

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Darzalex™ (daratumumab injection for intravenous use – Janssen Biotech, Inc.)

DATE REVIEWED: 02/26/2020

OVERVIEW

Darzalex is a CD38-directed cytolytic antibody.¹ It binds to CD38 and inhibits the growth of CD38-expressing tumor myeloma cells. It is approved adults with multiple myeloma who meet the following:

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
2. in newly diagnosed patients, in combination with Velcade (bortezomab injection), melphalan, and prednisone in those ineligible for autologous stem cell transplant; AND
3. in newly diagnosed patients, in combination with Velcade, Thalomid (thalidomide capsules), and dexamethasone, for treatment of patients who are eligible for autologous stem cell transplant; AND
4. in patients who have received at least one prior therapy, in combination with Velcade and dexamethasone; AND
5. in patients who have received at least two prior therapies (including Revlimid and a proteasome inhibitor), in combination with Pomalyst (pomalidomide capsules) and dexamethasone; AND
6. 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.

Safety and efficacy is not established in patients < 18 years of age.

Guidelines

The NCCN Multiple Myeloma clinical practice guidelines (version 2.2020 – October 9, 2020) recommend Darzalex in treatment regimens for primary therapy.²⁻³ Darzalex/Velcade/Thalomid/dexamethasone is recommended as primary therapy for transplant candidates. For patients who are non-transplant candidates, Darzalex/Revlimid/prednisone is a Preferred regimen, and Darzalex/Velcade/melphalen/prednisone is an Other regimen for primary treatment. For previously treated multiple myeloma, Darzalex/dexamethasone plus Velcade or Revlimid are among the Preferred regimens, whereas Darzalex monotherapy and Darzalex/ dexamethasone plus Kyprolis (carfilzomib injection) or Pomalyst are listed as other recommended regimens. The NCCN systemic light chain amyloidosis guidelines (version 1.2020 – December 6, 2019) list Darzalex as a therapy for previously treated disease.⁴

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Darzalex. Because of the specialized skills required for evaluation and diagnosis of patients treated with Darzalex as well as the monitoring required for adverse events and long-term efficacy, approval requires Darzalex to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Darzalex is recommended in those who meet 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 is used in combination with at least one other agent.
Note: Examples of agents that may be used in combination with Darzalex include Revlimid (lenalidomide capsules), Pomalyst (pomalidomide capsules), Thalomid (thalidomide capsules), melphalen, Velcade (bortezomab injection), or Kyprolis (carfilzomib 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 (bortezomab injection), Kyprolis (carfilzomib injection), Revlimid (lenalidomide capsules), cyclophosphamide, Ninlaro (ixazomib capsules); AND
 - B) Darzalex is prescribed by or in consultation with an oncologist or a hematologist.

Other Uses with Supportive Evidence

2. **Systemic Light Chain Amyloidosis.** Approve for 1 year if the patient meets BOTH of the following (A and B):
 - A) The patient has received at least one other regimen for this condition.
Note: Examples of agents used in other regimens include Velcade (bortezomab injection), Revlimid (lenalidomide capsules), cyclophosphamide, and melphalen; AND
 - B) The agent is prescribed by or in consultation with an oncologist or a hematologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Darzalex has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

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 [prescribing information]. Horsham, PA: Janssen Biotech, Inc.; September 2019.
2. The NCCN Drugs and Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on February 17, 2020. Search term: daratumumab.
3. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (Version 2.2020 – October 9, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on February 17, 2020.
4. The NCCN Systemic Light Chain Amyloidosis Clinical Practice Guidelines in Oncology (Version 1.2020 – December 6, 2019). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on February 17, 2020.