CLINICAL MEDICATION POLICY	
Policy Name:	VELCADE® (bortezomib)
Policy Number:	MP-014-MC-KY
Responsible Departments:	Medical Management; Clinical Pharmacy
Provider Notice Date:	06/19/2017
Original Effective Date:	07/19/2017
Annual Approval Date:	04/19/2018
Revision Date:	N/A
Products:	Kentucky Medicare Assured
Application:	All participating and nonparticipating hospitals and providers
Page Number(s):	1 of 5

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 benefits of the Company's Medicare products for medically necessary VELCADE® (bortezomib) intravenous administration in the treatment of multiple myeloma and mantle cell lymphoma.

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

VELCADE® (bortezomib) – A type of chemotherapy called a targeted therapy. It is in a class of medicines called proteasome inhibitors that performs activities that block or slow down the actions of proteasomes; to delay tumor growth and influence tumor cell death.

Multiple Myeloma – A cancer that forms in a type of white blood cell called plasma cell in the bone marrow. Plasma cells help you 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.

Mantle Cell Lymphoma – A cancer that forms in the lymph nodes

VMP Regimen – Bortezomib, melphalan, prednisone

VMPT-VT Regimen – Bortezomib, melphalan, prednisone, thalidomide; bortezomib, thalidomide

PROCEDURES

1. Velcade is considered medically necessary as an intravenous infusion:
   A. For the treatment of previously untreated multiple myeloma (MM) when the member meets the following criteria:
      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 with acyclovir (notated in chart documentation); AND
      D. The member's platelets and ANC lab values should be monitored before the start of treatment and at the beginning of each cycle; AND
      E. Member should not have hypersensitivity to bortezomib, boron or mannitol; AND
      F. The drug will be used as part of a VMP regimen in previously untreated members; OR
      G. The drug will be used in a combination therapy regimen with two other VMPT-VT drugs (e.g., melphalan and prednisone) to treat previously untreated multiple myeloma (MM); OR
      H. The drug will be used in combination therapy with dexamethasone as the primary therapy to treat members with relapsed multiple myeloma (MM), OR the primary therapy can be administered with or without doxorubicin, thalidomide, lenalidomide or cyclophosphamide.
      I. The drug will be used as subsequent therapy in combination with panobinostat and dexamethasone when member has received two or more previous lines of therapy; AND
      J. Dosing is consistent with FDA-approved labeling:
         a) VMP regimen: The dose should not exceed 1.3 mg/m2 for a total of 54 weeks
         b) VMPT-VT regimen: The dose should not exceed 1.3 mg/m2 for a maximum of 54 weeks during the induction phase, and the dose should not exceed 1.3 mg/m2 for a maximum of 2 years during the VT maintenance phase.
         c) Combination therapy with dexamethasone: The dose should not exceed 1.3 mg/m2
         d) Second-Line Therapy: The dose should not exceed 1.3 mg/m2

1. The drug may restart at last tolerated dose twice weekly every 3 weeks for a maximum of 8 cycles if relapsed at least 6 months after previous bortezomib therapy
2. The drug may administer alone or with dexamethasone

e) Subsequent Therapy in combination with panobinostat/dexamethasone: Previous therapy which includes an immunomodulatory drug (IMID) and bortezomib

B. For the treatment of mantle cell lymphoma when the member meets the following criteria:
   1) The member is aged 18 years or older; AND
   2) The prescribing physician must be a hematologist or oncologist; AND
   3) Prophylaxis for herpes zoster with acyclovir should be considered (notated in chart documentation); AND
   4) Platelets, ANC, hemoglobin should be monitored at the beginning of each cycle; AND
   5) The drug will be used as part of a VcR-CAP regimen in previously untreated members; OR
   6) The drug will be used as second-line therapy after disease progression on induction therapy; AND
   7) Dosing is consistent with FDA-approved labeling:
      a) VcR-CAP regimen: The dose should not exceed 1.3 mg/m2 for a total of 18 weeks
      b) Second-Line Therapy: The dose should not exceed 1.3 mg/m2

2. Contraindications
   Velcade is contraindicated in members with hypersensitivity to bortezomib, boron or mannitol, including anaphylactic reactions.

   Velcade is contraindicated for intrathecal administration.

3. When services are not covered
   Velcade is not covered for conditions other than those listed above because the scientific evidence has not been established.

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 Velcade is outpatient.

GOVERNING BODIES APPROVAL

On May 14, 2003, the FDA approved Velcade for the treatment of refractory or relapsed multiple myeloma. This approval is Velcade first approval and is the first in a new class of anticancer agents known as proteasome inhibitors.

In 2005, Velcade was approved for the treatment of patients with multiple myeloma who had received at least one prior therapy.

On December 8, 2006, the FDA approved Velcade for the treatment of patients with mantle cell lymphoma who have received at least one prior therapy.

On June 20, 2008, the FDA approved Velcade for the treatment of patients with untreated multiple myeloma.

On October 10, 2014, the FDA approved Velcade for use in previously untreated patients with mantle cell lymphoma. This is the first treatment in the United States to be approved for use in previously untreated patients with mantle cell lymphoma.

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). There is no specific NCD for this medication. For Kentucky, CGS, the local carrier, does not have a specific LCD for Velcade. For additional information, please see: http://www.cgsmedicare.com/partb/medicalpolicy/index.html

CODING REQUIREMENTS

Procedure Codes

HCPCS Codes	Description
J9041	Injection, bortezomib, 0.1 mg

Diagnosis Codes

ICD-10 Codes	Description
C83.10	Mantle cell lymphoma, unspecified site
C83.11	Mantle cell lymphoma, lymph nodes of head, face, and neck
C83.12	Mantle cell lymphoma, intrathoracic lymph nodes
C83.13	Mantle cell lymphoma, intra-abdominal lymph nodes
C83.14	Mantle cell lymphoma, lymph nodes of axilla and upper limb
C83.15	Mantle cell lymphoma, lymph nodes of inguinal region and lower limb
C83.16	Mantle cell lymphoma, intrapelvic lymph nodes
C83.17	Mantle cell lymphoma, spleen
C83.18	Mantle cell lymphoma, lymph nodes of multiple sites
C83.19	Mantle cell lymphoma, extranodal and solid organ sites

C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse

REIMBURSEMENT

Participating facilities will be reimbursed per their Gateway Health℠ contract.

POLICY SOURCE(S)

Velcade® (Bortezomib) [package insert]. Cambridge, MA: Millennium Pharms; 09/2015. Accessed on January 5, 2017 and retrieved from: http://www.velcade.com/.

Bortezomib. In: Micromedex 2.0 online. Ann Arbor (MI): Truven Health Analytics; [2016; accessed December 14, 2016].

Richardson P, Sonneveld P, Schuster M, et al. Bortezomib or high-dose dexamethasone for relapsed multiple myeloma. N Engl J Med. 2005; 352: 2487-2498 Accessed on January 5, 2017 and retrieved at: http://www.ncbi.nlm.nih.gov/pubmed15958804.

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

- NCCN Guidelines Version 3.2017: Multiple Myeloma
- NCCN Guidelines Version 1.2017: B-cell Lymphomas

Policy History

Date	Activity
03/27/2017	Initial policy developed
04/19/2017	QI/UM Committee approval
07/19/2017	Provider effective date