

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(Generic) **KYPROLIS**
(carfilzomib)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

MDC
Ref #817-A

FDA-APPROVED INDICATIONS¹

- Kyprolis in combination dexamethasone or with lenalidomide plus dexamethasone is indicated for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy.
- Kyprolis is indicated as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more prior lines of therapy.

Compendial Uses²

- Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of multiple myeloma? [If yes, no further questions.]	Yes	No
2	Does the patient have a diagnosis of Waldenström's macroglobulinemia/ lymphoplasmacytic lymphoma?	Yes	No

Guidelines for Approval			
Duration of Approval		12 Months	
Set 1: Multiple myeloma		Set 2: Waldenström's macroglobulinemia/ lymphoplasmacytic lymphoma	
Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)
1	None	2	1

Mapping Instructions			
	Yes	No	
1.	Approve, 12 months	Go to 2	
2.	Approve, 12 months	Deny	

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization.

REFERENCES

- Kyprolis [package insert]. Thousand Oaks, CA: Onyx Pharmaceuticals, Inc.; October 2019.
- The NCCN Drugs & Biologics Compendium 2018 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed October 16, 2019.
- The NCCN Clinical Practice Guidelines in Oncology Multiple Myeloma (Version 1.2019) 2018 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed October 16, 2019.

4. The NCCN Clinical Practice Guidelines in Oncology Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma (Version 2.2019) 2018 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed September 17, 2018.

DOCUMENT HISTORY

Written: Specialty Clinical Development (KP) 07/2012
Revised: KP 09/2012 (CAS set); WH 09/2013 (adapted from SGM), ST 09/2014, JP 08/2015, ST 02/2016, CN 10/2016, NU 10/2017, TE 07/2018 (CMS), BI 07/2019 (CMS), CM 07/2020 (CMS)
Reviewed: CDPR/DR 07/2012, SES 4/2014, 03/2015, MC 11/2015, SD 11/2016, AM 10/2017, DNC 10/2018, MMF 10/2019
External Review: 08/2012, 07/2014, 06/2015, 01/2016, 12/2016, 12/2017, 11/2018, 01/2020