CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable – Proteasome Inhibitor) – Bortezomib Products Utilization Management Medical Policy
- Boruzu® (bortezomib intravenous or subcutaneous injection – Amneal Pharmaceuticals)
- Velcade® (bortezomib intravenous or subcutaneous injection – Takeda, generic)

REVIEW DATE: 11/19/2025

OVERVIEW

Bortezomib, a proteasome inhibitor, is indicated in adults with the following conditions:[1,12]
- **Mantle cell lymphoma**.
- **Multiple myeloma**.

Guidelines

The National Comprehensive Cancer Network (NCCN) Compendium recommends use of bortezomib for the indications listed in the FDA-Approved Indications and Other Uses with Supportive Evidence sections.[3]

Dosing Information

Bortezomib (Velcade, generics) must be reconstituted prior to intravenous or subcutaneous administration.[1] Boruzu is available as a solution in a single-dose vial (3.5 mg/1.4 mL).[12] The final concentration for subcutaneous or intravenous administration is the same for Boruzu and Velcade (generics).[1,12] Dosing regimens vary and are dependent upon concomitant therapies and tolerability.[1,7,9] Additionally, dose modifications with bortezomib are recommended for the management of hematological toxicity (e.g., neutropenia, thrombocytopenia), non-hematological toxicity (e.g., Grade 3 or higher), peripheral neuropathy, and hepatic impairment. This may include reducing the dose or withholding the drug until the toxicity is resolved. See the respective Prescribing Information for more detail.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of bortezomib. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). 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 ALL of the following (A, B, and C):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient meets ONE of the following (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.
- **C)** The medication is prescribed by or in consultation with an oncologist or a hematologist.

Dosing. Approve if the requested dosing meets BOTH of the following (A and B):
- **A)** Each individual dose must not exceed 1.3 mg/m^2 administered intravenously or subcutaneously; AND
- **B)** Patient receives a maximum of six infusions over a 28-day period.

2. Multiple Myeloma. Approve for 1 year if the patient meets ALL of the following (A, B, and C):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient meets ONE of the following (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), lenalidomide, Thalomid (thalidomide capsules), cisplatin, etoposide, Darzalex (daratumumab intravenous infusion), Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection), Pomalyst (pomalidomide capsules), bendamustine, Empliciti (elotuzumab intravenous infusion), Farydak (panobinostat capsules).
  - **ii.** The medication is being used for maintenance therapy; AND
- **C)** The medication is prescribed by or in consultation with an oncologist or a hematologist.

Dosing. Approve if the requested dosing meets BOTH of the following (A and B):
- **A)** Each individual dose must not exceed 1.6 mg/m^2 administered intravenously or subcutaneously; AND
- **B)** Patient receives a maximum of six infusions over a 28-day period.

Other Uses with Supportive Evidence

3. Acute Lymphoblastic Leukemia. 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.

Dosing. Approve if the requested dosing meets BOTH of the following (A and B):
- **A)** Each individual dose must not exceed 1.6 mg/m^2 administered intravenously or subcutaneously; AND
- **B)** Patient receives a maximum of six infusions over a 28-day period.

4. Castleman Disease. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient has multicentric Castleman disease; AND
- **C)** Patient has relapsed, refractory, or progressive disease; AND
- **D)** The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve if the requested dosing meets BOTH of the following (A and B):
- **A)** Each individual dose must not exceed 1.6 mg/m^2 administered intravenously or subcutaneously; AND
- **B)** Patient receives a maximum of six infusions over a 28-day period.

5. Classic Hodgkin Lymphoma. Approve for 1 year if the patient meets BOTH of the following (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.

Dosing. Approve if the requested dosing meets BOTH of the following (A and B):
- **A)** Each individual dose must not exceed 1.6 mg/m^2 administered intravenously or subcutaneously; AND
- **B)** Patient receives a maximum of six infusions over a 28-day period.

