

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

## 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 has not received treatment with an anti-CD38 agent (such as isatuximab, daratumumab, or daratumumab and hyaluronidase-fihj); **AND**
- III. 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, thalidomide and dexamethasone;
  - OR**
  - C. 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. As combination therapy following treatment with at least one prior line of therapy including a PI or an immunomodulatory agent when used with one of the following:

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- 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**

- IV. Individual has a diagnosis of systemic light chain amyloidosis; **AND**
- V. Individual has relapsed or refractory disease after at least one prior therapy; **AND**
- VI. Individual has not received treatment with an anti-CD38 agent (such as isatuximab, daratumumab, or daratumumab and hyaluronidase-fihj); **AND**
- VII. Individual is using as a single agent.

Requests for Darzalex (daratumumab) or Darzalex Faspro (daratumumab and hyaluronidase-fihj) may not be approved for the following:

- I. All other indications not included above; **OR**
- II. The reason for treatment is other than for a diagnosis of multiple myeloma, including plasma-cell leukemia.

**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. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 3, 2020.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. 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.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
7. Rousset 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.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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<b>Applicable</b>	X	X	X	X	X	X	X

8. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed April 2020.
- a. Multiple Myeloma. V4.2020. Revised May 8, 2020.
  - b. Systemic Light Chain Amyloidosis. V1.2020. Revised December 6, 2019.

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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