Daratumumab (Darzalex®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered covered benefits 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 are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
Documentation of testing or laboratory results confirming 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 the treatment of T-cell acute lymphoblastic leukemia (T-cell) when the member has relapsed or refractory disease and the requested medication will be used in combination with any of the following:

a. Vincristine, pegaspargase, doxorubicin, and prednisone or dexamethasone
b. Vincristine, calaspargase. doxorubicin, and prednisone or dexamethasone

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when either of the following regimen or indication-specific criteria is met:

A. All members (including new members) requesting the requested medication in combination with bortezomib, thalidomide, and dexamethasone for multiple myeloma must meet all initial criteria.
B. For all other regimens and indications listed in Section III, there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

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. The NCCN Clinical Practice Guidelines in Oncology Multiple Myeloma (Version 1.2024) 2023 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed October 2, 2023.
4. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com/ Accessed: October 2, 2023.

EFFECTIVE DATE 7/31/2024

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