Velcade (bortezomib)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Velcade (bortezomib)

APPROVAL CRITERIA

Requests for Velcade (bortezomib) may be approved if the following criteria are met:

I. Individual has a diagnosis of one of the following:

A. Multiple myeloma; **OR**
B. Mantle cell lymphoma; **OR**
C. 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 (NCCN 2B); **OR**
D. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (NCCN 2A); **OR**
E. Relapsed or refractory Philadelphia chromosome negative T-cell acute lymphoblastic leukemia (T-ALL) (NCCN 2A); **OR**
F. Castleman's Disease (NCCN 2A); **OR**
G. T-Cell Lymphomas (NCCN 2A);

OR

H. Systemic light chain amyloidosis (NCCN 2A); **OR**
I. Other rare plasma cell dyscrasias requiring treatment, including but not limited to, POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal gammopathy, and skin changes) syndrome (Dispenzieri 2017); **OR**
J. Kaposi Sarcoma (NCCN 2A); **OR**
K. Relapsed or Refractory Pediatric Hodgkin Lymphoma (NCCN 2A); **OR**
L. Relapsed or Refractory Pediatric Acute Lymphoblastic Leukemia (NCCN 2A).

Requests for Velcade (bortezomib) may not be approved for the following:

I. All other indications not included above, including, but not limited to:
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), non-small cell lung cancer [NSCLC], or pancreatic carcinoma); **OR**
L. Solitary plasmacytoma.

Key References:

1. Bertaina A, Vinti L, Strocchio L, et al. The combination of bortezomib with chemotherapy to treat relapsed/refractory acute lymphoblastic leukaemia of childhood. Br J Haematol. 2017 Feb;176(4):629-636
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. URL: http://www.clinicalpharmacology.com. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.
4. Dispenzieri A. POEMS syndrome: 2017 update on diagnosis, risk-stratification, and management. Am J Hematol. 2017; 92:814-829.
5. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
6. Evens AM, Rosen ST, Helenowski I, et al. A phase I/II trial of bortezomib combined concurrently with gemcitabine for relapsed or refractory DLBCL and peripheral T-cell lymphomas. Br J Haematol. 2013; 163(1):55-61.
7. Horton TM, Whitlock JA, Lu X, et al. Bortezomib reintroduction chemotherapy in high-risk ALL in first relapse: a report from the Children's Oncology Group. Br J Haematol. 2019 Jul;186 (2): 274-285.
8. Horton TM, Drachtman RA, Chen L, et al. A phase 2 study of bortezomib in combination with ifosfamide/vinorelbine in paediatric patients and young adults with refractory/recurrent Hodgkin Lymphoma: a Children's Oncology Group study. Br J Haematol 2015; 170:118-122.
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10. Ishii Y, Yamazaki E, Ishiyama Y, et al. Successful treatment of POEMS syndrome with bortezomib and dexamethasone, combined with radiotherapy, and followed by autologous stem cell transplantation. Int J Hematol. 2013; 98(6):723-728.
11. Ishitsuka K, Utsunomiya A, Katsuya H, et al. A phase II study of bortezomib in patients with relapsed or refractory aggressive adult T-cell leukemia/lymphoma. Cancer Sci. 2015; 106(9):1219-1223.
12. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
13. Li J, Zhou DB. New advances in the diagnosis and treatment of POEMS syndrome. Br J Haematol. 2013; 161(3):303-315.
14. Reid E, Suazo A, Lensing S, et al. Pilot trial AMC-063: Safety and efficacy of bortezomib in AIDS-associated Kaposi Sarcoma. Clin Cancer Res 2019 Oct 17.
15. Zinzani PL, Musuraca G, Tani M, et al. Phase II trial of proteasome inhibitor bortezomib in patients with relapsed or refractory cutaneous T-cell lymphoma. J Clin Oncol. 2007; 25(27):4293-4297.
16. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on January 2, 2024.
    a. Acute Lymphoblastic Leukemia. V3.2023. Revised October 9, 2023.

b. B-Cell Lymphomas. V6.2023. Revised October 10, 2023.
c. Kaposi Sarcoma V1.2024. Revised November 7, 2023.
d. Multiple Myeloma. V2.2024. Revised November 1, 2023.
e. Pediatric Acute Lymphoblastic Leukemia V3.2024. Revised October 31, 2023.
f. Pediatric Hodgkin Lymphoma. V2.2023. Revised March 9, 2023.
g. Primary Cutaneous Lymphomas V1.2023. Revised January 5, 2023.
h. Systemic Light Chain Amyloidosis. V2.2024. Revised November 21, 2023.
i. T-Cell Lymphomas. V1.2023. Revised January 5, 2023.
j. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma. V2.2024. Revised December 5, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.