

PRIOR AUTHORIZATION POLICY

- POLICY:** Oncology (Injectable) – Darzalex Faspro Prior Authorization Policy
- Darzalex Faspro® (daratumumab and hyaluronidase-fihj subcutaneous injection – Janssen)

REVIEW DATE: 06/02/2021

OVERVIEW

Darzalex Faspro, a CD38-directed antibody, is approved for use in adults in the following situations:¹

- **Light chain amyloidosis**, in newly diagnosed patients, in combination with bortezomib, cyclophosphamide, and dexamethasone. It is a limitation of use that Darzalex Faspro is not indicated and is not recommended in patients with New York Heart Association Class IIIB or Class IV cardiac disease or Mayo Stage IIIB outside of clinical trials.
- **Multiple myeloma:**
 - 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 bortezomib injection, melphalan, and prednisone in those ineligible for autologous stem cell transplant; AND
 - in newly diagnosed patients, in combination with bortezomib, Thalomid® (thalidomide capsules), and dexamethasone, for treatment of patients who are eligible for autologous stem cell transplant; AND
 - in patients who have received at least one prior therapy, in combination with bortezomib 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.

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

Guidelines

Darzalex Faspro is addressed in guidelines from the National Comprehensive Cancer Network (NCCN).

- **Light Chain Amyloidosis:** The NCCN guidelines (version 2.2021 – February 8, 2021) specifically recommended Darzalex Faspro/cyclophosphamide/dexamethasone as a first-line therapy for systemic light chain amyloidosis. Darzalex Faspro or Darzalex intravenous are among the alternatives for previously treated disease.⁴
- **Multiple Myeloma:** The NCCN guidelines (version 7.2021 – April 26, 2021) include Darzalex Faspro in the recommendations for all of the daratumumab-containing regimens. NCCN does recommend Darzalex intravenous or Faspro in multiple regimens both as primary treatment and in previously treated disease. Darzalex/bortezomib/ dexamethasone in combination with Revlimid, Thalomid, or cyclophosphamide are among the regimens recommended as primary therapy for

transplant candidates. For patients who are non-transplant candidates, Darzalex/Revlimid/prednisone is a preferred regimen, and Darzalex/bortezomib/melphalan/prednisone and Darzalex/cyclophosphamide/bortezomib/dexamethasone are other recommended regimens for primary treatment. For previously treated multiple myeloma, there are multiple Darzalex-containing regimens in the guidelines, including Darzalex/dexamethasone plus bortezomib, Kyprolis, or Revlimid (preferred regimens). Darzalex/cyclophosphamide/bortezomib/dexamethasone and Darzalex/Pomalyst® (pomalidomide capsules)/dexamethasone are other recommended regimens, and Darzalex monotherapy (in patients who have received at least three prior therapies) and Xpovio® (selinexor tablets)/Darzalex/dexamethasone are listed as useful in certain circumstances.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Darzalex Faspro. All approvals are provided for the duration noted below. Because 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

- 1. Light Chain Amyloidosis.** Approve for 1 year if the patient meets all of the following conditions (A, B, C, and D):
 - A)** Patient is ≥ 18 years of age; AND
 - B)** Patient meets ONE of the following (i or ii):
 - i.** The medication is being used in combination with bortezomib injection, cyclophosphamide, and dexamethasone; OR
 - ii.** Patient has received at least one other regimen for this condition; AND
Note: Examples of agents used in other regimens include bortezomib injection, Revlimid (lenalidomide capsules), cyclophosphamide, and melphalan.
 - C)** Patient does NOT have severe heart failure, according to the prescriber; AND
Note: Severe heart failure is defined as New York Heart Association Class IIIB or IV cardiac disease or Mayo Stage IIIB.
 - D)** The medication is prescribed by or in consultation with an oncologist or a hematologist.
- 2. Multiple Myeloma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
 - A)** Patient is ≥ 18 years of age; AND
 - B)** Patient meets ONE of the following (i or ii):
 - i.** The medication is used in combination with at least one other medication; OR
Note: Examples of medications that may be used in combination with Darzalex Faspro include Revlimid (lenalidomide capsules), melphalen, or Velcade (bortezomib injection).
 - ii.** Patient has tried at least three different regimens for multiple myeloma; AND

Note: Examples of agents used in other regimens include bortezomib injection, Kyprolis (carfilzomib injection), Revlimid (lenalidomide capsules), cyclophosphamide, Ninlaro (ixazomib capsules).

C) The medication is prescribed by or in consultation with an oncologist or a hematologist.

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.; January 2021.
2. The NCCN Drugs and Biologics Compendium. © 2021 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on May 31, 2021. Search term: daratumumab, Darzalex Faspro.
3. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 7.2021 – April 26, 2021). © 2021 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on May 31, 2021.
4. The NCCN Systemic light chain amyloidosis Clinical Practice Guidelines in Oncology (version 2.2021 – February 8, 2021). © 2021 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on May 31, 2021.