Applicable Drugs: Darzalex (daratumumab injection for intravenous use), Darzalex Faspro (daratumumab and hyaluronidase-fihj) injection for subcutaneous use

Preferred: N/A

Non-preferred: N/A

Date of Origin: 3/15/2026

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to V are met.)

I. Documentation of one of the following FDA-approved diagnoses A or B AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Multiple Myeloma and meets ONE of the following (i, ii, iii or iv):

i. Newly diagnosed patients who are eligible for autologous stem cell transplant and meets ONE of the following (1 or 2):

1. Used in combination with bortezomib, lenalidomide, and dexamethasone for induction and consolidation (Darzalex Faspro only)
2. Used in combination with bortezomib, Thalomid (thalidomide), and dexamethasone

ii. Newly diagnosed patients who are NOT eligible for autologous stem cell transplant and meets ONE of the following (1, 2, or 3):

1. Used in combination with bortezomib, lenalidomide, and dexamethasone (Darzalex Faspro only)
2. Used in combination with bortezomib, melphalan and prednisone
3. Used in combination with lenalidomide and dexamethasone

iii. Relapsed or refractory disease and meets ONE of the following (1 or 2):

1. Has received at least 1 prior line of therapy and meets one of the following (a, b, c, or d):

a. Used in combination with lenalidomide and dexamethasone

b. Used in combination with bortezomib and dexamethasone

c. Used in combination with pomalidomide and dexamethasone

i. Prior treatment includes lenalidomide and a proteasome inhibitor (ex. bortezomib, Kyprolis [carfilzomib], Ninlaro [ixazomib], etc.)

d. Used in combination with carfilzomib and dexamethasone

2. Used as monotherapy and meets one of the following (a or b):
    a. Has received at least three prior lines of therapy including a proteasome inhibitor (ex. bortezomib, Kyprolis [carfilzomib], Ninlaro [ixazomib], etc.) and an immunomodulatory agent (lenalidomide, Pomalyst [pomalidomide], or Thalomid [thalidomide], etc.)
    b. Documentation of being double-refractory to a proteosome inhibitor (ex. bortezomib, Kyprolis [carfilzomib], Ninlaro [ixazomib], etc.) and an immunomodulatory agent (lenalidomide, Pomalyst [pomalidomide], or Thalomid [thalidomide], etc.)

iv. High-risk smoldering disease (Darzalex Faspro only)
    1. Darzalex Faspro will be used as monotherapy

B. Light chain amyloidosis (AL) (Darzalex Faspro only)
    i. Used in combination with bortezomib, cyclophosphamide and dexamethasone in newly diagnosed patients

Other Uses With Supportive Evidence

D. HIV-related B-cell lymphomas

E. Monoclonal gammopathy or renal significance (MGRS)

F. Monoclonal immunoglobulin deposition disease (MIDD)

G. Multiple myeloma - maintenance therapy for response or stable disease following hematopoietic cell transplant

H. Pediatric acute lymphoblastic leukemia

I. Polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes (POEMS)

J. Systemic light chain amyloidosis – relapsed/refractory disease

II. Minimum age requirement: 18 years old or older

III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantity is limited to a 28-day supply
- Recommended Darzalex Faspro dose: 1,800 mg daratumumab / 30,000 units hyaluronidase subcutaneously
- Recommended Darzalex dose: 16 mg/kg (actual body weight) administered via intravenous infusion. Week 1 infusion may be split into 8mg/kg x 2 consecutive days.
    - Multiple myeloma (Darzalex Faspro and Darzalex)
        - In combination with lenalidomide or Pomalyst (pomalidomide) and dexamethasone, or carfilzomib and dexamethasone, or for monotherapy:
            - Weeks 1 to 8: once weekly (total of 8 doses)
            - Weeks 9 to 24: once every 2 weeks (total of 8 doses)
            - Week 25 onward until disease progression: once every 4 weeks
        - In combination with bortezomib, melphalan, and prednisone:
            - Weeks 1 to 6: once weekly (total of 6 doses)
            - Weeks 7 to 54: once every 3 weeks (total of 16 doses)
            - Weeks 55 onward until disease progression: once every 4 weeks
        - In combination with bortezomib, Thalomid (thalidomide), and dexamethasone (Darzalex and Darzalex Faspro) or bortezomib, lenalidomide, and dexamethasone (Darzalex Faspro only) in patients eligible for autologous stem cell transplant (ASCT):
            - Induction weeks 1 to 8: once weekly (total of 8 doses)
            - Induction weeks 9 to 16: once every 2 weeks (total of 4 doses)
            - Consolidation weeks 1 to 8: every 2 weeks (total of 4 doses)
        - In combination with bortezomib, lenalidomide, and dexamethasone (Darzalex Faspro only)
            - Weeks 1 to 6: once weekly (total of 6 doses)
            - Weeks 7 to 24: once every 3 weeks (total of 6 doses)
            - Week 25 onward until disease progression: once every 4 weeks
        - In combination with bortezomib and dexamethasone
            - Weeks 1 to 9: once weekly (total of 9 doses)

- Weeks 10 to 24: once every 3 weeks (total of 5 doses)
- Week 25 onward until disease progression: once every 4 weeks

- Light Chain Amyloidosis
  - Darzalex Faspro only in combination with bortezomib, cyclophosphamide, and dexamethasone
    - Weeks 1 to 8: once weekly (total of 8 doses)
    - Weeks 9 to 24: once every 2 weeks (total of 8 doses)
    - Week 25 onward until disease progression (maximum of 2 years): once every 4 weeks

APPROVAL LENGTH

- **Authorization:** 1 year
- **Re-Authorization:** 1 year. An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease. Maximum of 2 years total treatment for newly diagnosed light chain amyloidosis.

APPENDIX

N/A

REFERENCES

1. Darzalex Faspro. Prescribing Information. Janssen Biotech, Inc. 2026. Accessed February 15, 2026. www.accessdata.fda.gov/drugsatfda_docs/label/2026/761145s039lbl.pdf
2. Darzalex. Prescribing Information. Janssen Biotech, Inc. 2025. Accessed February 15, 2026. www.accessdata.fda.gov/drugsatfda_docs/label/2025/761036s054lbl.pdf
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Multiple Myeloma. Version 5.2026. Updated January 9, 2026. Accessed February 15, 2026. www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf
4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Systemic Light Chain Amyloidosis. Version 1.2026. Updated June 11, 2025. Accessed February 15, 2026. www.nccn.org/professionals/physician_gls/pdf/amyloidosis.pdf
5. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. B-Cell Lymphomas. Version 3.2026. Updated March 12, 2026. Accessed February 15, 2026. www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf
6. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Pediatric Acute Lymphoblastic Leukemia. Version 1.2026. Updated August 11, 2025. Accessed February 15, 2026. www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.