| Reference number(s) |
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| 4479-A |

# STANDARD MEDICARE PART B MANAGEMENT

## VELCADE (bortezomib)
## bortezomib

**POLICY**

**I. INDICATIONS**

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

A. FDA-Approved Indications
1. Treatment of adult patients with multiple myeloma
2. Treatment of adult patients with mantle cell lymphoma

B. Compendial Uses
1. Systemic light chain amyloidosis
2. Waldenström macroglobulinemia/lymphoplasmacytic lymphoma
3. Multicentric Castleman disease
4. Adult T-cell leukemia/lymphoma
5. Antibody mediated rejection of solid organ
6. Acute lymphoblastic leukemia
7. Follicular lymphoma
8. Kaposi sarcoma
9. Classic Hodgkin Lymphoma
10. POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) Syndrome
11. Peripheral T-cell Lymphomas
    a. Anaplastic large cell lymphoma
    b. Peripheral T-cell lymphoma not otherwise specified
    c. Angioimmunoblastic T-cell lymphoma
    d. Enteropathy-associated T-cell lymphoma
    e. Monomorphic epitheliotropic intestinal T-cell lymphoma
    f. Nodal peripheral T-cell lymphoma with TFH phenotype
    g. Follicular T-cell lymphoma
12. Breast implant-associated anaplastic large cell lymphoma (ALCL)
13. Hepatosplenic T-cell lymphoma
14. Mycosis fungoides/Sezary syndrome
15. AIDS-related B-cell lymphomas
    a. AIDS-related diffuse large B-cell lymphoma
    b. HHV8-positive diffuse large B-cell lymphoma not otherwise specified
    c. Primary effusion lymphoma
16. Desensitization therapy – heart transplant

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

## 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 disease**
Authorization of 12 months may be granted for the treatment of multicentric Castleman disease as subsequent therapy.

**D. Systemic light chain amyloidosis**
Authorization of 12 months may be granted for the treatment of systemic light chain amyloidosis.

**E. Waldenström macroglobulinemia/lymphoplasmacytic lymphoma**
Authorization of 12 months may be granted for the treatment of Waldenström macroglobulinemia/lymphoplasmacytic lymphoma.

**F. Peripheral T-cell lymphomas**
Authorization of 12 months may be granted as a single agent for the treatment of any of the following peripheral T-cell lymphomas:
1. Anaplastic large cell lymphoma (ALCL)
2. Peripheral T-cell lymphoma not otherwise specified
3. Angioimmunoblastic T-cell lymphoma
4. Enteropathy-associated T-cell lymphoma
5. Monomorphic epitheliotropic intestinal T-cell lymphoma
6. Nodal peripheral T-cell lymphoma with TFH phenotype
7. Follicular T-cell lymphoma

**G. 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 subsequent therapy.

**H. Breast implant-associated ALCL**
Authorization of 12 months may be granted for the treatment of breast implant-associated ALCL when the requested medication will be used as a single agent for subsequent therapy.

**I. Hepatosplenic T-cell lymphoma**
Authorization of 12 months may be granted for the treatment of hepatosplenic T-cell lymphoma when the requested medication will be used as a single agent for refractory disease.

**J. Mycosis fungoides/Sezary syndrome**
Authorization of 12 months may be granted for the treatment of mycosis fungoides/Sezary syndrome when the requested medication will be used as a single agent for refractory disease.

**K. AIDS-related B-cell lymphomas**
Authorization of 12 months may be granted for the treatment of AIDS-related B-cell lymphomas when both of the following criteria are met:
1. The member has one of the following lymphomas:
    a. AIDS-related diffuse large B-cell lymphoma
    b. HHV8-positive diffuse large B-cell lymphoma, not otherwise specified
    c. Primary effusion lymphoma
2. The requested drug will be used as a component of bortezomib-ICE (ifosfamide, carboplatin, and etoposide)

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

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

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

**O. Kaposi sarcoma**
Authorization of 12 months may be granted for the treatment of Kaposi sarcoma as subsequent therapy.

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

**Q. 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.

**R. Desensitization therapy – heart transplant**
Authorization of 12 months may be granted for desensitization therapy for heart transplantation.

## III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with the requested medication
B. The requested medication is being used to treat an indication enumerated in Section II
C. The member is receiving benefit from therapy. Benefit is defined as:
    1. No evidence of unacceptable toxicity while on the current regimen, and
    2. No evidence of disease progression while on the current regimen

## IV. REFERENCES

1. Velcade [package insert]. Cambridge, MA: Millennium Pharmaceuticals, Inc.; August 2022.

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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.
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8. DRUGDEX® System (electronic version). Micromedex Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com. Accessed October 7, 2022.

 