Daratumumab and hyaluronidase-fihj (Darzalex Faspro®)

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

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.

FDA-Approved Indications

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

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

Compendial Uses

- For multiple myeloma and POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome, may be used as a single agent or in combination with other systemic therapies where intravenous daratumumab is recommended
- Systemic light chain amyloidosis

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

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.

COVERAGE CRITERIA

Multiple Myeloma

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

Authorization of 12 months may be granted for the treatment of multiple myeloma as primary therapy when any of the following criteria is met:

- The member is ineligible for a transplant and the requested medication will be used in combination with either:
  - Lenalidomide and dexamethasone
  - Bortezomib, melphalan, and prednisone
- The member is eligible for transplant and the requested medication will be used in combination with any of the following:
  - Bortezomib, thalidomide, and dexamethasone for a maximum of 16 doses
  - Bortezomib, lenalidomide, and dexamethasone for a maximum of 16 doses
  - Carfilzomib, lenalidomide, and dexamethasone

Authorization of 12 months may be granted for the treatment of previously treated multiple myeloma when any of the following criteria is met:

- The requested medication will be used in combination with lenalidomide and dexamethasone in members who have received at least one prior therapy
- The requested medication will be used in combination with bortezomib and dexamethasone in members who have received at least one prior therapy
- The requested medication will be used in combination with carfilzomib and dexamethasone in members who have received at least one prior therapy
- The requested medication will be used in combination with carfilzomib, pomalidomide, and dexamethasone
- 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.
- The requested medication will be used in combination with selinexor and dexamethasone
- The requested medication will be used in combination with venetoclax and dexamethasone for members with documented t(11:14) translocation
- 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
- The requested medication will be used as a single agent in members who are double refractory to a PI and an immunomodulatory agent

Authorization of 12 months may be granted for maintenance therapy of symptomatic multiple myeloma for transplant candidates when used in combination with lenalidomide.

POEMS (Polyneuropathy, Organomegaly, Endocrinopathy, Monoclonal protein, Skin changes) Syndrome

Authorization of 12 months may be granted for the treatment of POEMS syndrome when used in combination with lenalidomide and dexamethasone as induction therapy for transplant eligible member.

Systemic Light Chain Amyloidosis

Authorization of 12 months may be granted for the treatment of systemic light chain amyloidosis if either of the following criteria is met:

- The requested medication will be used in combination with bortezomib, cyclophosphamide and dexamethasone or as a single agent.
- For members with relapsed or refractory disease and the requested medication will be used in combination with lenalidomide and dexamethasone.

CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when any of the following criteria are met:

- All members (including new members) requesting the requested medication in combination with bortezomib, thalidomide, and dexamethasone or bortezomib, lenalidomide, and dexamethasone for multiple myeloma must meet all requirements in the coverage criteria section.
- For members requesting reauthorization for newly diagnosed systemic 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.
- For all other regimens and indications listed in the coverage criteria section, there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Daratumumab and hyaluronidase-fihj (Darzalex Faspro)	Multiple Myeloma	Route of Administration: Subcutaneous 1800/30,000mg-units per dose (dosing schedule varies by regimen)
Daratumumab and hyaluronidase-fihj (Darzalex Faspro)	Systemic Light Chain Amyloidosis	Route of Administration: Subcutaneous 1800/30,000mg-units every week for 8 doses, followed by every 2 weeks for 8 doses, then every 4 weeks

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 Faspro [package insert]. Horsham, PA: Janssen Biotech, Inc.; July 2024.
2. The NCCN Drugs & Biologics Compendium® ©2024 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 2, 2024.
3. The NCCN Clinical Practice Guidelines in Oncology Multiple Myeloma (Version 1.2025) 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed October 2, 2024.

EFFECTIVE DATE 8/30/2025

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