

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

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. One of the following non- Hodgkin lymphomas:
 1. Mantle cell lymphoma; **OR**
 2. 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**
 3. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (NCCN 2A);
- OR**
- C. Systemic light chain amyloidosis (NCCN 2A); **OR**
- D. Other rare plasma cell dyscrasias requiring treatment, including but not limited to, POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal gammopathy, and skin changes) syndrome (Dispenzieri 2017).

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**

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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- 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.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: March 30, 2019.
3. Dispenzieri A. POEMS syndrome: 2017 update on diagnosis, risk-stratification, and management. Am J Hematol. 2017; 92:814-829.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. 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.
6. 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.
7. 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.
8. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
9. Li J, Zhou DB. New advances in the diagnosis and treatment of POEMS syndrome. Br J Haematol. 2013; 161(3):303-315.
10. 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.
11. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on April 3, 2019.
 - a. T-Cell Lymphomas. V2.2019. Revised December 17, 2018.
 - b. Multiple Myeloma. V2.2019. Revised November 16, 2018.
 - c. B-Cell Lymphomas. V2.2019. Revised March 6, 2019.
 - d. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma. V2.2019. Revised September 14, 2018
 - e. Systemic Light Chain Amyloidosis. V1.2019. Revised October 26, 2018

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