



Medical Policy Manual

Draft Revised Policy: Do Not Implement

Bortezomib (Velcade®; Bortezomib, Boruzu™)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

**The proposal is to add text/statements in red and to delete text/statements with strikethrough:
POLICY**

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Treatment of adult patients with multiple myeloma
2. Treatment of adult patients with mantle cell lymphoma

B. Compendial Uses

1. Systemic light chain amyloidosis
2. Waldenström macroglobulinemia/lymphoplasmacytic lymphoma
3. Multicentric Castleman disease
4. Adult T-cell leukemia/lymphoma
5. Antibody mediated rejection of solid organ
6. Acute lymphoblastic leukemia
7. Follicular lymphoma
8. Kaposi sarcoma
9. Pediatric Classic Hodgkin Lymphoma
10. POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) Syndrome

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Multiple myeloma

Authorization of 12 months may be granted for the treatment of multiple myeloma.

B. Mantle cell lymphoma

Authorization of 12 months may be granted for the treatment of mantle cell lymphoma.

C. Multicentric Castleman disease

Authorization of 12 months may be granted for the treatment of multicentric Castleman disease as subsequent therapy.



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- D. Systemic light chain amyloidosis**
Authorization of 12 months may be granted for the treatment of systemic light chain amyloidosis.
- E. Waldenström macroglobulinemia/lymphoplasmacytic lymphoma**
Authorization of 12 months may be granted for the treatment of Waldenström macroglobulinemia/lymphoplasmacytic lymphoma.
- F. Adult T-cell Leukemia/Lymphoma**
Authorization of 12 months may be granted for the treatment of adult T-cell leukemia/lymphoma when the requested medication will be used as a single agent for subsequent therapy.
- G. Antibody mediated rejection of solid organ**
Authorization of 12 months may be granted for the treatment of antibody mediated rejection of solid organ.
- H. Acute lymphoblastic leukemia**
Authorization of 12 months may be granted for the treatment of acute lymphoblastic leukemia.
- I. Follicular Lymphoma**
Authorization of 12 months may be granted for the treatment of relapsed or refractory follicular lymphoma.
- J. Kaposi sarcoma**
Authorization of 12 months may be granted for the treatment of Kaposi sarcoma as subsequent therapy.
- K. Pediatric Classic Hodgkin Lymphoma**
Authorization of 12 months may be granted for the treatment of relapsed or refractory Pediatric Classic Hodgkin Lymphoma.
- L. POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) Syndrome**
Authorization of 12 months may be granted for treatment of POEMS syndrome in combination with dexamethasone.
- III. DOSAGE AND ADMINISTRATION**
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.
- For all indications, dosing does not exceed 1.6 mg/m² per dose and does not require more than 7 doses per 30-day period.
- IV. CONTINUATION OF THERAPY**
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

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BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Velcade [package insert]. Cambridge, MA: Millennium Pharmaceuticals, Inc.; August 2022.
2. Boruzu [package insert]. Telangana, India; Amneal Oncology Private Limited; August 2024.
3. bortezomib [package insert]. Lake Zurich, IL: Fresenius Kabi; April 2022.
4. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed October 4, 2023.
5. Ejaz NS, Alloway RR, Halleck F, et al. Review of bortezomib treatment of antibody-mediated rejection in renal transplantation. *Antioxid Redox Signal*. 2014;21(17):2401-2418.
6. Blanco B, Sanchez-Abarca LI, Caballero-Velazquez T, et al. Depletion of alloreactive T-cells in vitro using the proteasome inhibitor bortezomib preserves the immune response against pathogens. *Leuk Res*. 2011;35(10):1412-1415.
7. Claes DJ, Yin H, Goebel J. Protective immunity and use of bortezomib for antibody-mediated rejection in a pediatric kidney transplant recipient. *Pediatr Transplant*. 2014;18(4):E100-E105.
8. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; Updated September 24, 2022. <https://online.lexi.com>. Accessed October 4, 2023.
9. DRUGDEX® System (electronic version). Micromedex Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com>. Accessed October 4, 2023.

EFFECTIVE DATE

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