



CLINICAL MEDICAL POLICY	
Policy Name:	Kyprolis (carfilzomib)
Policy Number:	MP-043-MD-PA
Responsible Department(s):	Medical Management; Clinical Pharmacy
Provider Notice Date:	08/15/2017
Original Effective Date:	09/15/2017
Annual Approval Date:	07/15/2018
Revision Date:	N/A
Products:	Gateway Health SM Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 4

DISCLAIMER

Gateway HealthSM (Gateway) medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Gateway HealthSM provides coverage under the medical-surgical benefits of the Company's Medicaid products for medically necessary intravenous infusions of Kyprolis (carfilzomib).

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

DEFINITIONS

Multiple Myeloma (MM) – A cancer that forms in a type of white blood cell (plasma cell) in the bone marrow. Plasma cells help fight infections by making antibodies that recognize and attack germs. In patients with myeloma, the plasma cells form abnormal antibodies, which can damage the bone, bone marrow, and other organs.

Kyprolis (carfilzomib) – A proteasome inhibitor that exerts antiproliferative and proapoptotic activities to delay tumor growth.

PROCEDURES

1. Kyprolis is considered medically necessary as an intravenous infusion when the member meets the following criteria for multiple myeloma:
 - A. The member is aged 18 years or older; AND
 - B. The prescribing physician must be a Hematologist or Oncologist; AND
 - C. Prophylaxis for herpes zoster is needed (notated in chart documentation); AND
 - D. The drug will be used as monotherapy for the treatment of a member with relapsed or refractory multiple myeloma who has received one or more lines of therapy; OR
 - E. The drug will be used in combination with dexamethasone or lenalidomide for the treatment of relapsed or refractory multiple myeloma if the disease was previously treated with one to three lines of prior therapy; OR
 - F. The drug will be used in combination with dexamethasone or lenalidomide as primary treatment for relapsed/refractory multiple myeloma in stem cell transplant-eligible members who have received one to three lines of therapy and bortezomib-containing regimen is not suitable; AND
 - G. Dosing is consistent with FDA-approved labeling:
 - 1) Initial dose of 20mg/m² IV for two doses
 - 2) Maintenance dose of 27mg/m² IV with subsequent cycles
2. Contraindications
There are no known contraindications to Kyprolis.
3. When Kyprolis is not covered
Kyprolis is not covered for conditions other than those listed above because the scientific evidence has not been established.

Coverage may be provided for any non-FDA labeled indication or a medically accepted indication that is supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis for which it is prescribed and will be reviewed on a case-by-case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

4. Post-payment Audit Statement
The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Gateway HealthSM at any time pursuant to the terms of your provider agreement.

5. Place of Service

The place of service for the administration of Kyprolis is outpatient.

GOVERNING BODIES APPROVAL

On July 20, 2012, the FDA approved Kyprolis to treat patients with advanced multiple myeloma who have received at least two prior therapies, including treatment with bortezomib and an immunomodulatory therapy.

On July 24, 2015, the FDA approved Kyprolis to treat patients with relapsed multiple myeloma with a combination of lenalidomide and dexamethasone who have received one to three prior lines of therapy.

On January 21, 2016, the FDA approved Kyprolis to treat patients with relapsed or refractory multiple myeloma with a combination of dexamethasone (monotherapy) or with lenalidomide plus dexamethasone who have received one to three lines of therapy.

CODING REQUIREMENTS

Procedure Codes

HCPCS Code	Description
J9047	Injection, carfilzomib, 1 mg

Diagnosis Codes

ICD-10 Codes	Description
C90.00	Multiple myeloma not having achieved remission
C90.01	Multiple myeloma in remission
C90.02	Multiple myeloma in relapse
C90.10	Plasma cell leukemia
C90.11	Plasma cell leukemia in remission
C90.12	Plasma cell leukemia in relapse
C90.20	Extramedullary plasmacytoma not having achieved remission
C90.21	Extramedullary plasmacytoma in remission
C90.22	Extramedullary plasmacytoma in relapse
C90.30	Solitary plasmacytoma not having achieved remission
C90.31	Solitary plasmacytoma in remission
C90.32	Solitary plasmacytoma in relapse
Z85.72	Personal history of non-Hodgkin lymphoma
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues

REIMBURSEMENT

Participating facilities will be reimbursed per their Gateway HealthSM contract.

POLICY SOURCE(S)

Kyprolis® (carfilzomib) [package insert]. Thousand Oaks, CA: Amgen; 08/2016. Accessed on December 28, 2016 and available at: http://pi.amgen.com/~media/amgen/repositorysites/pi-amgen-com/kyprolis/kyprolis_pi.ashx.

The National Comprehensive Cancer Network® NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Accessed on December 28, 2016 and available at: <http://www.nccn.org/index.asp>.

- NCCN Guidelines Version 3.2017: Multiple Myeloma

Vij R, Siegel DS, Jagannath S, et al. An open-label, single-arm, phase 2 study of single-agent carfilzomib in patients with relapsed and/or refractory multiple myeloma who have been previously treated with bortezomib. Br J Haematol 2012. Accessed on December 28, 2016 and available at: <http://www.ncbi.nlm.nih.gov/pubmed/22845873>.

Stewart AK, Rajkumar SV, Dimopoulos MA, et al. Carfilzomib, lenalidomide, and dexamethasone for relapsed multiple myeloma. N Engl J Med 2015; 372:142-152. Accessed on December 28, 2016 and available at: <http://www.ncbi.nlm.nih.gov/pubmed/25482145>.

Policy History

Date	Activity
06/06/2017	Initial policy developed
07/19/2017	QI/UM Committee approval
09/15/2017	Provider effective date