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 carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy
6. in combination with pomalidomide and dexamethasone in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.
7. 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. Multiple myeloma
2. Systemic light chain amyloidosis
3. T-cell acute lymphoblastic leukemia (T-ALL)

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. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
Documentation of testing or laboratory results confirmation t(11:14) translocation, where applicable.

III. CRITERIA FOR INITIAL APPROVAL

A. Multiple Myeloma

1. Authorization of 12 months may be granted for the treatment of multiple myeloma when used in combination with cyclophosphamide, bortezomib, and dexamethasone.

2. Authorization of 12 months may be granted for the treatment of multiple myeloma as primary therapy when any of the following criteria is met:
    a. The member is ineligible for a transplant and the requested medication will be used in combination with either:
        i. Lenalidomide and dexamethasone
        ii. Bortezomib, melphalan, and prednisone
    b. The member is eligible for transplant and the requested medication will be used in combination with any of the following:
        i. Bortezomib, thalidomide, and dexamethasone for a maximum of 16 doses
        ii. Bortezomib, lenalidomide, and dexamethasone
        iii. Carfilzomib, lenalidomide, and dexamethasone
        iv. Ixazomib, lenalidomide, and dexamethasone

3. Authorization of 12 months may be granted for the treatment of previously treated multiple myeloma when any of the following criteria is met:
    a. The requested medication will be used in combination with lenalidomide and dexamethasone in members who have received at least one prior therapy
    b. The requested medication will be used in combination with bortezomib and dexamethasone in members who have received at least one prior therapy
    c. The requested medication will be used in combination with carfilzomib and dexamethasone in members who have received at least one prior therapy
    d. The requested medication will be used in combination with pomalidomide and dexamethasone in members who have received at least one prior therapy including a proteasome inhibitor (PI) and an immunomodulatory agent.
    e. The requested medication will be used in combination with selinexor and dexamethasone
    f. The requested medication will be used in combination with venetoclax and dexamethasone for members with documented t(11:14) translocation
    g. The requested medication will be used as a single agent in members who have received at least three prior therapies, including a PI and an immunomodulatory agent
    h. The requested medication will be used as a single agent in members who are double refractory to a PI and an immunomodulatory agent

4. Authorization of 12 months may be granted for maintenance therapy of symptomatic multiple myeloma for transplant candidates when either of the following criteria is met:
    a. The requested medication will be used as single agent
    b. The requested medication will be used in combination with lenalidomide in members who have high risk disease

B. Systemic Light Chain Amyloidosis

Authorization of 12 months may be granted as a single agent for the treatment of systemic light chain amyloidosis.

C. T-Cell Acute Lymphoblastic Leukemia (T-ALL)

Authorization of 12 months may be granted for treatment for relapsed/refractory T-cell acute lymphoblastic leukemia (T-ALL).

IV. 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 the requested medication
B. The requested medication is being used to treat an indication enumerated in Section III
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

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Darzalex.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology
3. NCCN Guideline: Systemic light chain amyloidosis
4. NCCN Guideline: Multiple myeloma

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Darzalex are covered in addition to the following:
1. Multiple myeloma
2. Systemic light chain amyloidosis
3. T-cell acute lymphoblastic leukemia (T-ALL)

VI. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Darzalex to treat multiple myeloma, and systemic light chain amyloidosis, and T-cell acute lymphoblastic leukemia (T-ALL) can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

Support for using Darzalex to treat relapsed or refractory systemic light chain amyloidosis can be found in the Micromedex DrugDex database. Use of information in the DrugDex database for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

VII. REFERENCES

1. Darzalex [package insert]. Horsham, PA: Janssen Biotech Inc; January 2023.

2. The NCCN Drugs & Biologics Compendium® ©2023 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed December 19, 2023.
3. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com/ Accessed: October 2, 2023.