

## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology (Injectable) – Bortezomib Prior Authorization Policy

- Velcade® (bortezomib intravenous or subcutaneous injection – Takeda, generic)

**REVIEW DATE:** 10/26/2022

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### OVERVIEW

Bortezomib, a proteasome inhibitor, is indicated in adults with the following conditions:<sup>1</sup>

- **Mantle cell lymphoma.**
- **Multiple myeloma.**

### Guidelines

Bortezomib is mentioned in several guidelines published by the National Comprehensive Cancer Network (NCCN).<sup>2-10</sup>

- **Acute lymphoblastic leukemia:** Guidelines for adults (version 1.2022 – April 4, 2022) and for pediatric patients (version 1.2022 – October 1, 2021) include bortezomib + chemotherapy among the other recommended regimens for relapsed or refractory disease.<sup>3,4</sup>
- **B-cell lymphomas:** Guidelines (version 5.2022 – July 12, 2022) recommend bortezomib (as a component of VR-CAP [bortezomib/rituximab/cyclophosphamide/ doxorubicin/prednisone]) as a preferred less aggressive therapy option for the initial treatment of patients (induction therapy) with newly diagnosed mantle cell lymphoma.<sup>5</sup> Bortezomib ± rituximab is also listed as second-line and subsequent therapy for relapsed or refractory mantle cell lymphoma. For patients with relapsed or refractory multicentric Castleman’s disease, bortezomib ± rituximab is listed among the treatment options.
- **Kaposi sarcoma:** Guidelines (version 1.2022 – February 3, 2022) include bortezomib among the subsequent systemic therapy options for patients who have relapsed or refractory disease.<sup>6</sup>
- **Classic Hodgkin lymphoma:** Guidelines for pediatric disease (version 1.2022 – April 8, 2022) include bortezomib/ifosfamide/vinorelbine among the subsequent therapy options for relapsed or refractory disease.<sup>7</sup>
- **Multiple myeloma:** Bortezomib features prominently in the NCCN Multiple Myeloma clinical practice guidelines (version 1.2023 – September 14, 2022).<sup>8</sup> Bortezomib-containing regimens are listed as preferred for primary therapy (transplant and nontransplant candidates) and previously treated disease. Bortezomib is also a component of multiple other regimens across the spectrum of disease. For maintenance therapy, bortezomib ± lenalidomide capsules (and ± dexamethasone for transplant candidates) are also listed as treatment options.
- **Systemic light chain amyloidosis:** Guidelines (version 1.2023 – September 1, 2022) list bortezomib alone or in combination with other agents for primary therapy (transplant and non-transplant candidates) and previously treated disease.<sup>9</sup> NCCN notes that bortezomib was well tolerated at doses up to 1.6 mg/m<sup>2</sup> on a once-weekly schedule and 1.3 mg/m<sup>2</sup> on a twice-weekly schedule. The once-weekly regimen was associated with lower neurotoxicity.
- **Waldenstrom’s macroglobulinemia/lymphoplasmacytic lymphoma:** Guidelines (version 1.2023 – July 6, 2022) recommend bortezomib/dexamethasone/rituximab as a preferred regimen for primary therapy and for previously treated disease.<sup>10</sup>

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## **POLICY STATEMENT**

Prior Authorization is recommended for prescription benefit coverage of bortezomib. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with bortezomib, as well as the monitoring required for adverse events and long-term efficacy, approval requires bortezomib to be prescribed by or in consultation with a physician who specializes in the condition being treated.

**Automation:** None.

## **RECOMMENDED AUTHORIZATION CRITERIA**

Coverage of bortezomib is recommended in those who meet one of the following criteria:

