Velcade

Description

Velcade (bortezomib)

Background
Velcade 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 slows this process and causes cancer cell death (1).

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

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

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).

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

**AND** the following:
   a. **NO** dual therapy with other proteasome inhibitors

**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
AND the following:
   a. NO dual therapy with other proteasome inhibitors

### Policy Guidelines

**Pre - PA Allowance**
None

**Prior - Approval Limits**

| Duration | 12 months |

**Prior – Approval Renewal Limits**

| Duration | 12 months |

### Rationale

**Summary**
Velcade is indicated for the treatment of patients with multiple myeloma and patients with mantle cell lymphoma. Velcade 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 in patient under the age of 18 has not been established (1).

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

**References**

### Policy History

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<td>September 2014</td>
<td>PMPC review</td>
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<tr>
<td>October 2014</td>
<td>Addition to PA</td>
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<tr>
<td>November 2014</td>
<td>Removed tried and failed at least 1 prior therapy for mantle cell lymphoma</td>
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<td>December 2014</td>
<td>Annual editorial review and reference update</td>
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Section: Prescription Drugs  Effective Date: July 1, 2019
Subsection: Antineoplastic Agents  Original Policy Date: October 1, 2014
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<td>June 2015</td>
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<tr>
<td>June 2016</td>
<td>Annual review and reference update&lt;br&gt;Addition of no dual therapy with other proteasome inhibitors&lt;br&gt;Policy number change from 5.04.45 to 5.21.45</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.