

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

Kyprolis (carfilzomib)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Kyprolis (carfilzomib)

APPROVAL CRITERIA

Requests for Kyprolis (carfilzomib) may be approved if the following criteria are met:

- I. Individual has a diagnosis of multiple myeloma; **AND**
- II. Individual does not have New York Heart Association (NYHA) class III or IV heart failure; **AND**
- III. Individual is using for one of the following:
 - A. Primary treatment in combination with lenalidomide plus dexamethasone (NCCN 2A); **OR**
 - B. Treatment for relapsed or refractory disease for one of the following:
 1. In combination with dexamethasone with or without lenalidomide when the individual has received one to three prior lines of therapy; **OR**
 2. As a single agent when the individual has received one or more prior lines of therapy; **OR**
 3. In combination with panobinostat when the individual has received at least two prior therapies, including a proteasome inhibitor and an immunomodulatory agent (for example, lenalidomide or thalidomide) (NCCN 2A); **OR**
 4. In combination with pomalidomide and dexamethasone when the individual has received at least two prior therapies, including a proteasome inhibitor and an immunomodulatory agent (for example, lenalidomide or thalidomide) (NCCN 2A); **OR**
 5. In combination with daratumumab and dexamethasone (NCCN 2A);

OR

- IV. Individual has a diagnosis of Waldenström's macroglobulinemia (NCCN 2A); **AND**
- V. Carfilzomib is used for one of the following:
 - A. As a primary agent, in combination with rituximab (or rituximab biosimilar) and dexamethasone; **OR**

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- B. For relapsed disease when the primary therapy of carfilzomib, rituximab (or rituximab biosimilar), and dexamethasone was given and relapse is greater than 12 months after therapy.

Requests for Kyprolis (carfilzomib) may **not** be approved when the criteria above are not met and for all other indications.

Key References:

1. Berenson JR, Hilger JD, Yellin O, et al. Replacement of bortezomib with carfilzomib for multiple myeloma patients progressing from bortezomib combination therapy. *Leukemia*. 2014; 28(7):1529-1536.
2. Brinthen S, Petrucci MT, Larocca A, et al. Carfilzomib, cyclophosphamide, and dexamethasone in patients with newly diagnosed multiple myeloma: a multicenter, phase 2 study. *Blood*. 2014; 124(1):63-69.
3. 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
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
5. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: January 23, 2020.
6. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
7. 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
8. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
9. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on January 23, 2020.
 - a. Multiple Myeloma. V2.2020. Revised October 9, 2019.
10. Shah JJ, Stadtmauer EA, Abonour R, et al. Carfilzomib, pomalidomide, and dexamethasone for relapsed or refractory myeloma. *Blood*. 2015; 126(20):2284-2290.

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.