VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION REVIEW MEDICAL POLICY

POLICY: Oncology (Injectable) – Darzalex Faspro Utilization Review Medical Policy
- Darzalex™ Faspro (daratumumab and hyaluronidase-fihj injection for subcutaneous use – Janssen Biotech, Inc.)

REVIEW DATE: 05/06/2020

OVERVIEW

Darzalex Faspro approved in multiple myeloma in the following situations:[1]

- in newly diagnosed patients, in combination with Revlimid (lenalidomide capsules) and dexamethasone, for the treatment of patients who are ineligible for autologous stem cell transplant and in relapsed/refractory disease, in combination with Revlimid and dexamethasone in patients who have received at least one prior therapy; AND
- in newly diagnosed patients, in combination with Velcade (bortezumab injection), melphalan, and prednisone in those ineligible for autologous stem cell transplant; AND
- in patients who have received at least one prior therapy, in combination with Velcade and dexamethasone; AND
- in patients who have received at least three prior lines of therapy (including a proteasome inhibitor and an immunomodulatory agent or who are double-refractory to a proteasome inhibitor and an immunomodulatory agent), as monotherapy.

In multiple myeloma, Darzalex Faspro binds to CD38 and inhibits the growth of CD38-expressing tumor myeloma cells. Darzalex Faspro is a fixed combination of daratumumab and hyaluronidase (recombinant human). It contains the identical molecular antibody of daratumumab available in Darzalex intravenous IV), but hyaluronidase has been added to facilitate systemic delivery. Darzalex Faspro should be administered under the care of a healthcare as a 3 to 5 minute subcutaneous injection. The dose of Darzalex Faspro is fixed regardless of the patient's body surface area (BSA); dose reductions are not recommended. Safety and efficacy is not established in patients < 18 years of age.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for multiple myeloma (version 4.2020 – May 8, 2020) address the diagnosis, treatment, and follow-up for patients with multiple myeloma.[2,3] In the most recent update, a footnote was added to clarify that Darzalex Faspro is included in the recommendations for all of the daratumumab-containing regimens. NCCN does recommend Darzalex IV in multiple regimens both as primary treatment and in previously treated disease. Darzalex IV/Velcade/Thalomid/dexamethasone is recommended as primary therapy for transplant candidates. For patients who are non-transplant candidates, Darzalex IV/Revlimid/prednisone is a Preferred regimen, and Darzalex IV/Velcade/melphalan/prednisone is an Other regimen for primary treatment. For previously treated multiple myeloma, Darzalex IV/dexamethasone plus Velcade or Revlimid are among the Preferred regimens, whereas Darzalex IV monotherapy, Darzalex IV/Kyprolis/dexamethasone, are Darzalex IV/Pomalyst/dexamethasone are listed as other recommended regimens.

Dosing Information

Darzalex Faspro is available as a single-dose vial containing 1,800 mg of daratumumab and 30,000 units of hyaluronidase per 15 mL. Dosing schedule varies depending on regimen prescribed. Refer to the

prescribing information for more specific FDA-approved regimens. Dose reductions are not recommended. In cases of myelosuppression, dose delay may be required to allow recovery of blood cell counts.

POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of Darzalex Faspro. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication(s). Extended approvals are allowed if the patient continues to meet the criteria and dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below.

Because of the of the specialized skills required for evaluation and diagnosis of patients treated with Darzalex Faspro, as well as the monitoring required for adverse events and long-term efficacy, approval requires Darzalex Faspro to be prescribed by or in consultation with a physician who specializes in the condition being treated.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Darzalex Faspro is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. Multiple Myeloma. Approve for 1 year if the patient meets BOTH of the following (A and B):

A) The patient meets ONE of the following (i or ii):

i. Darzalex Faspro is used in combination with at least one other agent.
Note: Examples of agents that may be used in combination with Darzalex Faspro include Revlimid (lenalidomide capsules), melphalen, or Velcade (bortezumab injection); OR

ii. The patient has tried at least three different regimens for multiple myeloma.
Note: Examples of agents used in other regimens include Velcade (bortezumab injection), Kyprolis (carfilzomib injection), Revlimid (lenalidomide capsules), cyclophosphamide, Ninlaro (ixazomib capsules); AND

B) Darzalex Faspro is prescribed by or in consultation with an oncologist or a hematologist.

Dosing. Approve if the requested dosing meets the following:

A) The dose is1,800 mg/30,000 units; AND

B) 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

C) After 1 year of therapy, doses are separated by at least 4 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Darzalex Faspro is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Darzalex Faspro [prescribing information]. Horsham, PA: Janssen Biotech, Inc.; May 2020.
2. The NCCN Drugs and Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 4,, 2020. Search term: daratumumab, Darzalex Faspro.
3. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (Version 3.2020 – March 10, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on February 18, 2020.

HISTORY

Type of Revision	Summary of Changes	Date Reviewed
New policy	--	05/06/2020
Update	06/16/2020: Update overview to include updated NCCN guidelines. No criteria changes.	NA