Velcade® (bortezomib)  

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**Velcade® (bortezomib)**  

Last Review Date: 2/6/2018  
Date of Origin: 11/28/2011  

I. **Length of Authorization**  
Coverage will be provided for 6 months and may be renewed.

II. **Dosing Limits**  
A. **Quantity Limit (max daily dose) [Pharmacy Benefit]**:  
   - Velcade 3.5 mg powder for injection: 4 vials per 21 day supply

B. **Max Units (per dose and over time) [Medical Benefit]**:  
   - 140 billable units every 21 days

III. **Initial Approval Criteria**  
Coverage is provided in the following conditions:

- Patient aged 18 years or older; **AND**

**Multiple myeloma †**

**Mantle cell lymphoma †**

**Systemic Light Chain Amyloidosis ‡**

- Used as a single agent; **OR**
- Used in combination with dexamethasone with or without melphalan; **OR**
- Used in combination with dexamethasone and cyclophosphamide

**Waldenström's macroglobulinemia/Lymphoplasmacytic Lymphoma ‡**

- Used as a single agent; **OR**
- Used in combination with dexamethasone; **OR**
- Used in combination with rituximab with or without dexamethasone
**Multicentric Castleman’s Disease ‡**
- Must be used as subsequent therapy; **AND**
- Patient has relapsed/refractory or progressive disease; **AND**
- Used as a single agent or in combination with rituximab

**Primary cutaneous CD30+ T-Cell Lymphoproliferative Disorders ‡**
- Used as single agent; **AND**
  - Patient has primary cutaneous anaplastic large cell lymphoma (pcALCL) with multifocal lesions; **OR**
  - Patient has cutaneous ALCL with regional nodes (excludes systemic ALCL)

**Adult T-Cell Leukemia/Lymphoma ‡**
- Must be used as a single agent for acute disease or lymphoma; **AND**
  - Used second-line for non-responders to first-line therapy; **OR**
  - Subsequent therapy after high-dose therapy with autologous stem cell rescue (HDT/ASCR)

† FDA Approved Indication(s); ‡ Compendia recommended indication(s)

**IV. Renewal Criteria**

Coverage can be renewed based upon the following criteria:
- Patient continues to meet the criteria identified in section III: **AND**
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Example of unacceptable toxicity include: peripheral neuropathy, hypotension, cardiac toxicity, pulmonary toxicity, posterior reversible encephalopathy syndrome, gastrointestinal toxicity, thrombocytopenia, neutropenia, tumor lysis syndrome, hepatic toxicity, etc.

**V. Dosage/Administration**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple myeloma – previously untreated</td>
<td>1.3 mg/m² IV/SC in combination with oral melphalan and oral prednisone for nine 6-week treatment cycles. In cycles 1-4, Velcade is given twice weekly (days 1, 4, 8, 11, 22, 25, 29, and 32). In cycles 5-9, Velcade is given once weekly (days 1, 8, 22, and 29).</td>
</tr>
<tr>
<td>Mantle Cell Lymphoma –</td>
<td>1.3 mg/m² IV/SC in combination with rituximab, cyclophosphamide, doxorubicin, and oral prednisone for six 3-week cycles. Velcade is given twice</td>
</tr>
</tbody>
</table>
previously untreated weekly for two weeks (Days 1, 4, 8, and 11) followed by a 10-day rest period on Days 12-21. For patients with a response first documented at cycle 6, two additional cycles are recommended.

Multiple myeloma & Mantle Cell Lymphoma - relapsed 1.3 mg/m² IV/SC twice weekly x 4 doses (days 1, 4, 8, and 11) followed by a 10-day rest period (days 12-21).

For extended therapy of more than 8 cycles, bortezomib may be administered on the standard schedule or, for relapsed multiple myeloma, on a maintenance schedule of once weekly for 4 weeks (days 1, 8, 15, and 22), followed by a 13-day rest period (days 23 to 35)

Waldenström’s macroglobulinemia 1.3 mg/m² IV/SC twice weekly for 2 weeks (days 1, 4, 8, and 11) in a 21 day cycle: OR

In combination with rituximab alone: 1.6mg/m² days 1, 8, and 15 of a 28 day cycle

All Other Indications 1.3 mg/m² IV/SC twice weekly (days 1, 4, 8, and 11) for 2 weeks of a 21 day cycle

VI. Billing Code/Availability Information

Jcode:

- J9041—Injection, bortezomib, 0.1 mg; 1 billable unit = 0.1 mg

NDC(s):

- Velcade 3.5 mg single-use vial powder for injection: 63323-0721-xx -xx

VII. References


2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Bortezomib. National Comprehensive Cancer Network, 2017. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed January 2018.


