Medical Policy:

Kyprolis™ (carfilzomib) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.64	March 24, 2025	

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Kyprolis (carfilzomib) is a proteasome inhibitor that irreversibly binds to the N-terminal threonine-containing active sites of the 20S proteasome, the proteolytic core particle within the 26S proteasome. Carfilzomib had antiproliferative and proapoptotic activities in vitro in solid and hematologic tumor cells. In animals, carfilzomib inhibited proteasome activity in blood and tissue and delayed tumor growth in models of multiple myeloma, hematologic, and solid tumors.

Kyprolis (carfilzomib) is FDA approved as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy. It is also indicated in combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy.

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits [Medical Benefit]

Cap dose at a single dose limit body surface area (BSA) of 2.2m^2

Max Units (per dose and over time) [HCPCS Unit]:

Multiple Myeloma

720 billable units (720 mg) every 28 days

Guideline

I. Initial Approval Criteria

Kyprolis (carfilzomib) may be considered medically necessary when any of the following criteria is met:

Indication

1. **Multiple Myeloma†**

   The member has multiple myeloma and Kyprolis (carfilzomib) is being used as **ONE** of the following:

   A. Patient has relapsed or refractory disease who has received one to three lines of therapy:
      i. Used in combination with lenalidomide plus dexamethasone **OR**
      ii. In combination with dexamethasone **OR**
      iii. Used in combination with Daratumumab and dexamethasone; **OR**
      iv. Used in combination with Daratumumab and hyaluronidase-fihj and dexamethasone; **OR**
      v. Used in combination with Isatuximab and dexamethasone; **OR**
      vi. As a single agent

Limitations:

Kyprolis (carfilzomib) is not considered medically necessary when any of the following selection criteria is met:

1. Member has disease progression while taking Kyprolis (carfilzomib).
2. Kyprolis (carfilzomib) exceeds single dose limit BSA of 2.2 $m^{2.}$
3. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

† FDA Approved Indication

II. Renewal Criteria

Same as initial prior authorization policy criteria.

Dosage/Administration:

Dose
See package insert for dosing information

Applicable Procedure Codes

Code	Description
J9047	Injection, Carfilzomib, 1 mg

Applicable NDCs

Code	Description
76075-0101-01	Kyprolis 60mg Solution Reconstituted
76075-0102-01	Kyprolis 30mg Solution Reconstituted
76075-0103-01	Kyprolis 10mg Solution Reconstituted

ICD-10 Diagnoses

Code	Description
C90.02	Multiple myeloma in relapse
C90.10	Plasma cell leukemia not having achieved remission
C90.11	Plasma cell leukemia in remission
C90.12	Plasma cell leukemia in relapse

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/24/2025	Annual Review: Updated ICD-10 codes. No criteria changes.
EmblemHealth & ConnectiCare	2/5/2024	Annual Review: Updated dosing limits, no criteria changes
EmblemHealth & ConnectiCare	06/12/2023	Annual Review: Multiple Myeloma: Initial Criteria: Added "iii. Used in combination with Daratumumab and dexamethasone; OR iv. Used in combination with Daratumumab and hyaluronidase-fihj and dexamethasone; OR v. Used in combination with Isatuximab and dexamethasone; OR" Removed: "a. In combination with pomalidomide and dexamethasone for members who have received at least two prior therapies, including an immunomodulatory agent and a proteasome inhibitor, and have demonstrated disease progression on or within 60 days of completion of the last therapy OR b. In combination with panobinostat in members who have received at least two prior regimens, including bortezomib and an immunomodulatory agent OR c. Used in combination with lenalidomide and dexamethasone for transplant candidates and non-transplant patients with active multiple myeloma after 6 months following primary chemotherapy with the same regimen."
EmblemHealth & ConnectiCare	09/01/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	10/30/2019	-Under Initial Approval Criteria, added: Patient has relapsed or refractory disease who has received one to three lines of therapy AND Used in combination with lenalidomide plus dexamethasone OR In combination with dexamethasone **OR** As a single agent. - Used in combination with lenalidomide and dexamethasone for transplant candidates and non-transplant patients with active multiple myeloma after 6 months following primary chemotherapy with the same regimen.

References

1. Kyprolis prescribing information. ONYX Pharmaceuticals, Inc. South San Francisco, CA 2019.
2. Clinical Pharmacology Elsevier Gold Standard. 2017.

3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2017.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2017.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs .Bethesda, MD. 2017.