

Clinical Policy: Bortezomib (Velcade)

Reference Number: PA.CP.PHAR.410

Effective Date: 01/2019

Last Review Date: 01/2025

Description

Bortezomib (Velcade[®]) is a proteasome inhibitor.

FDA Approved Indication(s) Velcade is indicated for treatment of patients with:

- multiple myeloma (MM)
- mantle cell lymphoma (MCL)

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness[®] that bortezomib is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Multiple Myeloma and Mantle Cell Lymphoma (must meet all):

1. Diagnosis of one of the following (a or b):
 - a. MM;
 - b. MCL (B-cell lymphoma subtype);
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age \geq 18 years;
4. For Velcade requests, member must use bortezomib, if available, unless contraindicated or clinically significant adverse effects are experienced;
5. Request meets one of the following (a or b):
 - a. Dose does not exceed 1.3 mg/m²;
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. NCCN Recommended Uses (off-label) (must meet all):

1. Diagnosis of one of the following (a-k):
 - a. Kaposi sarcoma - as subsequent systemic therapy, for relapsed/refractory advanced cutaneous, oral, visceral, or nodal disease that has progressed on or not responded to first-line systemic therapy, and progressed on alternate first-line systemic therapy;
 - b. Mantle cell lymphoma (B-cell lymphoma);
 - c. HIV-related B-cell lymphoma;
 - d. Multicentric Castleman's disease (B-cell lymphoma subtype) - as subsequent therapy;
 - e. Systemic light chain amyloidosis;
 - f. Adult T-cell leukemia/lymphoma;

- g. Waldenström macroglobulinemia/lymphoplasmacytic lymphoma;
 - h. T-cell acute lymphoblastic leukemia (T-ALL)-for relapsed or refractory disease;
 - i. Pediatric acute lymphoblastic leukemia (ALL);
 - j. Pediatric Hodgkin lymphoma (HL) - as subsequent therapy in combination with ifosafamide and vinorelbine;
 - k. Other category 1, 2A, or 2B NCCN-recommended uses not listed;
2. Prescribed by or in consultation with an oncologist or hematologist;
 3. Age \geq 18 years (all indications except pediatric ALL and HL);
 4. For Velcade requests, member must use bortezomib, if available, unless contraindicated or clinically significant adverse effects are experienced;
 5. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

C. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

A. All Indications in Section I (must meet all):

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy;
3. For Velcade requests, member must use bortezomib, if available, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, request meets one of the following (a or b):
 - a. New dose does not exceed 1.3 mg/m^2 ;
 - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

Single-dose vials for injection:

- Sterile lyophilized powder for reconstitution: 1 mg, 2.5 mg, 3.5 mg
- Solution: 3.5 mg/3.5mL, 3.5 mg/1.4 mL

**The branded product, Velcade, is only available as 3.5 mg sterile lyophilized powder*

VII. References

1. Velcade Prescribing Information. Lexington, MA: Takeda Pharmaceuticals America, Inc.; August 2022. Available at: <https://www.takedaoncology.com/medicines/united-states/>. Accessed November 21, 2024.
2. Bortezomib Prescribing Information. Lake Forest, IL: Hospira, Inc.; December 2022. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/209191s000lbl.pdf. Accessed November 21, 2024.
3. Bortezomib Prescribing Information. Princeton, NJ: Maia Pharmaceuticals, Inc; July 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215441s000lbl.pdf. Accessed November 21, 2024.
4. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed November 21, 2024.
5. National Comprehensive Cancer Network. Multiple Myeloma Version 1.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed November 21, 2024.
6. National Comprehensive Cancer Network. Adult T-Cell Lymphomas Version 1.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf. Accessed November 21, 2024.
7. National Comprehensive Cancer Network. Pediatric Acute Lymphoblastic Leukemia Version 1.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf. Accessed November 21, 2024.
8. National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed November 21, 2024.
9. National Comprehensive Cancer Network. B-Cell Lymphomas Version 3.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed November 21, 2024.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9041	Injection, bortezomib (Velcade), 0.1 mg
J9046	Injection, bortezomib, (dr. reddy's), not therapeutically equivalent to J9041, 0.1 mg
J9048	Injection, bortezomib (fresenius kabi), not therapeutically equivalent to J9041, 0.1 mg
J9049	Injection, bortezomib (hospira), not therapeutically equivalent to J9041, 0.1 mg

HCPCS Codes	Description
J9051	Injection, bortezomib (maia), not therapeutically equivalent to J9041, 0.1 mg

Reviews, Revisions, and Approvals	Date
Policy created.	01/2019
1Q 2020 annual review: references reviewed and updated.	01/2020
1Q 2021 annual review: AIDS-related Kaposi sarcoma pediatric HL NCCN recommended uses added; references reviewed and updated.	01/2021
1Q 2022 annual review: removed requirement for Velcade to be prescribed in combination with HIV therapy for Kaposi sarcoma indication per NCCN; added T-ALL indication per NCCN; references reviewed and updated.	01/2022
1Q 2023 annual review; added new 1mg and 2.5mg strengths of bortezomib (available generically only from Hospira); added redirection to generic bortezomib for brand Velcade requests. Added also new 2.5 and 3.5mg formulations (available generically only) as solution for a single-dose injection. Added verbiage directing to the use of generic bortezomib unless contraindicated or clinically significant adverse effects are experienced	01/2023
1Q 2024 annual review: removed specification that 1 mg and 2.5 mg were specifically indicated after 1 prior therapy per PI update; revised product availability for solutions from 2.5 mg/mL to 3.5 mg/3.5mL per PI; Added HCPCS code [J9051], removed inactive HCPCS code [J9044]; references reviewed and updated.	01/2024
1Q 2025 annual review: for NCCN recommended uses (off-label) initial criteria: added mantle cell lymphoma (B-cell lymphoma) and HIV-related B-cell lymphoma as supported by NCCN compendium; references reviewed and updated.	01/2025