

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. Primary treatment in combination with daratumumab, lenalidomide, and dexamethasone (NCCN 2A); **OR**
 - C. Primary treatment in combination with cyclophosphamide and dexamethasone for individuals with renal insufficiency and/or peripheral neuropathy (NCCN 2A); **OR**
 - D. In combination with lenalidomide as maintenance therapy for high-risk multiple myeloma in transplant candidates (NCCN 2A); **OR**
 - E. Treatment for previously treated relapsed, refractory, or progressive disease with 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 (Label); **OR**
 3. In combination with pomalidomide and dexamethasone (NCCN 2A); **OR**
 4. In combination with daratumumab (or daratumumab and hyaluronidase-fihj) and dexamethasone; **OR**
 5. In combination with isatuximab and dexamethasone; **OR**
 6. In combination with selinexor and dexamethasone (NCCN 2A); **OR**
 7. In combination with cyclophosphamide and dexamethasone (NCCN 2A); **OR**
 8. In combination with cyclophosphamide, thalidomide, and dexamethasone (NCCN 2A); **OR**
 9. In combination with venetoclax and dexamethasone for patients with t(11;14) (NCCN 2A); **OR**
 10. In combination with bendamustine and dexamethasone when the individual has received at least 3 prior therapies (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**
 - 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;

OR

- VI. Individual has a diagnosis of Systemic Light Chain Amyloidosis (NCCN 2A); **AND**
- VII. Carfilzomib is used as a single agent or in combination with dexamethasone for relapsed or refractory non-cardiac disease; **OR**
- VIII. Carfilzomib is used in combination with dexamethasone for individuals with significant neuropathy.

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

Key References:

1. Brinchen 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.
2. Brinchen S, D'agostino M, De Paoli L, et al. Phase I/II study of weekly carfilzomib, cyclophosphamide, dexamethasone in newly diagnosed transplant-ineligible myeloma. *Leukemia* 2018; 32: 979-985.
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. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: September 6, 2024.
5. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
6. 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
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
8. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on September 6, 2024.
 - a. Multiple Myeloma. V4.2024. Revised April 26, 2024.
 - b. Systemic Light Chain Amyloidosis. V2.2024. Revised December 12, 2023.
 - c. Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma. V2.2024. Revised December 5, 2023.
9. Shah JJ, Stadtmauer EA, Abonour R, et al. Carfilzomib, pomalidomide, and dexamethasone for relapsed or refractory myeloma. *Blood*. 2015; 126(20):2284-2290.
10. Manwani R, Mahmood S, Sachchithanatham S, et al. Carfilzomib is an effective upfront treatment in AL amyloidosis patients with peripheral and autonomic neuropathy. *Br J Haematol*. 2019; 187:638-641.
11. Mikhael JR, Reeder CB, Libby EN, et al. A phase I/II trial of cyclophosphamide, carfilzomib, thalidomide and dexamethasone (CYCLONE) in patients with newly diagnosed multiple myeloma: Final Results of MTD expansion cohort. *Blood* 2013; 122:3179.

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.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.