

Reference number(s)
2233-A

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. Angioimmunoblastic T-cell lymphoma
6. Peripheral T-cell lymphoma NOS
7. Anaplastic large cell lymphoma
8. Enteropathy-associated T-cell lymphoma
9. Monomorphic epitheliotropic intestinal T-cell lymphoma
10. Nodal peripheral T-cell lymphoma with TFH phenotype
11. Follicular T-cell lymphoma
12. Antibody mediated rejection of solid organ
13. Primary cutaneous anaplastic large cell lymphoma

All other indications are considered experimental/investigational and are not covered benefits.

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 melphalan and dexamethasone
2. In combination with cyclophosphamide and dexamethasone

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3. In combination with dexamethasone
4. As a single agent

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. Peripheral T-cell lymphoma

Authorization of 12 months may be granted for the treatment of angioimmunoblastic T-cell lymphoma, peripheral T-cell lymphoma not otherwise specified, anaplastic large cell lymphoma, enteropathy-associated T-cell lymphoma, monomorphic epitheliotropic intestinal T-cell lymphoma, nodal peripheral T-cell lymphoma with TFH phenotype, or follicular T-cell lymphoma when all of the following criteria are met:

1. The disease is relapsed or refractory
2. The requested medication is used as a single agent for second-line and subsequent therapy
3. The member is not a candidate for autologous stem cell transplantation

H. Antibody mediated rejection of solid organ

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

I. Primary cutaneous anaplastic large cell lymphoma

Authorization of 12 months may be granted for the treatment of relapsed or refractory primary cutaneous anaplastic large cell lymphoma (ALCL) when the requested medication is used as a single agent.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II who have not experienced an unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

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4. The NCCN Clinical Practice Guidelines in Oncology® Multiple Myeloma (Version 1.2019) © 2018 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed March 29, 2018.
5. The NCCN Clinical Practice Guidelines in Oncology® B-cell Lymphomas (Version 5.2018) © 2018 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed March 29, 2019.
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8. The NCCN Clinical Practice Guidelines in Oncology® T-Cell Lymphomas (Version 5.2018) © 2018 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed March 21, 2019.
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10. 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.
11. 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.