JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP062
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	Subject **Velcade**	*Revision Date*	04/20/2022
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Velcade

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I. POLICY

A. Velcade (bortezomib) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. Velcade may be approved for patients who meet the following:
   1. Multiple myeloma
      a. Documentation has been submitted showing the patient has a diagnosis of multiple myeloma
   2. Mantle cell lymphoma
      a. Documentation has been submitted showing the patient has a diagnosis of mantle cell lymphoma
   3. Multicentric Castleman's disease
      a. Documentation has been submitted showing the patient has a diagnosis of relapsed, refractory or progressive multicentric Castleman's disease
   4. Systemic light chain amyloidosis
      a. Documentation has been submitted showing Velcade will be used in one of the following clinical situations:
         I. Combination with dexamethasone
         II. Combination with melphalan and dexamethasone
         III. Combination with cyclophosphamide and dexamethasone
         IV. Combination with lenalidomide and dexamethasone
         V. Combination with daratumumab and hyaluronidase-fihj, cyclophosphamide, and dexamethasone
         VI. Monotherapy
   5. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma
      a. Documentation has been submitted showing Velcade will be used in one of the following clinical situations:
         I. Combination with rituximab
         II. Combination with dexamethasone
         III. Combination with rituximab and dexamethasone
         IV. Monotherapy
   6. Adult T-cell Leukemia/Lymphoma

a. Documentation has been submitted showing that Velcade will be used as monotherapy for second-line or subsequent therapy for adult T-cell leukemia/lymphoma

7. Antibody mediated rejection of solid organ
   a. Documentation has been submitted showing the patient has a diagnosis of antibody mediated rejection of solid organ
8. Acute lymphoblastic leukemia
   a. Documentation has been submitted showing the patient has a diagnosis of relapsed or refractory acute lymphoblastic leukemia
9. Follicular Lymphoma
   a. Documentation has been submitted showing the patient has a diagnosis of relapsed or refractory follicular lymphoma
10. AIDS-related Kaposi's sarcoma
    a. Documentation has been submitted showing the following:
       I. Patient has a diagnosis of relapsed or refractory AIDS-related Kaposi's sarcoma
       II. Velcade will be used in combination with antiretroviral therapy (ART)
11. Hodgkin Lymphoma
    a. Documentation has been submitted showing the patient has a diagnosis of relapsed or refractory Hodgkin Lymphoma
12. POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) Syndrome
    a. Documentation has been submitted showing the following:
       I. Patient has a diagnosis of POEMS syndrome
       II. Velcade will be used in combination with dexamethasone

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 12 months of therapy
B. Continuation of therapy may be approved in 12-month intervals with documentation showing the patient is continuing to tolerate the regimen and there has not been disease progression while on treatment.

IV. EXCLUSIONS

A. Velcade will not be covered for the following:
   1. Any indications or uses that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSAGE

A. Please refer to the FDA-approved prescribing information, or clinical guidelines for indication-specific dosing details.
B. For all indications, dosing should not exceed 1.6 mg/m2 per dose, and doses should exceed 7 doses per 30 day period.

VI. CODES

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/ HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Injection, bortezomib (velcade), 0.1 mg	J9041

VII. REFERENCES

1. Velcade [prescribing information]. Lexington, MA: Takeda Pharmaceuticals USA, Inc.; Novemember 2021.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 4, 2022.
3. Ejaz NS, Alloway RR, Halleck F, et al. Review of bortezomib treatment of antibody-mediated rejection in renal transplantation. Antioxid Redox Signal. 2014;21(17):2401-2418.
4. Blanco B, Sanchez-Abarca LI, Caballero-Velazquez T, et al. Depletion of alloreactive T-cells in vitro using the proteasome inhibitor bortezomib preserves the immune response against pathogens. Leuk Res. 2011;35(10):1412-1415.
5. Claes DJ, Yin H, Goebel J. Protective immunity and use of bortezomib for antibody-mediated rejection in a pediatric kidney transplant recipient. Pediatr Transplant. 2014;18(4):E100-E105.

VIII. APPROVALS

Signature on file at JHHC

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