for induction of remission
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	8.2023
Annual Review	Updated to oncology template; updated duration to 1 year	5.2024

REFERENCE:

1. Zykadia. [Prescribing Information]. New York, NY. Novartis Pharmaceuticals Corporation: August 2023.

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Prior Authorization Criteria for ZYMFENTRA™ (infliximab-dyyb)

FDA-Approved Indications

- Moderately to severely active ulcerative colitis following treatment with an infliximab product administered intravenously (maintenance treatment only)
- Moderately to severely active Crohn's disease following treatment with an infliximab product administered intravenously (maintenance treatment only)

Diagnosis: Moderately to severely active Crohn's disease:

1. Patient has diagnosis of Crohn's disease **AND**
2. Patients is 18 years of age and older **AND**
3. Dosage and Direction for Use: 120 mg subcutaneously every two weeks (week 10 and thereafter an intravenous induction regimen with an infliximab product). All patients must complete an intravenous induction regimen with an infliximab product before starting Zymfentra **AND**
4. Quantity requested does not exceed: 240 mg (two-120 mg syringe/pen)/4 weeks **AND**
5. Patient had an adequate trial and failure of at least one of the following: azathioprine, 6-mercaptopurine, methotrexate, glucocorticoids). A trial of a mesalamine product does not count as a systemic therapy for Crohn's disease **AND**
6. Patient is not receiving medication in combination with other biologic therapies **AND**
7. Prescribed by or in consultation with a gastroenterologist.

Diagnosis: Moderately to severely active Ulcerative Colitis:

1. Patient has diagnosis of Ulcerative Colitis **AND**
2. Patients is 18 years of age or older **AND**
3. Dosage and Direction for Use: 120 mg subcutaneously every two weeks (week 10 and thereafter an intravenous induction regimen with an infliximab product). All patients must complete an intravenous induction regimen with an infliximab product before starting Zymfentra **AND**
4. Quantity requested does not exceed: 240 mg (two-120 mg syringe/pen)/4 weeks **AND**
5. Patient has the patient had an adequate trial and failure of at least ONE oral systemic agent for ulcerative colitis (e.g., 6-mercaptopurine, azathioprine, methotrexate, cyclosporine, tacrolimus, corticosteroid (e.g., prednisone). A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis **AND**
6. Patient is not receiving medication in combination with other biologic therapies **AND**
7. Prescribed by or in consultation with a gastroenterologist.

INITIAL APPROVALS

- ✓ Initial approval will be granted for a period of 1 year

RENEWALS

- ✓ Documentation of positive clinical response to therapy has been provided **AND**
- ✓ Patient is not receiving medication in combination with other biologic therapies **AND**
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created based on CAB 3.7.2024	3.2024

Updated	Updated trial and failure language for Crohn's Disease; updated renewal criteria	6.2024

REFERENCE:

1. Zymfentra (infliximab-dyyb) [prescribing information]. Jersey City, NJ: Celltrion USA; October 2023
2. Inflectra (infliximab-dyyb) [prescribing information]. New York, NY: Pfizer; June 2019.
3. Larry W Moreland, MD, Amy Cannella, MD, General Principles of Management of Rheumatoid Arthritis in Adults. UpToDate: Apr 2018.
4. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed April 17, 2018.
5. Remicade (infliximab) [prescribing information]. Horsham, PA: Janssen Biotech, Inc; June 2018.
6. Bernell O, Lapidus A, Hellers G. Risk Factors for Surgery and Postoperative Recurrence in Crohn's Disease. Annals of Surgery. 2000; 231(1): 38-45.
7. Braun J, van den berg R, et al. 2010 Update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. Am Rheu Dis. 2011: 70; 896-904.
8. Lichtenstein GR, Loftus Jr. EV, Isaacs KI, Regueiro MD, Gerson LB, and Sands BE. ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2018; 113:481-517
9. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;65(1):137-174.
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Prior Authorization Criteria for ZYTIGA®, YONSA® (abiraterone)

FDA-APPROVED INDICATIONS

- In combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC) (Zytiga)
- In combination with prednisone for the treatment of patients with metastatic high-risk castration-sensitive prostate cancer (CSPC) (Zytiga)
- In combination with methylprednisolone for the treatment of patients with metastatic castration resistant prostate cancer (CRPC) (Yonsa)

1. Patient has an FDA approved diagnosis **AND**
2. Patient's age is appropriate based on FDA labeling **AND**
3. Requested medication follows appropriate therapy for diagnosis (based on NCCN guidelines/FDA labeling) **AND**
4. Prescribed by or in consultation with an oncologist

INITIAL APPROVALS

- ✓ Confirm regimen meets NCCN recommendations (for off-label use, please refer to "Off-Label Use Policy").
- ✓ Initial authorization will be granted for a period of 1 year.

RENEWALS

- ✓ Documentation or claim data supports continuation of treatment
- ✓ Patient has a positive response to therapy
- ✓ Approval duration for renewal: 1 year

HISTORY:

ACTION	SUMMARY OF CHANGES	DATE
Created	Created	3.2017
Update	Update Format/Add Denial Message	2.2020
Annual Review	No Changes	3.2021
Updated	Updated quantity for Zytiga and Yonsa based on package size for 30 days. Updated denial message.	3.2022
Updated	Updated dosing for Zytiga	4.2023
Annual Review	Updated criteria to include FDA-approved indications based on package insert and NCCN guidelines and updated initial and renewal approval duration	4.2024
Updated	Updated criteria to include FDA approved age	7.2024

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