Reference number(s)
4232-A

STANDARD MEDICARE PART B MANAGEMENT

DARZALEX (daratumumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
Darzalex is indicated for the treatment of adult patients with multiple myeloma:
1. 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.
2. in combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant.
3. in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant.
4. in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy.
5. in combination with pomalidomide and dexamethasone in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.
6. 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.

B. Compendial Uses
1. Therapy for previously treated multiple myeloma for relapsed or progressive
2. Treatment for relapsed/refractory systemic light chain amyloidosis

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

A. Multiple Myeloma
Authorization of 12 months may be granted for the treatment of multiple myeloma.

B. Systemic Light Chain Amyloidosis
Authorization of 12 months may be granted for the treatment of systemic light chain amyloidosis when the member has relapsed or refractory disease.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

A. The member is currently receiving therapy with Darzalex
B. Darzalex is being used to treat an indication enumerated in Section II
C. The member is receiving benefit from therapy. Benefit is defined as:
    1. No evidence of unacceptable toxicity while on the current regimen or
    2. No evidence of disease progression while on the current regimen

IV. REFERENCES

1. Darzalex [package insert]. Horsham, PA: Janssen Biotech Inc; May 2020.
2. The NCCN Drugs & Biologics Compendium 2020 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed September 13, 2020.
3. The NCCN Clinical Practice Guidelines in Oncology Multiple Myeloma (Version 1.2020) 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed September 13, 2020.