

Darzalex (daratumumab), Darzalex Faspro (daratumumab and hyaluronidase-fihj)

Override	Approval Duration
Prior Authorization	1 year

Medication
Darzalex (daratumumab) Darzalex Faspro (daratumumab and hyaluronidase-fihj)

APPROVAL CRITERIA

Requests for Darzalex (daratumumab) or Darzalex Faspro (daratumumab and hyaluronidase-fihj) may be approved when the following criteria are met:

- I. Individual has a diagnosis of multiple myeloma, including plasma cell leukemia; **AND**
- II. Individual is using for one of the following:
 - A. Newly diagnosed multiple myeloma for those who are ineligible for stem cell transplantation:
 1. In combination with melphalan, prednisone and a proteasome inhibitor (PI) (for example, bortezomib); **OR**
 2. In combination with lenalidomide and dexamethasone;
 - OR**
 - B. Newly diagnosed multiple myeloma for those who are eligible for stem cell transplant, in combination with bortezomib, dexamethasone, and either thalidomide or lenalidomide (Label, NCCN 2A);
 - OR**
 - C. Newly diagnosed multiple myeloma in combination with carfilzomib, lenalidomide, and dexamethasone (NCCN 2A);
 - OR**
 - D. Newly diagnosed multiple myeloma in combination with cyclophosphamide, bortezomib, and dexamethasone;
 - OR**
 - E. Relapsed or refractory multiple myeloma (Label, NCCN 2A):
 1. As a single agent following therapy with at least two prior lines of therapy including a PI (for example, bortezomib, carfilzomib, or ixazomib) and an immunomodulatory agent (for example, thalidomide, lenalidomide, or pomalidomide); **OR**
 2. In combination with cyclophosphamide, bortezomib, and dexamethasone; **OR**
 3. In combination with selinexor and dexamethasone; **OR**

4. As combination therapy following treatment with at least one prior line of therapy when used with one of the following:

- a. A PI (for example, bortezomib, carfilzomib, or ixazomib) and dexamethasone; **OR**
- b. An immunomodulatory agent (for example, thalidomide, lenalidomide, or pomalidomide) and dexamethasone;

OR

- F. As single-agent maintenance therapy for multiple myeloma in transplant candidates (NCCN 2A);

OR

- G. In combination with lenalidomide for maintenance therapy of high-risk multiple myeloma in transplant candidates (NCCN 2A);

OR

- III. Individual has a diagnosis of systemic light chain amyloidosis; **AND**

- IV. Individual is using as a single agent (NCCN 2A);

OR

- V. Individual is using in combination with:

- A. Bortezomib, cyclophosphamide, and dexamethasone;

OR

- B. Dexamethasone with or without bortezomib (DP B IIa);

OR

- VI. Individual has a diagnosis of pediatric Acute Lymphoblastic Leukemia (ALL), as T-ALL (NCCN 2A); **AND**

- VII. Individual is using a daratumumab-containing regimen (e.g. daratumumab, vincristine, pegaspargase or calaspargase, doxorubicin, and prednisone or dexamethasone) for relapsed/refractory T-ALL.

Requests for Darzalex (daratumumab) or Darzalex Faspro (daratumumab and hyaluronidase-fihj) may not be approved if the above criteria are not met and for all other indications not included above.

Key References:

1. Chari A, Martinez-Lopez J, Mateos M, et al. Daratumumab in combination with carfilzomib and dexamethasone in lenalidomide-refractory patients with relapsed multiple myeloma: Subgroup analysis of MMY1001. J Clin Oncol. 2018; 36(15):8002-8002
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: January 17, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Jakubowiak A, Chari A, Lonial S, et al. Daratumumab in combination with carfilzomib, lenalidomide and dexamethasone in patients with newly diagnosed multiple myeloma (MMY1001). J Clin Oncol. 2017; 35(15):8000-8000.
5. Kimmich CR, Terzer T, Benner A, et al: Daratumumab for systemic AL amyloidosis: prognostic factors and adverse outcome with nephrotic-range albuminuria. Blood 2020; 135(18):1517-1530.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
7. Roussel M, Merlini G, Chevret S, et al. A prospective phase II of daratumumab in previously treated systemic light chain amyloidosis (AL) patients. Blood. 2020; 135: 1531-1540.

8. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed October 2023.
- a. Multiple Myeloma. V1.2024. Revised September 22, 2023.
 - b. Systemic Light Chain Amyloidosis. V2.2023. Revised November 28, 2022.
 - c. Pediatric Acute Lymphoblastic Leukemia. V1.2024. Revised August 17, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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