6. Kaposi Sarcoma. Approve for 1 year if the patient meets ALL of the following (A, B, and C):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient has tried at least one systemic chemotherapy; AND
  Note: Examples of systemic chemotherapies include doxorubicin and paclitaxel.
- **C)** The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve if the requested dosing meets BOTH of the following (A and B):
- **A)** Each individual dose must not exceed 1.6 mg/m^2 administered intravenously or subcutaneously; AND
- **B)** Patient receives a maximum of three infusions over a 28-day period.

7. Systemic Light Chain Amyloidosis. Approve for 1 year if the patient meets BOTH of the following (A and B):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** The medication is prescribed by or in consultation with an oncologist or a hematologist.

Dosing. Approve if the requested dosing meets BOTH of the following (A and B):
- **A)** Each individual dose must not exceed 1.6 mg/m^2 administered intravenously or subcutaneously; AND
- **B)** Patient receives a maximum of six infusions over a 28-day period.

8. T-Cell Lymphoma. Approve for 1 year if the patient meets ALL of the following (A, B, and C):

A) Patient is ≥ 18 years of age; AND
B) Patient has tried at least one systemic therapy; AND
Note: Examples of systemic therapies include EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, and doxorubicin), Adcetris (brentuximab vedotin intravenous infusion) + CHP (cyclophosphamide, doxorubicin, and prednisone), zidovudine + interferon, CHOEP (cyclophosphamide, doxorubicin, vincristine, etoposide, and prednisone), HyperCVAD (cyclophosphamide, vincristine, doxorubicin, and dexamethasone) alternating with high-dose methotrexate and cytarabine.
C) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve if the requested dosing meets BOTH of the following (A and B):
A) Each individual dose must not exceed 1.6 mg/m^2 administered intravenously or subcutaneously; AND
B) Patient receives a maximum of six infusions over a 28-day period.

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9. Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma. Approve for 1 year if the patient meets ALL of the following (A, B, and C):
A) Patient is ≥ 18 years of age; AND
B) The medication will be used in combination with rituximab and dexamethasone; AND
C) The medication is prescribed by or in consultation with an oncologist or a hematologist.

Dosing. Approve if the requested dosing meets BOTH of the following (A and B):
A) Each individual dose must not exceed 1.6 mg/m^2 administered intravenously or subcutaneously; AND
B) Patient receives a maximum of six infusions over a 28-day period.

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. Boruzu® subcutaneous injection or intravenous infusion [prescribing information]. Bridgewater, NJ: Amneal Pharmaceuticals; July 2025.
3. The NCCN Drugs and Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 12, 2025. Search term: bortezomib.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Mantle Cell Lymphoma:** An age requirement of ≥ 18 years was added. **Multiple Myeloma:** An age requirement of ≥ 18 years was added. **Castleman's Disease:** An age requirement of ≥ 18 years was added. **Kaposi Sarcoma:** An age requirement of ≥ 18 years was added. **Systemic Light Chain Amyloidosis:** An age requirement of ≥ 18 years was added. **Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma:** An age requirement of ≥ 18 years was added. **Acute Lymphoblastic Leukemia:** The condition of approval was changed to as listed; previously listed as "Acute Lymphoblastic Lymphoma". **T-Cell Lymphoma:** Added new approval condition and criteria.	11/15/2023
Annual Revision	No criteria changes.	11/20/2024
Selected Revision	Changed policy name to "Oncology (Injectable) – Bortezomib Products". Added Boruzu, a ready-to-use injectable formulation of bortezomib to the policy.	12/11/2024
Update	04/11/2025: The policy name was changed from "Oncology (Injectable) - Bortezomib UM Medical Policy" to "Oncology (Injectable - Proteasome Inhibitor) - Bortezomib UM Medical Policy"	N/A
Annual Revision	**Castleman Disease:** "Castleman's Disease" was reworded to Castleman Disease. **Multiple Myeloma:** Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection) was added to the Note of examples of agents used with bortezomib.	11/19/2025