

<b>Clinical Policy Title:</b>	daratumumab and hyaluronidase-fihj, daratumumab
<b>Policy Number:</b>	RxA.638
<b>Drug(s) Applied:</b>	Darzalex Faspro®, Darzalex®
<b>Original Policy Date:</b>	07/09/2020
<b>Last Review Date:</b>	10/19/2023
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. Multiple Myeloma (must meet all):

1. Diagnosis of multiple myeloma;
  2. Prescribed by or in consultation with an oncologist or hematologist;
  3. Age ≥ 18 years;
  4. Darzalex Faspro® and Darzalex® are prescribed in one of the following ways (a or b):
    - a. Primary therapy (i or ii):
      - i. Ineligible for autologous stem cell transplant (ASCT) (a or b):
        - a) In combination with lenalidomide\* and dexamethasone;
        - b) In combination with bortezomib\*, melphalan, and prednisone;
      - ii. Eligible for ASCT in combination with one of the following (a, b, c, or d):
        - a) bortezomib\*, thalidomide\*, and dexamethasone;
        - b) bortezomib\*, lenalidomide\*, and dexamethasone;
        - c) bortezomib\*, cyclophosphamide, dexamethasone;
        - d) carfilzomib\*, lenalidomide\*, and dexamethasone;
    - b. Subsequent therapy (i or ii or iii):
      - i. For Darzalex Faspro®: In combination with dexamethasone and either lenalidomide\*, bortezomib\*, carfilzomib\* or pomalidomide\* after ≥ 1 prior therapy;
      - ii. For Darzalex®: In combination with dexamethasone and either lenalidomide\*, bortezomib\*, carfilzomib\* after ≥ 1 prior therapy or with dexamethasone and pomalidomide\* after ≥ 2 prior therapy;
      - iii. For Darzalex Faspro®; Darzalex®: As monotherapy in patients who have received at least three prior line therapies, including (a and b):
        - a) An immunomodulatory agent (e.g., thalidomide\*, lenalidomide\*);
        - b) Proteasome inhibitor (PI) (e.g., ixazomib\*, bortezomib\*, carfilzomib\*);
- \*Prior authorization may be required.\*
5. Dose does not exceed any one of the following (a, b or c):
    - a. Darzalex Faspro®: 1,800 mg daratumumab and 30,000 units hyaluronidase (15 mL) subcutaneously once weekly;
    - b. Darzalex®: 16 mg/kg/dose (actual body weight) intravenously.
    - c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use; (prescriber must submit supporting evidence).
- \*Prescribed regimen must be FDA-approved or recommended by NCCN

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

**Approval Duration**

**Commercial:** 6 months

**Medicaid:** 6 months

**B. Systemic Light Chain Amyloidosis (Off label for Darzalex®) (must meet all):**

1. Diagnosis of systemic light chain amyloidosis;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. The requested agent will be used as a preferred treatment for newly diagnosed disease or considered for relapse/refractory disease as a repeat of initial therapy if relapse-free for several years in combination with bortezomib\*, cyclophosphamide, and dexamethasone;
6. Dose does not exceed any one of the following (a or b):
  - a. Darzalex Faspro®: 1,800 mg daratumumab and 30,000 units hyaluronidase (15 mL) subcutaneously once weekly;
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use; (prescriber must submit supporting evidence).

\*Prescribed regimen must be FDA-approved or recommended by NCCN

**Approval Duration**

**Commercial:** 6 months

**Medicaid:** 6 months

**II. Continued Therapy Approval**

**A. All Indications in Section I (must meet all):**

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for dose increase, dose does not exceed (a, b or c):
  - a. Darzalex Faspro®: 1,800 mg daratumumab and 30,000 units hyaluronidase (15 mL) subcutaneously once weekly.
  - b. Darzalex®: 16 mg/kg/dose (actual body weight) intravenously.
  - c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use; (prescriber must submit supporting evidence).

