

# 5.21.45

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	July 1, 2022
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	October 1, 2014
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**Last Review Date:** June 16, 2022

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## Velcade

### Description

#### Velcade (bortezomib) SC/IV, Bortezomib IV

##### Background

Velcade/bortezomib targets proteasomes inside cells and blocks or slows down the action of these cells. Proteasomes break down proteins in both healthy and cancerous cells. Once this activity is blocked or slowed down then the proteins build up causing an imbalance within the cell. Cancer cells divide and multiply faster than most other cells. Velcade/bortezomib slows this process and causes cancer cell death (1-2).

Bortezomib is not considered a true generic of Velcade and thus is not interchangeable. Velcade is for subcutaneous (SC) or intravenous (IV) use. Bortezomib is only for IV use (1-2).

##### Regulatory Status

FDA-approved indications: Velcade SC/IV is a proteasome inhibitor indicated for the treatment of adult patients with multiple myeloma and adult patients with mantle cell lymphoma (1).

Velcade SC is also indicated for the treatment of adult patients with newly diagnosed light chain (AL) amyloidosis in combination with daratumumab/hyaluronidase-fihj, cyclophosphamide and dexamethasone (3).

Bortezomib IV is a proteasome inhibitor indicated for the treatment of adult patients with multiple myeloma and adult patients with mantle cell lymphoma who have received at least 1 prior therapy (2).

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Velcade/bortezomib is contraindicated for intrathecal administration. Fatal events have occurred with intrathecal administration of Velcade/bortezomib (1-2).

Patients should be monitored for cardiac toxicity, pulmonary toxicity, thrombocytopenia or neutropenia, tumor lysis syndrome, hepatic toxicity, and thrombotic microangiopathy. Caution should be used when prescribing for patients with peripheral neuropathy, hypotension, and gastrointestinal toxicity. Patients with posterior reversible encephalopathy syndrome should consider MRI imaging for onset of visual or neurological symptoms. Women should avoid getting pregnant while on this medication (1-2).

Patients being treated for light chain (AL) amyloidosis should be treated with Velcade SC until disease progression, unacceptable toxicity or a maximum of 2 years (1).

The safety and effectiveness of Velcade/bortezomib in pediatric patients have not been established (1-2).

## Related policies

Kyprolis, Ninlaro

### Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Velcade/bortezomib may be considered **medically necessary** in patients 18 years of age or older with multiple myeloma or mantle cell lymphoma; and if the conditions indicated below are met.

Velcade SC may be considered **medically necessary** in patients 18 years of age or older with light chain (AL) amyloidosis and if the conditions indicated below are met.

Velcade/bortezomib may be considered **investigational** in patients less than 18 years of age and for all other indications.

## Prior-Approval Requirements

**Age** 18 years of age or older

### Diagnoses

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Patient must have **ONE** of the following:

1. Multiple myeloma
2. Mantle cell lymphoma
3. Light chain (AL) amyloidosis
  - a. Velcade SC use **ONLY**
  - b. Used in combination with daratumumab/hyaluronidase-fihj, cyclophosphamide and dexamethasone

**AND** the following:

- a. **NO** dual therapy with other proteasome inhibitors [e.g., ixazomib (Ninlaro) and carfilzomib (Kyprolis)]

## Prior – Approval *Renewal* Requirements

**Age** 18 years of age or older

### Diagnoses

Patient must have **ONE** of the following:

1. Multiple myeloma
2. Mantle cell lymphoma
3. Light chain (AL) amyloidosis
  - a. Velcade SC use **ONLY**
  - b. Treatment with Velcade has not exceeded 2 years

**AND ALL** of the following:

- a. **NO** disease progression or unacceptable toxicity
- b. **NO** dual therapy with other proteasome inhibitors [e.g., ixazomib (Ninlaro) and carfilzomib (Kyprolis)]

### Policy Guidelines

#### Pre - PA Allowance

None

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## Prior - Approval Limits

**Duration** 12 months

## Prior – Approval *Renewal* Limits

**Duration** 12 months (**ONE** renewal **ONLY** for light chain amyloidosis)

## Rationale

### Summary

Velcade/bortezomib targets proteasomes inside cells and blocks or slows down the action of these cells. Once this activity is blocked or slowed down then the proteins build up causing an imbalance within the cell. This disruption of normal homeostatic mechanisms can lead to cell death. The safety and effectiveness of Velcade/bortezomib in patients under the age of 18 has not been established (1-2).

Prior approval is required to ensure the safe, clinically appropriate and cost-effective use of Velcade/bortezomib while maintaining optimal therapeutic outcomes.

### References

1. Velcade [package insert]. Lexington, MA: Takeda Pharmaceuticals USA, Inc.; November 2021.
2. Bortezomib [package insert]. Visakhapatnam, India: Dr. Reddy's Laboratories Limited; October 2019.
3. Darzalex Faspro [package insert]. Horsham, PA: Janssen Biotech, Inc.; January 2022.
4. NCCN Drugs & Biologics Compendium<sup>®</sup> Bortezomib 2022. National Comprehensive Cancer Network, Inc. Accessed on April 12, 2022.

## Policy History

Date	Action
September 2014	PMPC review
October 2014	Addition to PA
November 2014	Removed tried and failed at least 1 prior therapy for mantle cell lymphoma
December 2014	Annual editorial review and reference update

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June 2015	Annual review and reference update
June 2016	Annual review and reference update Addition of no dual therapy with other proteasome inhibitors Policy number change from 5.04.45 to 5.21.45
September 2016	Annual review
June 2017	Annual editorial review
June 2018	Annual editorial review and reference update
June 2019	Annual editorial review and reference update
June 2020	Annual review
December 2020	Annual review
February 2021	Addition of statement that Velcade and bortezomib are not interchangeable and Velcade can be SC/IV while bortezomib is IV only. Addition of no disease progression or unacceptable toxicity renewal requirement. Added examples of proteasome inhibitors. Addition of indication: light chain (AL) amyloidosis
March 2021	Annual review and reference update
June 2022	Annual review and reference update

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.**