Reference number(s)
3854-A

Specialty Guideline Management
Darzalex Faspro

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Darzalex Faspro	daratumumab and hyaluronidase-fihj

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[1]

- 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, lenalidomide, and dexamethasone in newly diagnosed patients who are ineligible 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.
  - as monotherapy, in patients who have high risk smoldering disease.
- 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[2,3]

- For multiple myeloma, POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome, monoclonal immunoglobulin deposition disease (MIDD), and monoclonal gammopathy of renal significance (MGRS), 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[1-3]

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 has asymptomatic high risk smoldering disease.

- The member is ineligible for a transplant or transplant-deferred and the requested medication will be used in combination with lenalidomide and dexamethasone.
- The member is ineligible for a transplant and the requested medication will be used in combination with bortezomib, melphalan, and prednisone.
- The member is eligible for transplant and the requested medication will be used in combination with either of the following:
    - Bortezomib, thalidomide, and dexamethasone for a maximum of 16 doses.
    - Carfilzomib, lenalidomide, and dexamethasone.
- The requested medication will be used in combination with bortezomib, 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 are bortezomib-refractory.
- The requested medication will be used in combination with bortezomib and dexamethasone in members who are lenalidomide-refractory.
- The requested medication will be used in combination with teclistamab-cqyv (Tecvayli) in members who are bortezomib- refractory or lenalidomide-refractory.
- The requested medication will be used in combination with carfilzomib and dexamethasone in members who are bortezomib- refractory or lenalidomide-refractory.
- 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 either of the following criteria is met:

- The requested medication will be used in combination with lenalidomide and the member has high risk disease.
- The requested medication will be used as a single agent.

POEMS (Polyneuropathy, Organomegaly, Endocrinopathy, Monoclonal protein, Skin changes) Syndrome, Monoclonal Immunoglobulin Deposition Disease (MIDD), and Monoclonal Gammopathy of Renal Significance (MGRS)[2,3]

Authorization of 12 months may be granted for the treatment of POEMS syndrome, plasma cell-related MIDD, and plasma cell-related MGRS.

Systemic Light Chain Amyloidosis[1,2]

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

- The requested medication will be used in combination with bortezomib, cyclophosphamide and dexamethasone or as a single agent.
- The requested medication will be used in combination with lenalidomide and dexamethasone and the member has relapsed or refractory disease.
- The requested medication will be used in combination with venetoclax and the member has relapsed or refractory disease with documented t(11:14) translocation.

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 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.

References

1. Darzalex Faspro [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2026.
2. The NCCN Drugs & Biologics Compendium® ©2026 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed February 3, 2026.

3. The NCCN Clinical Practice Guidelines in Oncology Multiple Myeloma (Version 5.2026) 2026 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed February 3, 2026.