### **FDA-Approved Indications**

- 1. Mantle Cell Lymphoma.** Approve for 1 year if the patient meets BOTH of the following (A and B):
  - A)** Patient meets ONE of the following criteria (i or ii):
    - i.** Patient has previously tried at least one other therapy for mantle cell lymphoma; **OR**  
Note: Examples of other therapies for mantle cell lymphoma include regimens containing a rituximab product, cytarabine, cisplatin, cyclophosphamide, doxorubicin, vincristine, or bendamustine.
    - ii.** The medication is used in combination with at least one other agent; **AND**  
Note: Examples of other agents used in combination with bortezomib for mantle cell lymphoma include a rituximab product, bendamustine, cyclophosphamide, and doxorubicin.
  - B)** The medication is prescribed by or in consultation with an oncologist or a hematologist.
- 2. Multiple Myeloma.** Approve for 1 year if the patient meets BOTH of the following (A and B):
  - A)** Patient meets ONE of the following criteria (i or ii):
    - i.** The medication will be used in combination with at least one other agent; **OR**  
Note: Examples of other agents that may be used in combination with bortezomib include dexamethasone, cyclophosphamide, doxorubicin, Doxil (doxorubicin liposomal intravenous infusion), Revlimid (lenalidomide capsules), Thalomid (thalidomide capsules), cisplatin, etoposide, Darzalex (daratumumab intravenous infusion), Pomalyst (pomalidomide capsules), bendamustine, Empliciti (elotuzumab intravenous infusion), Farydak (panobinostat capsules).
    - ii.** The medication is being used for maintenance therapy; **AND**
  - B)** The medication is prescribed by or in consultation with an oncologist or a hematologist.

### **Other Uses with Supportive Evidence**

- 3. Acute Lymphoblastic Lymphoma.** Approve for 1 year if the patient meets BOTH of the following (A and B):
  - A)** Patient has relapsed or refractory disease; **AND**
  - B)** The medication is prescribed by or in consultation with an oncologist.
- 4. Castleman's Disease.** Approve for 1 year if the patient meets BOTH of the following (A, B, and C):
  - A)** Patient has multicentric Castleman's disease; **AND**
  - B)** Patient has relapsed, refractory, or progressive disease; **AND**
  - C)** The medication is prescribed by or in consultation with an oncologist.

5. **Classic Hodgkin Lymphoma.** Approve for 1 year if the patient meets BOTH of the following criteria (A and B):
  - A) Patient has tried at least one systemic chemotherapy regimen; AND  
Note: Examples of systemic chemotherapies used in regimens for Hodgkin lymphoma include doxorubicin, bleomycin, vincristine, etoposide, and dacarbazine.
  - B) The medication is prescribed by or in consultation with an oncologist.
6. **Kaposi Sarcoma.** Approve for 1 year if the patient meets BOTH of the following (A and B):
  - A) Patient has tried at least one systemic chemotherapy; AND  
Note: Examples of systemic chemotherapies include doxorubicin and paclitaxel.
  - B) The medication is prescribed by or in consultation with an oncologist.
7. **Systemic Light Chain Amyloidosis.** Approve for 1 year if prescribed by or in consultation with an oncologist or a hematologist.
8. **Waldenstrom’s Macroglobulinemia/Lymphoplasmacytic Lymphoma.** Approve for 1 year if the patient meets BOTH of the following (A and B):
  - A) The medication will be used in combination with rituximab and dexamethasone; AND
  - B) The medication is prescribed by or in consultation with an oncologist or a hematologist.

#### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of bortezomib is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

#### REFERENCES

1. Velcade® subcutaneous injection or intravenous infusion [prescribing information]. Lexington, MA: Takeda; November 2021.
2. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on October 17, 2022. Search term: bortezomib.
3. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 1.2021 – April 4, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on October 17, 2022.
4. The NCCN Pediatric Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 1.2022 – October 1, 2021). © 2021 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on October 17, 2022.
5. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 5.2022 – July 12, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed October 17, 2022.
6. The NCCN Kaposi Sarcoma Clinical Practice Guidelines in Oncology (version 1.2022 – February 3, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on October 16, 2022.
7. The NCCN Pediatric Hodgkin Lymphoma Clinical Practice Guidelines in Oncology (version 1.2022 – April 8, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on October 17, 2022.
8. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 1.2023 – September 14, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on October 17, 2022.
9. The NCCN Systemic Light Chain Amyloidosis Clinical Practice Guidelines in Oncology (version 1.2023 – September 1, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed October 17, 2022.
10. The NCCN Waldenstrom’s Macroglobulinemia/Lymphoplasmacytic Lymphoma Clinical Practice Guidelines in Oncology (version 1.2023 – July 6, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed October 16, 2022.

