Reference number(s)
2233-C

SPECIALTY GUIDELINE MANAGEMENT

VELCADE (bortezomib)
bortezomib

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Multiple myeloma
2. Mantle cell lymphoma

B. Compendial Uses
1. Systemic light chain amyloidosis
2. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma
3. Multicentric Castleman's disease
4. Adult T-cell leukemia/lymphoma
5. Antibody mediated rejection of solid organ
6. Acute lymphoblastic leukemia
7. Follicular lymphoma
8. AIDS-related Kaposi's sarcoma
9. Hodgkin Lymphoma
10. POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) Syndrome

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Multiple myeloma
Authorization of 12 months may be granted for the treatment of multiple myeloma.

B. Mantle cell lymphoma
Authorization of 12 months may be granted for the treatment of mantle cell lymphoma.

C. Multicentric Castleman's disease
Authorization of 12 months may be granted for the treatment of relapsed, refractory or progressive multicentric Castleman's disease.

D. Systemic light chain amyloidosis
Authorization of 12 months may be granted for the treatment of systemic light chain amyloidosis when the requested medication will be used in any of the following regimens:
1. In combination with dexamethasone
2. In combination with melphalan and dexamethasone
3. In combination with cyclophosphamide and dexamethasone
4. As a single agent

5. In combination with lenalidomide and dexamethasone
6. In combination with daratumumab and hyaluronidase-fihj, cyclophosphamide, and dexamethasone

E. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma
Authorization of 12 months may be granted for the treatment of Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma when the requested medication will be used in any of the following regimens:
1. In combination with rituximab
2. In combination with dexamethasone
3. In combination with rituximab and dexamethasone
4. As a single agent

F. Adult T-cell Leukemia/Lymphoma
Authorization of 12 months may be granted for the treatment of adult T-cell leukemia/lymphoma when the requested medication will be used as a single agent for second-line or subsequent therapy.

G. Antibody mediated rejection of solid organ
Authorization of 12 months may be granted for the treatment of antibody mediated rejection of solid organ.

H. Acute lymphoblastic leukemia
Authorization of 12 months may be granted for the treatment of relapsed or refractory acute lymphoblastic leukemia.

I. Follicular Lymphoma
Authorization of 12 months may be granted for the treatment of relapsed or refractory follicular lymphoma.

J. AIDS-related Kaposi's sarcoma
Authorization of 12 months may be granted for the treatment of relapsed or refractory AIDS-related Kaposi's sarcoma in combination with antiretroviral therapy (ART).

K. Hodgkin Lymphoma
Authorization of 12 months may be granted for the treatment of relapsed or refractory Hodgkin Lymphoma.

L. POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) Syndrome
Authorization of 12 months may be granted for treatment of POEMS syndrome in combination with dexamethasone.

III. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

For all indications, dosing does not exceed 1.6 mg/m^2 per dose and does not require more than 7 doses per 30 day period.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Velcade [package insert]. Cambridge, MA: Millenium Pharmaceuticals, Inc.; April 2019.
2. bortezomib [package insert]. Lake Zurich, IL: Fresenius Kabi; November 2019.
3. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 9, 2021.
4. 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.
5. 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.
6. 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.
7. Lexi-drugs online. Hudson (OH): Lexicomp, Inc.; 2019. Available with subscription. URL: http://online.lexi.com/lco. Accessed October 6, 2020.