Reference number
4465-A

Aetna Medicare Part B Drug Criteria

DARZALEX FASPRO (daratumumab and hyaluronidase-fihj)

This policy is for Aetna Medicare members. Find the Aetna Commercial Medical Drug Criteria.

For Aetna Medicare members, National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) will be applied to Part B drug requests when applicable. Aetna Medicare Part B Drug Criteria documents will be used in the absence of an NCD and LCD.

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

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 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

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

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

A. **Multiple Myeloma**
Authorization for 12 months may be granted for multiple myeloma when all of the following criteria are met:
1. The member is currently receiving therapy with the requested medication.
2. The member meets any of the following criteria:
    a. The requested drug will be used in combination with bortezomib, thalidomide, and dexamethasone and the member has not received a maximum of 16 doses
    b. The member is receiving benefit from therapy. Benefit is defined as:
        i. No evidence of unacceptable toxicity while on the current regimen or
        ii. No evidence of disease progression while on the current regimen

B. **Light Chain Amyloidosis**
Authorization for 12 months may be granted for light chain amyloidosis when all of the following criteria are met:
1. The member is currently receiving therapy with the requested medication
2. For members requesting reauthorization for newly diagnosed light chain amyloidosis, the maximum treatment duration is 24 months
1 The member is receiving benefit from therapy. Benefit is defined as:
    a. No evidence of unacceptable toxicity while on the current regimen or
    b. No evidence of disease progression while on the current regimen

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Darzalex Faspro.
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

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 Faspro are covered in addition to the following:

A. Relapsed/refractory systemic light chain amyloidosis
B. In combination with other systemic therapies where IV daratumumab is recommended

V. EXPLANATION OF RATIONALE

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

Support for using Darzalex Faspro as a single agent for relapsed/refractory systemic light chain amyloidosis 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 Faspro as a single agent or in combination with other systemic therapies for the treatment of multiple myeloma 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).

VI. 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.

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