Daratumumab and hyaluronidase-fihj

(Darzalex Faspro®) J9144 (10mg)

Covered with prior authorization

Requests for Darzalex Faspro® (daratumumab and hyaluronidase-fihj) may be approved if the following criteria are met:

- Individual has a diagnosis of multiple myeloma, including plasma cell leukemia; **AND**
- Individual is 18 years of age or older
- Individual has not received treatment with an anti-CD38 agent (such as isatuximab, daratumumab, or daratumumab and hyaluronidase-fihj); **AND**
- Individual is using for one of the following:
    - Newly diagnosed multiple myeloma for those who are ineligible for stem cell transplantation:
        - In combination with melphalan, prednisone and a proteasome inhibitor (PI) (for example, bortezomib); **OR**
        - In combination with lenalidomide and dexamethasone;

      OR
    - Newly diagnosed multiple myeloma for those who are eligible for stem cell transplant, in combination with bortezomib, dexamethasone, and either thalidomide or lenalidomide (Label, NCCN 2A);

      OR
    - Newly diagnosed multiple myeloma in combination with cyclophosphamide, bortezomib, and dexamethasone;

      OR
    - Relapsed or refractory multiple myeloma (Label, NCCN 2A):
        - As a single agent following therapy with at least two prior lines of therapy including a PI (for example, bortezomib, carfilzomib, or ixazomib) and an immunomodulatory agent (for example, thalidomide, lenalidomide, or pomalidomide); **OR**
        - In combination with cyclophosphamide, bortezomib, and dexamethasone; **OR**
        - As combination therapy following treatment with at least one prior line of therapy including a PI or an immunomodulatory agent, when used with one of the following:
            a. A PI (for example, bortezomib, carfilzomib, or ixazomib) and dexamethasone; **OR**
            b. An immunomodulatory agent (for example, thalidomide, lenalidomide, or pomalidomide) and dexamethasone.

- Individual's usual dosing comes from 1,800 mg/30,000 unit dosage form **AND**;
- During Year 1, Darzalex Faspro® is administered no more frequently than once weekly for up to nine subcutaneous injections, followed by injections separated by 2 or more weeks **AND**
- After 1 year of therapy, doses are separated by at least 4 weeks.

OR

- Individual has a diagnosis of systemic light chain amyloidosis; **AND**
- Individual has not received treatment with an anti-CD38 agent (such as isatuximab, daratumumab, or daratumumab and hyaluronidase-fihj); **AND**
- Individual is using as a single agent (NCCN 2A); **OR**
- Individual is using in combination with:
    - Bortezomib, cyclophosphamide, and dexamethasone; **OR**
    - Dexamethasone with or without bortezomib (DP B IIa).
- Individual's usual dosing comes from 1,800 mg/30,000 unit dosage form **AND**;
- Dose is administered no more frequently than once weekly for up to eight subcutaneous injections followed by subcutaneous injections separated by 2 or more weeks;
- After 6 months of therapy, doses are separated by at least 4 weeks.

Exclusion Criteria

- Requests for Darzalex Faspro® (daratumumab and hyaluronidase-fihj) may **not** be approved if the above criteria are not met and for all other indications not included above.
- 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.

Initial authorization is 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.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage. Darzalex Faspro® is a combination of daratumumab, a CD38-directed cytolytic antibody, and hyaluronidase, an endoglycosidase, for the treatment of adult patients with multiple myeloma:

- in combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant
- in combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy
- in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy
- as monotherapy, in patients who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent

Key References Accessed 8/2022:
1. Chari A, Martinez-Lopez J, Mateos M, et al. Daratumumab in combination with carfilzomib and dexamethasone in lenalidomiderefractory patients with relapsed multiple myeloma: Subgroup analysis of MMY1001. J Clin Oncol. 2018; 36(15):8002-8002
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
3. Jakubowiak A, Chari A, Lonial S, et al. Daratumumab in combination with carfilzomib, lenalidomide and dexamethasone in patients with newly diagnosed multiple myeloma (MMY1001). J Clin Oncol. 2017; 35(15):8000-8000.
4. Kimmich CR, Terzer T, Benner A, et al: Daratumumab for systemic AL amyloidosis: prognostic factors and adverse outcome with nephrotic-range albuminuria. Blood 2020; 135(18):1517-1530.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
6. Roussel M, Merlini G, Chevret S, et al. A prospective phase II of daratumumab in previously treated systemic light chain amyloidosis (AL) patients. Blood. 2020; 135: 1531-1540.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp.
    a. Multiple Myeloma. V5.2022. Revised March 9, 2022.
    b. Systemic Light Chain Amyloidosis. V1.2022. Revised June 29, 2022.

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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