PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Kyprolis Prior Authorization Policy
- Kyprolis (carfilzomib intravenous infusion – Amgen/Onyx)

REVIEW DATE: 04/06/2022

OVERVIEW

Kyprolis, a proteasome inhibitor, is approved for **multiple myeloma** the following situations:[1]

- for relapsed or refractory disease, in combination with dexamethasone ± lenalidomide or Darzalex (daratumumab injection)/dexamethasone in patients who have received one to three lines of previous therapy.
- for relapsed or refractory disease, as a single agent in those who have received one or more lines of therapy.

Guidelines

Kyprolis is discussed in guidelines from the National Comprehensive Cancer Network (NCCN).[2]

- **Multiple Myeloma:** The NCCN guidelines (version 5.2022 – March 9, 2022) recommend multiple therapeutic regimens that may be used for primary therapy and previously treated multiple myeloma.[3] For transplant and non-transplant candidates, Kyprolis/lenalidomide/dexamethasone is recommended as an other regimen for primary treatment, and Kyprolis/cyclophosphamide/dexamethasone is among the regimens that are useful in certain circumstances. Additionally, Kyprolis/Darzalex/dexamethasone is listed as useful in certain circumstances as primary therapy for transplant candidates. For previously treated multiple myeloma, multiple preferred regimens are listed, including Kyprolis/lenalidomide/dexamethasone, Kyprolis/Sarclisa (isatuximab-irfc intravenous infusion)/dexamethasone, and Kyprolis/Darzalex/dexamethasone. Additionally, there are multiple Kyprolis-containing regimens recommended as other or useful in certain circumstances.
- **Systemic Light Chain Amyloidosis:** The NCCN guidelines (version 1.2022 – February 8, 2021) list Kyprolis ± dexamethasone as a therapy for previously treated disease, for patients with non-cardiac amyloidosis.[6] Of note, cardiac toxicity and hypertension are among the Warnings listed for Kyprolis.[1]
- **Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma:** In NCCN guidelines (version 2.2022 – December 7, 2021), Kyprolis/rituximab/dexamethasone is listed among other recommended regimens for primary treatment of Waldenstrom's Macroglobulinemia/lymphoplasmacytic lymphoma.[4]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Kyprolis. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Kyprolis as well as the monitoring required for adverse events and long-term efficacy, approval requires Kyprolis to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Kyprolis is recommended in those who meet one of the following criteria:

FDA-Approved Indication

1. **Multiple Myeloma**. Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i or ii):
     - **i.** Kyprolis will be used in combination with lenalidomide and dexamethasone; OR
     - **ii.** Patient has tried at least ONE prior regimen for multiple myeloma; AND
       Note: Examples include bortezomib, lenalidomide, Darzalex (daratumumab injection), Ninlaro (ixazomib capsules).
   - **C)** The medication is prescribed by or in consultation with an oncologist or a hematologist.

Other Uses with Supportive Evidence

2. **Light Chain Amyloidosis.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has non-cardiac amyloidosis; AND
   - **C)** Patient has received at least one other regimen for this condition; AND
     Note: Examples of agents used in other regimens include bortezomib, lenalidomide, cyclophosphamide, and melphalan.
   - **D)** The medication is prescribed by or in consultation with an oncologist or a hematologist.

3. **Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The medication will be used in combination with a rituximab product and dexamethasone; AND
   - **C)** The medication is prescribed by or in consultation with an oncologist or a hematologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Kyprolis is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Kyprolis® intravenous infusion [prescribing information]. Onyx/Amgen: Thousand Oaks, CA; November 2021.
2. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 1, 2022. Search term: carfilzomib.
3. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (Version 5.2022 – March 9, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 1, 2022.
4. The NCCN Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma Clinical Practice Guidelines in Oncology (Version 2.2022 – December 7, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 1, 2022.
5. Treon SP, Tripsas CK, Meid K, et al. Carfilzomib, rituximab, and dexamethasone (CaRD) treatment offers a neuropathy-sparing approach for treating Waldenström's macroglobulinemia. *Blood*. 2014;124(4):503-510.
6. The NCCN Systemic Light Chain Amyloidosis Clinical Practice Guidelines in Oncology (Version 1.2022 – June 29, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 1, 2022.