Clinical Policy Title:	daratumumab and hyaluronidase-fihj, daratumumab
Policy Number:	RxA.638
Drug(s) Applied:	Darzalex Faspro®
Original Policy Date:	07/09/2020
Last Review Date:	09/04/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Multiple Myeloma (must meet all):

1. Diagnosis of multiple myeloma;
2. Darzalex Faspro® is prescribed in one of the following ways (a or b):
   a. Primary therapy and meets one of the following (i or ii):
      i. Ineligible for autologous stem cell transplant (ASCT) and meets one of the following (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 and meets one of the following (i or ii):
      i. In combination with dexamethasone and either lenalidomide*, bortezomib*, carfilzomib* or pomalidomide* after ≥ 1 prior therapy;
      ii. 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.

Approval Duration

All Lines of Business (except Medicare): 6 months

B. Systemic Light Chain Amyloidosis (must meet all):

1. Diagnosis of systemic light chain amyloidosis;
2. 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;
   *Prior authorization may be required.

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

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

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 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. Accessed September 4, 2024.
2. National Comprehensive Cancer Network. Systemic Light Chain Amyloidosis. Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/amyloidosis.pdf. Accessed September 4, 2024.
3. Palladini G, Kastritis 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 September 4, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	07/09/2020	09/14/2020
Policy was reviewed: 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." 2. Initial Approval Criteria I.B was updated to include new indication "Systemic Light Chain Amyloidosis...". 3. Continued Therapy Approval Criteria II.A was updated from "Multiple Myeloma" to "All Indications in Section I." 4. References were reviewed and updated.	06/29/2021	09/14/2021
Policy was reviewed: 1. Clinical Policy Title, Drug(s) Applied: Updated to include generic daratumumab. 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): 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*,	2/24/2022	04/18/2022

Review/Revision History	Review/Revision Date	P&T Approval Date
melphalan, and prednisone; ii. Eligible for ASCT in combination with bortezomib*, thalidomide*, and dexamethasone; b. Subsequent therapy (i or ii): i. In combination with dexamethasone and either lenalidomide*, bortezomib*, carfilzomib* after ≥ 1 prior therapy; ii. 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*); to 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 bortezomib*, thalidomide*, 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.,		

Review/Revision History	Review/Revision Date	P&T Approval Date
thalidomide*, lenalidomide*); b. Proteasome inhibitor (PI) (e.g., ixazomib*, bortezomib*, carfilzomib*); *Prior authorization may be required.* 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). 4. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 5. References were reviewed and updated.		
Policy was reviewed: 1. References were reviewed and updated.	01/25/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed Darzalex from policy	03/15/2024	02/28/2024
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.	9/4/2024	09/13/2024