Ascension
Personalized Care

Ascension

Tildrakizumab-asmn

(Ilumya®) J3245 (1mg)

Covered with prior authorization

Requests for Ilumya® (tildrakizumab-asmn) may be approved if the following criteria are met:

- Plaque psoriasis (Ps) when each of the following criteria are met:
    - Individual is 18 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque Ps with either of the following (AAD 2019):
        - Plaque Ps involving greater than three percent (3%) body surface area (BSA); **OR**
        - Plaque Ps involving less than or equal to three percent (3%) BSA involving sensitive areas or areas that significantly impact daily function (e.g.,palms, soles of feet, head/neck, or genitalia); **AND**
    - Individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or other systemic therapy (e.g., acitretin, cyclosporine, or methotrexate).

- The individual has concomitant severe psoriatic arthritis (PsA) (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive); **OR**
- The individual's medication history indicates use of another biologic immunomodulator agent OR Otezla that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence, or NCCN compendium recommended use 1 or 2a for the treatment of PS.

NOTE: Initiation of therapy for Plaque Psoriasis (Ps): May approve up to 1 additional syringe in the first 28 days (4 weeks) of treatment. Usual dosing after loading dose is 1 injection per 84 days (12 weeks).

Requests for Ilumya® (tildrakizumab-asmn) may **not** be approved if the above criteria are not met and for all other indications not included above.

Initial and renewal authorizations are for up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Exclusion criteria:

- Ilumya® (tildrakizumab-asmn) is not considered medically necessary when any of the following selection criteria is met:
    - The agent is being used/given by self administration.
    - In combination with JAK inhibitors, apremilast, other IL-23 inhibitors, other biologic drugs (such as TNF antagonists, IL-17 inhibitors, abatacept or ustekinumab) or phototherapy; OR II. Tuberculosis, other active serious infections, or a history of recurrent infections.
    - If initiating therapy, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC) and Prevention recommended equivalent to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors).
    - Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.
    - Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.) Ilumya® is a monoclonal antibody which binds to the interleukin-23 (IL-23) cytokine and disrupts its interaction with the IL-23 receptor thereby inhibiting the release of proinflammatory cytokines and chemokines. Ilumya® is approved for the treatment of plaque psoriasis. For plaque psoriasis (otherwise known as psoriasis vulgaris), the American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) published joint guidelines on the management and treatment of psoriasis with biologics. The guidelines do not include a treatment algorithm or compare biologics to each other or conventional therapy. The guideline notes that patients with mild or moderate disease may be adequately controlled with topical therapy and/or phototherapy while moderate to severe disease may necessitate treatment with a biologic. Moderate to severe disease is defined as involvement in > 3% of body surface area (BSA) or involvement in sensitive areas that significantly impact daily function (e.g., palms, soles of feet, head/neck, or genitalia). Tumor necrosis factor inhibitor (TNFi) biologics, ustekinumab, IL17 inhibitors, and IL23 inhibitors are all recommended as monotherapy treatment options for adult patients with moderate to severe plaque psoriasis.

Key References Accessed 8/2022:
1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. Centers for Disease Control and Prevention (CDC). Tuberculosis (TB). Available at: https://www.cdc.gov/tb/topic/basics/risk.htm. Last updated: March 18, 2016.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
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: 1029-72.

7. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheum. 2019; 71(1): 5-32.

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team.

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