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/m² 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