Reference number(s)
3854-A

SPECIALTY GUIDELINE MANAGEMENT

DARZALEX FASPRO (daratumumab and hyaluronidase-fihj)

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
1. Darzalex Faspro is indicated for the treatment of adult patients with multiple myeloma:
   a. in combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant.
   b. 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.
   c. in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant.
   d. in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy.
   e. in combination with pomalidomide and dexamethasone in patients who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor.
   f. in combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy.
   g. 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.

2. Darzalex Faspro is indicated for the treatment of adult patients with newly diagnosed light chain amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone.

B. Compendial Uses
1. For multiple myeloma, may be used as a single agent or in combination with other systemic therapies where intravenous daratumumab is recommended
2. For light chain amyloidosis, may be used for relapsed/refractory disease

All other indications are considered experimental/investigational and not medically necessary.

II. 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

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 as a single agent in members who have received at least three prior therapies, including a PI and an immunomodulatory agent
    g. 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 the single-agent maintenance therapy of symptomatic multiple myeloma for transplant candidates

B. Light Chain Amyloidosis

Authorization of 12 months may be granted for the treatment of light chain amyloidosis in either of the following settings:

1. For newly diagnosed members when used in combination with bortezomib, cyclophosphamide and dexamethasone.
2. For relapsed or refractory disease.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when any of the following criteria are 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 members requesting reauthorization for newly diagnosed light chain amyloidosis, the maximum treatment duration is 24 months and there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

C. For all other regimens and indications listed in Section II, there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Darzalex Faspro [package insert]. Horsham, PA: Janssen Biotech, Inc.; April 2022.
2. The NCCN Drugs & Biologics Compendium® ©2022 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 11, 2022.
3. The NCCN Clinical Practice Guidelines in Oncology Multiple Myeloma (Version 1.2023) 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed October 11, 2022.