| Reference number(s) |
|---|
| 2370-C |

# SPECIALTY GUIDELINE MANAGEMENT

## KYPROLIS (carfilzomib)

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

B. Compendial Uses
1. Waldenström macroglobulinemia/lymphoplasmacytic lymphoma
2. Refer to Section II, Criteria for Initial Approval, for additional approvable regimens

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

### II. 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 or progressive disease
2. In combination with cyclophosphamide and dexamethasone
3. In combination with lenalidomide and dexamethasone
4. In combination with daratumumab and dexamethasone when the member has relapsed or progressive disease
5. In combination with panobinostat for members who have received at least two prior regimens, including bortezomib and an immunomodulatory agent
6. In combination with pomalidomide and dexamethasone for members who have received at least two prior therapies, including an immunomodulatory agent and a proteasome inhibitor
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 received at least one prior therapy
9. 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 when the requested medication will be used as a component of the CaRD (carfilzomib, rituximab, and dexamethasone) regimen.

## III. 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

## IV. CONTINUATION OF THERAPY

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

## V. REFERENCES

1. Kyprolis [package insert]. Thousand Oaks, CA: Onyx Pharmaceuticals, Inc.; August 2020.
2. The NCCN Drugs & Biologics Compendium 2020 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 06, 2020.
3. Sarclisa [package insert]. Bridgewater, NJ: Sanofi-aventis; March 2021.