



<b>POLICY NUMBER</b> UM ONC_1136	<b>SUBJECT</b> Velcade™ (bortezomib)		<b>DEPT/PROGRAM</b> UM Dept	<b>PAGE 1 OF 3</b>
<b>DATES COMMITTEE REVIEWED</b> 07/22/11, 03/13/13, 04/10/13, 07/24/14, 08/13/14, 12/16/15, 12/21/16, 12/14/17, 11/08/18, 08/14/19, 12/11/19, 03/11/20, 06/10/20	<b>APPROVAL DATE</b> June 10, 2020	<b>EFFECTIVE DATE</b> June 26, 2020	<b>COMMITTEE APPROVAL DATES</b> (latest version listed last) 07/22/11, 03/13/13, 04/10/13, 07/24/14, 08/13/14, 12/16/15, 12/21/16, 12/14/17, 11/08/18, 08/14/19, 12/11/19, 03/11/20, 06/10/20	
<b>PRIMARY BUSINESS OWNER: UM</b> <b>APPROVED BY:</b> Dr. Andrew Hertler		<b>COMMITTEE/BOARD APPROVAL</b> Utilization Management Committee		
<b>URAC STANDARDS</b> HUM 1		<b>NCQA STANDARDS</b> UM 2	<b>ADDITIONAL AREAS OF IMPACT</b>	
<b>CMS REQUIREMENTS</b>	<b>STATE/FEDERAL REQUIREMENTS</b>		<b>APPLICABLE LINES OF BUSINESS</b> All	

**I. PURPOSE**

To define and describe the accepted indications for Velcade (bortezomib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

**II. INDICATIONS FOR USE/INCLUSION CRITERIA**

**1. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:**

- a. When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**
- b. When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**
- c. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies **AND**
- d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
- e. When available, generic dug alternatives are preferred over Brand name drugs.

**2. Multiple Myeloma**

- a. **NOTE: The preferred agent, per NCH policy, is generic bortezomib over brand bortezomib (Velcade) for all indications, unless there are contraindications or intolerance to generic bortezomib.**
- b. The member has a diagnosis of solitary plasmacytoma, smoldering multiple myeloma, or multiple myeloma **AND**



- c. Velcade (bortezomib) is being used as **ONE** of the following
  - i. As initial/first line therapy:
    - A. In combination with daratumumab + melphalan + prednisone
    - B. In combination with lenalidomide + dexamethasone. **NOTE: this is the NCH Pathway Preferred Regimen in this setting.**
    - C. In combination with dexamethasone
    - D. In combination with cyclophosphamide + dexamethasone
    - E. In VTD-PACE (bortezomib, thalidomide, dexamethasone, cisplatin, doxorubicin, cyclophosphamide, and etoposide) regimen.
    - F. In combination with another NCCN compendium-approved multiagent regimen for first line therapy.
  - ii. For relapsed/refractory myeloma in combination with **ANY** of the following
    - A. Daratumumab +/- dexamethasone. **NOTE: This is the NCH Pathway Preferred Regimen in this setting.**
    - B. Lenalidomide +/- dexamethasone
    - C. Cyclophosphamide +/- dexamethasone
    - D. Bendamustine +/- dexamethasone
    - E. Liposomal doxorubicin +/- dexamethasone
    - F. Dexamethasone
    - G. In VTD-PACE (bortezomib, dexamethasone, thalidomide, cisplatin, doxorubicin, cyclophosphamide, and etoposide) regimen
    - H. In combination with panobinostat and dexamethasone for members who have received at least 2 prior regimens, including bortezomib and an immunomodulatory agent
    - I. Combination with pomalidomide and dexamethasone for members who have received at least two prior therapies, including an immunomodulatory agent and a proteasome inhibitor
    - J. In combination with another NCCN compendium-approved multiagent regimen for subsequent line therapy.
  - iii. Maintenance therapy as a single agent following response/stable disease after primary myeloma therapy or as maintenance following stem cell transplant.
- 3. **Non-Hodgkin's Lymphoma (NHL)**
  - a. The member has a diagnosis of relapsed or refractory mantle cell lymphoma **AND**
  - b. Velcade (bortezomib) is being used in ANY line of therapy as a single agent, OR in combination with rituximab, OR in combination with bendamustine and rituximab, or as a component of VR-CAP (bortezomib, rituximab, cyclophosphamide, doxorubicin, and prednisone) regimen (if not previously given).

### III. EXCLUSION CRITERIA

- 1. Dosing exceeds single dose limit of Velcade (bortezomib) 1.6 mg/m<sup>2</sup> weekly



2. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

**IV. MEDICATION MANAGEMENT**

Please refer to the FDA label/package insert for details regarding these topics.

**V. APPROVAL AUTHORITY**

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

**VI. ATTACHMENTS**

None

**VII. REFERENCES**

1. Velcade prescribing information. Millennium Pharmaceuticals, Inc. Cambridge, MA. 2020.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
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4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2020.
5. Wang Y, Ai L, Cui G, Gowrea B, Li M, Hu Y. Once- versus twice-weekly bortezomib induction therapy with dexamethasone in newly diagnosed multiple myeloma. *J Huazhong Univ Sci Technolog Med Sci.* 2012 Aug;32(4):495-500.
6. Fukushima T, Nakamura T, Iwao H, Nakajima A, Miki M, Sato T, Sakai T, Sawaki, T, Fujita Y, Tanaka M, Masaki Y, Nakajima H, Motoo Y, Umehara H. Efficacy and safety of bortezomib plus dexamethasone therapy for refractory or relapsed multiple myeloma: once-weekly administration of bortezomib may reduce the incidence of gastrointestinal adverse events. *Anticancer Res.* 2011 Jun;31(6):2297-302.
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8. Reeder CB, et al. Cyclophosphamide, bortezomib and dexamethasone induction for newly diagnosed multiple myeloma: high response rates in a phase II clinical trial. *Leukemia.* 2009;23:1337-41.
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10. Sonneveld P, et al. Bortezomib induction and maintenance treatment in patients with newly diagnosed multiple myeloma: results of the randomized phase III HOVON-65/ GMMG-HD4 trial. *J Clin Oncol.* 2012 Aug 20;30(24):2946-55.