ATRIO HEALTH PLANS

Chemotherapy: Mantle Cell Lymphoma

Bortezomib Products: Dr. Reddy's J9046 / Fresenia J9048 / Hospira J9049 are Non-preferred products. The preferred product is generic bortezomib (velcade) J9041

Prior Authorization Step Therapy

Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

- ☐ Patient has a diagnosis of one of the following:
  - ☐ Multiple myeloma; OR
  - ☐ One of the following non-Hodgkin lymphomas:
    - ☐ Mantle cell lymphoma; OR
    - ☐ Peripheral T-cell lymphomas (that is, peripheral T-cell lymphoma [PTCL], anaplastic large cell lymphoma [ALCL], or angioimmunoblastic T cell lymphoma [AITL]) as therapy for refractory or relapsed disease ; OR
    - ☐ Waldenström's macroglobulinemia/ lymphoplasmacytic lymphoma ;
    - ☐ Relapsed or refractory Philadelphia chromosome negative T-cell acute lymphoblastic leukemia OR
    - ☐ Castleman's Disease); OR
    - ☐ T-Cell Lymphomas);

☐ Systemic light chain amyloidosis OR
☐ Other rare plasma cell dyscrasias requiring treatment, including but not limited to, POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal gammopathy, and skin changes) syndrome OR
☐ Kaposi Sarcoma; OR
☐ Relapsed or Refractory Pediatric Hodgkin Lymphoma; OR
☐ Relapsed or Refractory Pediatric Acute Lymphoblastic Leukemia.

- Requests for Velcade (bortezomib) may not be approved for the following:
  A. Chronic lymphocytic lymphoma (CLL); OR
  B. Chronic myeloid leukemia (CML); OR
  C. Diffuse large B-cell lymphoma (DLBCL); OR
  D. Follicular lymphoma (FL); OR
  E. Gastric and non-gastric mucosa-associated lymphoid tissue (MALT) lymphoma; OR
  F. Hodgkin lymphoma (HL); OR
  G. Mycosis fungoides/Sézary syndrome; OR
  H. Myelodysplastic syndrome; OR
  I. Neuroendocrine tumors (for example, carcinoid or islet cell tumors); OR
  J. Sarcoma (for example, osteosarcoma); OR
  K. Solid tumors (for example, biliary tract, colorectal, head and neck, metastatic melanoma (lung), nonsmall cell lung cancer [NSCLC], or pancreatic carcinoma); OR
  L. Solitary plasmacytoma.

☐ Continuation Requests: (Clinical documentation required for all requests)
☐ Patient had an adequate response or significant improvement while on this medication.
If not, please provide clinical rationale for continuing this medication: _____
_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Chemotherapy: Mantle Cell Lymphoma PA

Drug Name(s):

BORTEZOMIB VELCADE DR. REDDY'S FRESENIUS KABI HOSPIRA

Criteria for approval of Prior Authorization Drug:

Bortezomib may be indicated when ALL of the following are present(1)(2):

1. Age 18 years or older
2. Clinical diagnosis of 1 or more of the following:
    a. Mantle cell lymphoma and 1 or more of the following:
        i. Previously untreated disease and ALL of the following:
            1. Absolute neutrophil count 1500/mm3 (1.5 x109/L) or greater
            2. Hemoglobin 8.0 g/dL (80 g/L) or greater
            3. Platelet count 100,000/mm3 (100 x109/L) or greater
        ii. Relapsed disease or refractory to at least one prior therapy
    b. Multiple myeloma and 1 or more of the following:
        i. Previously untreated disease and ALL of the following
            1. Absolute neutrophil count 1000/mm3 (1.0 x109/L) or greater
            2. Platelet count 70,000/mm3 (70 x109/L) or greater
        ii. Relapsed disease
    c. Herpes zoster prophylaxis coadministered with bortezomib therapy
    d. Patient not pregnant
3. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

Cannot be prescribed for experimental or investigational use.

Prescriber Restrictions:

Oncologist or other cancer specialist

Coverage Duration:

New Start: Approval will be for 6 months
Continuation: Approval will be for 12 months

FDA Indications:

Velcade

- Mantle cell lymphoma
- Multiple myeloma

Off-Label Uses:

Velcade

- AL amyloidosis
- Graft versus host disease
- Waldenstrom macroglobulinemia
- Cardiac transplant rejection, antibody-mediated, adjunctive treatment
- Desensitization therapy – transplantation of heart

- Liver transplant rejection, antibody-mediated, adjunctive treatment

Age Restrictions:
Safety and effectiveness not established in pediatric patients

Other Clinical Considerations:
Cancer diagnoses: Criteria as per NCCN or other FDA-approved cancer related guidelines.

Resources:
https://www.micromedexsolutions.com/micromedex2/librarian/CS/9D34BE/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/70D83D/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=927753&contentSetId=100&title=Bortezomib&servicesTitle=Bortezomib&brandName=Velcade&UserMdxSearchTerm=velcade&=null#