Drug Policy:

Velcade™ (bortezomib)

POLICY NUMBER UM ONC_1136	SUBJECT Velcade™ (bortezomib)		DEPT/PROGRAM UM Dept	PAGE 1 OF 4
DATES COMMITTEE REVIEWED 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, 09/11/20	**APPROVAL DATE** September 11, 2020	**EFFECTIVE DATE** September 25, 2020	**COMMITTEE APPROVAL DATES** (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, 09/11/20	
PRIMARY BUSINESS OWNER: UM **APPROVED BY:** Dr. Andrew Hertler		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM 1	**NCQA STANDARDS** UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

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 Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH 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

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. 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

2. 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
3. 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
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When available, generic alternatives are preferred over brand-name drugs.

B. Multiple Myeloma

1. NOTE: Both SC Velcade and IV bortezomib are supported for use when the following criteria are met.
2. The member has a diagnosis of solitary plasmacytoma, smoldering multiple myeloma, or multiple myeloma AND
3. Velcade (bortezomib) is being used as ONE of the following
   a. As initial/first line therapy:
      i. In combination with daratumumab + melphalan + prednisone
      ii. In combination with lenalidomide + dexamethasone. NOTE: this is the NCH Pathway Preferred Regimen in this setting.
      iii. In combination with dexamethasone
      iv. In combination with cyclophosphamide + dexamethasone
      v. In VTD-PACE (bortezomib, thalidomide, dexamethasone, cisplatin, doxorubicin, cyclophosphamide, and etoposide) regimen.
      vi. In combination with another NCCN compendium-approved multiagent regimen for first line therapy.
   b. For relapsed/refractory myeloma in combination with ANY of the following
      i. Daratumumab +/- dexamethasone. NOTE: This is the NCH Pathway Preferred Regimen in this setting.
      ii. Lenalidomide +/- dexamethasone
      iii. Cyclophosphamide +/- dexamethasone
      iv. Bendamustine +/- dexamethasone
      v. Liposomal doxorubicin +/- dexamethasone
      vi. Dexamethasone
      vii. In VTD-PACE (bortezomib, dexamethasone, thalidomide, cisplatin, doxorubicin, cyclophosphamide, and etoposide) regimen
      viii. In combination with panobinostat and dexamethasone for members who have received at least 2 prior regimens, including bortezomib and an immunomodulatory agent
      ix. Combination with pomalidomide and dexamethasone for members who have received at least two prior therapies, including an immunomodulatory agent and a proteasome inhibitor
      x. In combination with another NCCN compendium-approved multiagent regimen for subsequent line therapy.

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c. Maintenance therapy as a single agent following response/stable disease after primary myeloma therapy or as maintenance following stem cell transplant.

C. Non-Hodgkin's Lymphoma (NHL)

1. The member has a diagnosis of relapsed or refractory mantle cell lymphoma AND
2. 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

A. Dosing exceeds single dose limit of Velcade (bortezomib) 1.6 mg/m^2 weekly

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

IV. MEDICATION MANAGEMENT

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

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

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B. Clinical Pharmacology Elsevier Gold Standard. 2020.

C. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.

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J. 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.

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