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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Antineoplastic Agents	**Original Policy Date:**	October 1, 2014
Subject:	Velcade	**Page:**	1 of 5

Last Review Date: March 12, 2021

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).

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 is considered **investigational** in patients less than 18 years of age and all other indications.

Prior-Approval 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. Used in 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 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

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]. Cambridge, MA: Millenium Pharmaceuticals, Inc.; April 2019.
2. Bortezomib [package insert]. Visakhapatnam, India: Dr. Reddy's Laboratories Limited; October 2019.
3. Darzalex Faspro [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2021.

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
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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.