CLINICAL MEDICATION POLICY	
Policy Name:	Kyprolis® (carfilzomib)
Policy Number:	MP-026-MC-PA
Approved By:	Medical Management; Clinical Pharmacy
Provider Notice Date:	07/01/2017
Original Effective Date:	08/01/2017
Annual Approval Date:	06/01/2018
Revision Date:	N/A
Products:	Pennsylvania Medicare Assured
Application:	All participating hospitals and providers
Page Number(s):	1 of 4

DISCLAIMER

Gateway Health℠ (Gateway) clinical medication policy is intended to serve only as a general reference resource regarding payment and 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 Health℠ provides coverage under the medical surgical benefits of the Company's Medicare products for medically necessary 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.

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 patient meets the following criteria for multiple myeloma:
    A. The patient 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 patient 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 with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who has received one to three lines of therapy; AND
    F. Dosing is consistent with FDA-approved labeling:
        1) The dose does not exceed an initial dose of 20 mg/m2 IV for two doses (in Cycle 1 - Days 1 and 2) or maintenance dose of 27 mg/ m2 IV with subsequent cycles when used in combination with lenalidomide and dexamethasone; AND
        2) The dose not exceed 18 cycles when used in combination with lenalidomide and dexamethasone; OR
        3) The dose does not exceed an initial dose of 20 mg/m2 IV for two doses (in Cycle 1 - Days 1 and 2) or a maintenance dose of 56 mg/m2 IV with subsequent cycles when used as a 10-minute infusion monotherapy; OR
        4) The dose does not exceed an initial dose of 20mb/m2 Iv for two doses (in Cycle 1-Days 1 and 2) or a maintenance dose of 27mg/m2 IV with subsequent cycles when used as a 10 minute infusion monotherapy; OR
        5) The dose does not exceed an initial dose of 20 mg/m2 IV for two doses (in Cycle 1 - Days 1 and 2) or a maintenance dose of 56 mg/m2 IV with subsequent cycles when used as a 30-minute infusion monotherapy.

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 Health℠ 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.

6. Coverage Determination
   Gateway Health ℠ follows the coverage determinations made by CMS as outlined in either the national coverage determinations (NCD) or the state-specific local carrier determination (LCD).

   For Pennsylvania, please use the following link for Novitas Solutions List of LCDS:
   https://www.novitassolutions.com/webcenter/portal/MedicareJL/page/pagebyid?contentId=00024370&_afrLoop=578664761207593#!%40%40%3F_afrLoop%3D578664761207593%26contentId%3D00024370%26_adf.ctrl-state%3D49ww9vpbm_55

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 Health℠ 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
06/21/2017	QI/UM Committee approval
07/20/2017	Revision: Removed reimbursement language from Position Statement
08/01/2017	Provider effective date