Carfilzomib (Kyprolis®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Kyprolis is indicated 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
   - Dexamethasone; or
   - Daratumumab and dexamethasone; or
   - Daratumumab and hyaluronidase-fihj and dexamethasone; or
   - Isatuximab and dexamethasone.
2. Kyprolis is indicated as a single agent for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.

B. Compendial Uses
1. Multiple Myeloma
2. Waldenström macroglobulinemia/lymphoplasmacytic lymphoma
3. Systemic light chain amyloidosis

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
Documentation of the presence of translocation t(11:14) (where applicable).

III. CRITERIA FOR INITIAL APPROVAL

A. Multiple Myeloma
Authorization of 12 months may be granted for treatment of multiple myeloma when the requested medication will used in any of the following regimens:
1. In combination with dexamethasone when the member has relapsed, refractory, or progressive disease
2. In combination with cyclophosphamide and dexamethasone

3. In combination with lenalidomide and dexamethasone
4. In combination with daratumumab, lenalidomide and dexamethasone
5. In combination with daratumumab and dexamethasone or daratumumab and hyaluronidase-fihj and dexamethasone when the member has relapsed, refractory, or progressive disease
6. In combination with pomalidomide and dexamethasone when the member has relapsed or progressive disease
7. In combination with cyclophosphamide, thalidomide, and dexamethasone when the member has relapsed or progressive disease
8. In combination with isatuximab-irfc and dexamethasone when the member has relapsed, refractory, or progressive disease
9. In combination with selinexor and dexamethasone when the member has relapsed or progressive disease
10. In combination with lenalidomide as maintenance therapy for symptomatic disease
11. In combination with bendamustine and dexamethasone when the member has received more than 3 prior therapies and has relapsed or refractory disease
12. In combination with venetoclax and dexamethasone when the member has relapsed or progressive disease and has translocation t(11:14) with supporting documentation.
13. As a single agent when the member has received one or more lines of therapy

B. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma
Authorization of 12 months may be granted for treatment of Waldenström macroglobulinemia/lymphoplasmacytic lymphoma.

C. Systemic Light Chain Amyloidosis
Authorization of 12 months may be granted for treatment of relapsed or refractory systemic light chain amyloidosis.

IV. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

For all indications, dosing does not exceed the following:
A. If using twice weekly: 56 mg/m^2 (not to exceed 124 mg) per dose, not to exceed 6 doses per 28 days
B. If using once weekly: 70 mg/m^2 (not to exceed 154 mg) per dose, not to exceed 3 doses per 28 days

V. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Kyprolis [package insert]. Thousand Oaks, CA: Onyx Pharmaceuticals, Inc.; June 2022.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 5, 2023.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma. Version 1.2024. https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed October 5, 2023.

EFFECTIVE DATE 7/31/2024

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