Reference number(s)
3858-A

JURISDICTION SPECIFIC MEDICARE PART B

VELCADE (bortezomib)
bortezomib

POLICY

I. COVERED USES

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

The list of covered ICD-10 codes is prohibitively long to include within this policy. A complete list can be found at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. The FDA-labeled indications and recognized compendia (off-label) uses are listed below:

A. Multiple myeloma
B. Mantle cell lymphoma
C. Systemic light chain amyloidosis
D. Anaplastic large cell lymphoma
E. Peripheral T-cell lymphoma not otherwise specified
F. Angioimmunoblastic T-cell lymphoma
G. Enteropathy-associated T-cell lymphoma
H. Monomorphic epitheliotropic intestinal T-cell lymphoma
I. Nodal peripheral T-cell lymphoma with TFH phenotype
J. Follicular T-cell lymphoma
K. Adult T-cell leukemia/lymphoma
L. AIDS-related Kaposi sarcoma
M. Multicentric Castleman's disease
N. Pediatric acute lymphoblastic leukemia
O. Mycosis fungoides/Sezary syndrome
P. Primary cutaneous anaplastic large cell lymphoma
Q. Cutaneous anaplastic large cell lymphoma
R. Waldenstrom macroglobulinemia/lymphoblastic lymphoma
S. Follicular lymphoma
T. Chronic lymphocytic leukemia/small lymphocytic lymphoma
U. AIDS-related B-cell lymphoma
V. Breast implant associated ALCL
W. Hepatosplenic T-cell lymphoma
X. Extranodal NK-T-cell lymphoma, nasal type
Y. Subcutaneous panniculitis-like T-cell lymphoma
Z. Blastic NK-cell lymphoma

AA. Heavy chain disease
BB. Malignant immunoproliferative disease
CC. Hairy cell leukemia
DD. Prolymphocytic leukemia, B-cell type
EE. Prolymphocytic leukemia, T-cell type
FF. T-cell large granular lymphocytic leukemia
GG. Langerhans cell histiocytosis
HH. Systemic mastocytosis

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. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
A. Relevant medical history, physical examination, results of pertinent diagnostic tests or procedures
B. Medical record with name of drug administered, route of administration, dosage, duration of the administration.

III. CRITERIA FOR APPROVAL

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

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

C. Systemic Light Chain Amyloidosis
Authorization of 12 months may be granted for treatment of systemic light chain amyloidosis.

D. Anaplastic Large Cell Lymphoma
Authorization of 12 months may be granted for treatment of anaplastic large cell lymphoma.

E. Peripheral T-cell Lymphoma, Not Otherwise Specified
Authorization of 12 months may be granted for treatment of peripheral T-cell lymphoma, not otherwise specified.

F. Angioimmunoblastic T-cell lymphoma
Authorization of 12 months may be granted for treatment of angioimmunoblastic T-cell lymphoma.

G. Enteropathy-Associated T-cell Lymphoma
Authorization of 12 months may be granted for treatment of enteropathy-associated T-cell lymphoma.

H. Monomorphic Epitheliotropic Intestinal T-cell Lymphoma
Authorization of 12 months may be granted for treatment of monomorphic epitheliotropic intestinal T-cell lymphoma.

I. Nodal Peripheral T-cell Lymphoma with TFH Phenotype
Authorization of 12 months may be granted for treatment of nodal peripheral T-cell lymphoma with TFH phenotype.

J. Follicular T-cell Lymphoma
Authorization of 12 months may be granted for treatment of follicular T-cell lymphoma.

K. Adult T-cell leukemia/lymphoma
Authorization of 12 months may be granted for treatment of adult T-cell leukemia/lymphoma.

L. AIDS-Related Kaposi Sarcoma
Authorization of 12 months may be granted for treatment of AIDS-related Kaposi sarcoma.

M. Multicentric Castleman's Disease
Authorization of 12 months may be granted for treatment of multicentric Castleman's disease.

N. Pediatric Acute Lymphoblastic Leukemia
Authorization of 12 months may be granted for treatment of pediatric acute lymphoblastic leukemia.

O. Mycosis Fungoides/Sezary Syndrome
Authorization of 12 months may be granted for treatment of mycosis fungoides/Sezary syndrome.

P. Primary Cutaneous Anaplastic Large Cell Lymphoma
Authorization of 12 months may be granted for treatment of primary cutaneous anaplastic large cell lymphoma.

Q. Cutaneous Anaplastic Large Cell Lymphoma
Authorization of 12 months may be granted for treatment of cutaneous anaplastic large cell lymphoma.

R. Waldenstrom Macroglobulinemia/ Lymphoplasmacytic Lymphoma
Authorization of 12 months may be granted for treatment of Waldenstrom macroglobulinemia/ lymphoplasmacytic lymphoma.

S. Follicular Lymphoma
Authorization of 12 months may be granted for treatment of follicular lymphoma.

T. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Authorization of 12 months may be granted for treatment of chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL).

U. AIDS-related B-cell lymphoma[2]
Authorization of 12 months may be granted for treatment of AIDS-related B-cell lymphoma.

V. Breast Implant-Associated Anaplastic Large Cell Lymphoma
Authorization of 12 months may be granted for treatment of breast implant-associated anaplastic large cell lymphoma.

W. Hepatosplenic T-cell Lymphoma
Authorization of 12 months may be granted for treatment of hepatosplenic T-cell lymphoma.

X. Extranodal NK T-cell Lymphoma, Nasal Type
Authorization of 12 months may be granted for treatment of extranodal NK T-cell lymphoma, nasal type.

Y. Subcutaneous Panniculitis-like T-cell Lymphoma
Authorization of 12 months may be granted for treatment of subcutaneous panniculitis-like T-cell lymphoma.

Z. Blastic NK-cell Lymphoma
Authorization of 12 months may be granted for treatment of blastic NK-cell lymphoma.

AA. Heavy Chain Disease
Authorization of 12 months may be granted for treatment of heavy chain disease.

BB. Malignant Immunoproliferative Disease
Authorization of 12 months may be granted for treatment of malignant immunoproliferative disease.

CC. Hairy Cell Leukemia
Authorization of 12 months may be granted for treatment of hairy cell leukemia.

DD. Prolymphocytic Leukemia, B-cell Type
Authorization of 12 months may be granted for treatment of prolymphocytic leukemia, B-cell type.

EE. Prolymphocytic Leukemia, T-cell Type
Authorization of 12 months may be granted for treatment of prolymphocytic leukemia, T-cell type.

FF. T-cell Large Granular Lymphocytic Leukemia
Authorization of 12 months may be granted for treatment of T-cell large granular lymphocytic leukemia.

GG. Langerhans Cell Histiocytosis
Authorization of 12 months may be granted for treatment of Langerhan's cell histiocytosis.

HH. Systemic Mastocytosis
Authorization of 12 months may be granted for treatment of systemic mastocytosis.

IV. DOSAGE AND ADMINISTRATION

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

Reference number(s)
3858-A

V. REFERENCES

1. Drugs and Biologicals LCD (L33394) Version R14. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed October 14, 2020.
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4. Velcade [package insert]. Cambridge, MA: Millennium Pharmaceuticals, Inc.; April 2019.
5. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed October 2, 2020.
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