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. Antibody mediated rejection of solid organ
6. Pediatric acute lymphoblastic leukemia
7. Follicular lymphoma

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

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. Pediatric acute lymphoblastic leukemia

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

I. Follicular Lymphoma

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

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 when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

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9. 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.
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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.
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