Blue Cross Blue Shield Blue Care Network of Michigan

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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

Retired

Effective Date: 10/06/2022

Kyprolis® (carfilzomib)

HCPCS: J9047

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Criteria:
   a. Prescribed by or in consultation with an oncologist or hematologist
   b. Diagnosis of relapsing and refractory multiple myeloma
   c. If prescribed in combination with dexamethasone OR lenalidomide plus dexamethasone OR daratumumab and dexamethasone OR datatumumab and hyaluronidase-fihj and dexamethasone, the patient must have prior treatment failure with one to three lines of therapy
   d. If prescribed as monotherapy, the patient must have prior treatment failure of at least one other line of therapy

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing
   b. Authorization Period: 6 months at a time
   c. Renewal Criteria:
      i. For combination therapy with dexamethasone, dexamethasone and daratumumab, daratumumab and hyaluronidase-fihj and dexamethasone, or as monotherapy, treatment continued until unacceptable toxicity, disease progression, or treatment failure occurs.
      ii. For combination therapy with lenalidomide and dexamethasone treatment continued until Cycle 18 or earlier if disease progression or unacceptable toxicity occurs

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Kyprolis is FDA approved for the following indications:
    - For the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy in combination with
        - Lenalidomide and dexamethasone, or
        - Dexamthasone, or
        - Daratumumab and dexamethasone
        - Daratumumab and hyaluronidase-fihj and dexamethasone
    - As a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy

References:

1. Kyprolis [prescribing information]. Thousand Oaks, CA: Onyx Pharmaceuticals, Inc.; November 2021.
2. National Comprehensive Cancer Network. Multiple myeloma (Version 4.2022). 2021 Dec 14. Avaialble at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed on December 17, 2021
3. Lonial, Sagar, Mitsiades, Constantine, Richardson, Paul; Treatment options for relapsed and refractory Multiple Myeloma; Clin Cancer Res 2011;17:1264-1277. Published online March 15, 2011.
4. Dimopoulos MA, Moreau P, Palumbo A et al. Carfilzomib and dexamethasone versus bortezomib and dexamethasone for patients with relapsed or refractory multiple myeloma (ENDEAVOR): a randomized, phase 3 open-label, multicentre study. Lancet 2016;17(1):27-38.
5. Dimopoulos M, Wang M, Maisnar V, et al. Response and progression-free survival according to planned treatment duration in patients with relapsed multiple myeloma treated with carfilzomib, lenalidomide, and dexamethasone (KRd) versus lenalidomide and dexamethasone (Rd) in the phase III ASPIRE study. J Hematol Oncol. 2018 Apr 4; 11 (1) :49.
6. Moreau P, Mateos MV, Berenson JR, et al. Once weekly versus twice weekly carfilzomib dosing in patients with relapsed and refractory multiple myeloma (ARROW): interim analysis results of a randomised, phase 3 study. Lancet Oncol. 2018 Jul; 19 (7): 953 - 64.
7. Dimopoulos M, Quach H, Mateos MV, et al. Carfilzomib, dexamethasone, and daratumumab versus carfilzomib and dexamethasone for patients with relapsed or refractory multiple myeloma (CANDOR): results from a randomised, multicentre, open-label, phase 3 study. Lancet. 2020 Jul 18; 396 (10245): 186 - 97.
8. Chari A, Martinez-Lopez J, Mateos MV, et al. Daratumumab plus carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma. Blood. 2019 Aug 1; 134 (5): 421 - 31.

<table>
<tr><th colspan="3">Policy/UM Medical Management System Update History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>2.3</td><td>Effective Date: 10/06/2022</td><td>Retiring policy and adding Kyprolis to the Medical Oncology Drug Class Policy</td></tr>
<tr><td>2.2</td><td>Effective Date: 02/10/2022</td><td>Updated with the new indication in combination with daratumumab and hyaluronidase-fihj and dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma</td></tr>
<tr><td>2.1</td><td>Effective Date: 10/07/2021</td><td>Annual review of policy. No changes were made to the criteria</td></tr>
<tr><td>2.0</td><td>Effective Date: 12/01/2020</td><td>UM medical management system update for BCBS
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table></td></tr>
<tr><td>1.9</td><td>Effective Date: 10/08/2020</td><td>Updated to include new indication for use with daratumumab and dexamethasone after one to three prior lines of therapy</td></tr>
<tr><td>1.8</td><td>Effective Date: 04/16/2020</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>1.7</td><td>Effective Date: 05/09/2019</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>1.6</td><td>Effective Date: 05/03/2018</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>1.5</td><td>Effective Date: 07/05/2017</td><td>UM medical management system update for BCNA and MAPPO
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table></td></tr>
<tr><td>1.4</td><td>Effective Date: 05/04/2017</td><td>Annual Review of Medical Policy and Medicare Disclaimer added</td></tr>
<tr><td>1.3</td><td>Effective Date: 08/11/2016</td><td>Added new indication</td></tr>
<tr><td>1.2</td><td>Effective Date: 11/05/2015</td><td>Added new indication</td></tr>
<tr><td>1.1</td><td>Effective Date: 07/01/2015</td><td>UM medical management system update for BCN
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1.0	Effective Date: 11/08/2012	New Policy

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*