Reference number(s)
2370-C

Specialty Guideline Management Kyprolis

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Kyprolis	carfilzomib

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.

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.
- 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.

Compendial Uses[2]

- Multiple Myeloma
- Waldenström macroglobulinemia/lymphoplasmacytic lymphoma

- Systemic light chain amyloidosis
- POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) Syndrome

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

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).

Coverage Criteria

Multiple Myeloma[1-3]

Authorization of 12 months may be granted for treatment of multiple myeloma when the requested medication will used in any of the following regimens:

- In combination with dexamethasone when the member has relapsed, refractory, or progressive disease
- In combination with cyclophosphamide and dexamethasone
- In combination with lenalidomide and dexamethasone
- In combination with daratumumab, lenalidomide and dexamethasone
- In combination with daratumumab and dexamethasone or daratumumab and hyaluronidase-fihj and dexamethasone when the member has relapsed, refractory, or progressive disease
- In combination with pomalidomide and dexamethasone when the member has relapsed or progressive disease
- In combination with pomalidomide, daratumumab, and dexamethasone for relapsed or progressive disease
- In combination with cyclophosphamide, thalidomide, and dexamethasone when the member has relapsed or progressive disease
- In combination with isatuximab-irfc and dexamethasone when the member has relapsed, refractory, or progressive disease
- In combination with selinexor and dexamethasone when the member has relapsed or progressive disease
- In combination with lenalidomide as maintenance therapy for symptomatic disease
- In combination with isatuximab-irfc, lenalidomde, and dexamethasone as primary therapy for symptomatic disease in members who are transplant candidates
- In combination with bendamustine and dexamethasone when the member has received more than 3 prior therapies and has relapsed or refractory disease

- In combination with venetoclax and dexamethasone when the member has relapsed or progressive disease and has translocation t(11:14) with supporting documentation.
- As a single agent when the member has received one or more lines of therapy

Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma[2]

Authorization of 12 months may be granted for treatment of Waldenström macroglobulinemia/lymphoplasmacytic lymphoma.

Systemic Light Chain Amyloidosis[2]

Authorization of 12 months may be granted for treatment of systemic light chain amyloidosis.

POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) Syndrome

Authorization of 12 months may be granted for treatment of POEMS syndrome in combination with dexamethasone.

Continuation of Therapy

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

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:

- If using twice weekly: 56 mg/m^2 (not to exceed 124 mg) per dose, not to exceed 6 doses per 28 days
- If using once weekly: 70 mg/m^2 (not to exceed 154 mg) per dose, not to exceed 3 doses per 28 days

References

1. Kyprolis [package insert]. Thousand Oaks, CA: Onyx Pharmaceuticals, Inc.; June 2022.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 4, 2024.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma. Version 1.2025. https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed October 4, 2024.