\*Prescribed regimen must be FDA-approved or recommended by NCCN

**Approval Duration**

**Commercial:** 12 months

**Medicaid:** 12 months

**References**

1. National Comprehensive Cancer Network. Multiple Myeloma. Version 3.2023. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/myeloma.pdf](https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf). Accessed February 3, 2023.
2. National Comprehensive Cancer Network. Systemic Light Chain Amyloidosis. Version 2.2023. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/amyloidosis.pdf](https://www.nccn.org/professionals/physician_gls/pdf/amyloidosis.pdf). Accessed February 3, 2023.
3. Palladini G, Kastiris E, Maurer MS, et al. Daratumumab plus CyBorD for patients with newly diagnosed AL amyloidosis: safety run-in results of ANDROMEDA. Blood. 2020;136(1):71-80. doi: 10.1182/blood.2019004460. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7332897/>. Accessed February 3, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	07/09/2020	09/14/2020
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Initial Approval Criteria I.A.4.b.ii was updated from “As monotherapy or in combination with pomalidomide and dexamethasone after ≥ 2 prior therapies” to “As monotherapy in patients who have received at least three prior line therapies.”</li> <li>2. Initial Approval Criteria I.B was updated to include new indication “Systemic Light Chain Amyloidosis...”.</li> <li>3. Continued Therapy Approval Criteria II.A was updated from “Multiple Myeloma” to “All Indications in Section I.”</li> <li>4. References were reviewed and updated.</li> </ol>	06/29/2021	09/14/2021
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Clinical Policy Title, Drug(s) Applied: Updated to include generic daratumumab.</li> <li>2. Initial Approval Criteria I.A.4: updated combination/monotherapy criteria from Darzalex Faspro® is prescribed in one of the following ways (a or b): <ol style="list-style-type: none"> <li>a. Primary therapy (i or ii): <ol style="list-style-type: none"> <li>i. Ineligible for autologous stem cell transplant (ASCT) (a or b): <ol style="list-style-type: none"> <li>a) In combination with lenalidomide* and dexamethasone;</li> <li>b) In combination with bortezomib*, melphalan, and prednisone;</li> </ol> </li> <li>ii. Eligible for ASCT in combination with bortezomib*, thalidomide*, and dexamethasone;</li> </ol> </li> <li>b. Subsequent therapy (i or ii): <ol style="list-style-type: none"> <li>i. In combination with dexamethasone and either lenalidomide*, bortezomib*, carfilzomib* after ≥ 1 prior therapy;</li> <li>ii. As monotherapy in patients who have received at least three prior line therapies, including (a and b): <ol style="list-style-type: none"> <li>a. An immunomodulatory agent (e.g., thalidomide*, lenalidomide*);</li> <li>b. Proteasome inhibitor (PI) (e.g., ixazomib*, bortezomib*, carfilzomib*);</li> </ol> </li> </ol> </li> </ol> <p>to Darzalex Faspro® and Darzalex® are</p> </li> </ol>	2/24/2022	04/18/2022

Review/Revision History	Review/Revision Date	P&T Approval Date
<p>prescribed in one of the following ways (a or b):</p> <ul style="list-style-type: none"> <li>a. Primary therapy (i or ii):               <ul style="list-style-type: none"> <li>i. Ineligible for autologous stem cell transplant (ASCT) (a or b):                   <ul style="list-style-type: none"> <li>a) In combination with lenalidomide* and dexamethasone;</li> <li>b) In combination with bortezomib*, melphalan, and prednisone;</li> </ul> </li> <li>ii. Eligible for ASCT in combination with bortezomib*, thalidomide*, and dexamethasone;</li> </ul> </li> <li>b. Subsequent therapy (i or ii or iii):               <ul style="list-style-type: none"> <li>i. For Darzalex Faspro®: In combination with dexamethasone and either lenalidomide*, bortezomib*, carfilzomib* or pomalidomide* after ≥ 1 prior therapy;</li> <li>ii. For Darzalex®: In combination with dexamethasone and either lenalidomide*, bortezomib*, carfilzomib* after ≥ 1 prior therapy or with dexamethasone and pomalidomide* after ≥ 2 prior therapy;</li> <li>iii. For Darzalex Faspro®; Darzalex®: As monotherapy in patients who have received at least three prior line therapies, including (a and b):                   <ul style="list-style-type: none"> <li>a. An immunomodulatory agent (e.g., thalidomide*, lenalidomide*);</li> <li>b. Proteasome inhibitor (PI) (e.g., ixazomib*, bortezomib*, carfilzomib*);</li> </ul> </li> </ul> </li> </ul> <p>*Prior authorization may be required.*</p> <p>3. Initial Approval Criteria I.B: Updated from Systemic Light Chain Amyloidosis (must meet all) to Systemic Light Chain Amyloidosis (Off label for Darzalex®) (must meet all).</p> <p>4. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...".</p> <p>5. References were reviewed and updated.</p>		
<p>Policy was reviewed:</p> <ul style="list-style-type: none"> <li>1. References were reviewed and updated.</li> </ul>	01/25/2023	04/13/2023
<p>Policy was reviewed.</p>	10/19/2023	10/19/2023