**Appendix 1 – Covered Diagnosis Codes**

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C83.00</td>
<td>Small cell B-cell lymphoma, unspecified site</td>
</tr>
<tr>
<td>C83.01</td>
<td>Small cell B-cell lymphoma, lymph nodes of head, face and neck</td>
</tr>
<tr>
<td>C83.02</td>
<td>Small cell B-cell lymphoma, intrathoracic lymph nodes</td>
</tr>
<tr>
<td>C83.03</td>
<td>Small cell B-cell lymphoma, intra-abdominal lymph nodes</td>
</tr>
<tr>
<td>C83.04</td>
<td>Small cell B-cell lymphoma, lymph nodes of axilla and upper limb</td>
</tr>
<tr>
<td>C83.05</td>
<td>Small cell B-cell lymphoma, lymph nodes of inguinal region and lower limb</td>
</tr>
<tr>
<td>C83.06</td>
<td>Small cell B-cell lymphoma, intrapelvic lymph nodes</td>
</tr>
<tr>
<td>C83.07</td>
<td>Small cell B-cell lymphoma, spleen</td>
</tr>
<tr>
<td>C83.08</td>
<td>Small cell B-cell lymphoma, lymph nodes of multiple sites</td>
</tr>
<tr>
<td>C83.09</td>
<td>Small cell B-cell lymphoma, extranodal and solid organ sites</td>
</tr>
<tr>
<td>C83.10</td>
<td>Mantle cell lymphoma, unspecified site</td>
</tr>
<tr>
<td>C83.11</td>
<td>Mantle cell lymphoma, lymph nodes of head, face and neck</td>
</tr>
<tr>
<td>C83.12</td>
<td>Mantle cell lymphoma, intrathoracic lymph nodes</td>
</tr>
<tr>
<td>ICD-10</td>
<td>ICD-10 Description</td>
</tr>
<tr>
<td>--------</td>
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<tr>
<td>C83.13</td>
<td>Mantle cell lymphoma, intra-abdominal lymph nodes</td>
</tr>
<tr>
<td>C83.14</td>
<td>Mantle cell lymphoma, lymph nodes of axilla and upper limb</td>
</tr>
<tr>
<td>C83.15</td>
<td>Mantle cell lymphoma, lymph nodes of inguinal region and lower limb</td>
</tr>
<tr>
<td>C83.16</td>
<td>Mantle cell lymphoma, intrapelvic lymph nodes</td>
</tr>
<tr>
<td>C83.17</td>
<td>Mantle cell lymphoma, spleen</td>
</tr>
<tr>
<td>C83.18</td>
<td>Mantle cell lymphoma, lymph nodes of multiple sites</td>
</tr>
<tr>
<td>C83.19</td>
<td>Mantle cell lymphoma, extranodal and solid organ sites</td>
</tr>
<tr>
<td>C86.6</td>
<td>Primary cutaneous CD30-positive T-cell proliferations</td>
</tr>
<tr>
<td>C88.0</td>
<td>Waldenstrom macroglobulinemia</td>
</tr>
<tr>
<td>C90.00</td>
<td>Multiple myeloma not having achieved remission</td>
</tr>
<tr>
<td>C90.01</td>
<td>Multiple myeloma in remission</td>
</tr>
<tr>
<td>C90.02</td>
<td>Multiple myeloma, in relapse</td>
</tr>
<tr>
<td>C90.10</td>
<td>Plasma cell leukemia not having achieved remission</td>
</tr>
<tr>
<td>C90.11</td>
<td>Plasma cell leukemia in remission</td>
</tr>
<tr>
<td>C90.12</td>
<td>Plasma cell leukemia in relapse</td>
</tr>
<tr>
<td>C90.20</td>
<td>Extramedullary plasmacytoma not having achieved remission</td>
</tr>
<tr>
<td>C90.21</td>
<td>Extramedullary plasmacytoma in remission</td>
</tr>
<tr>
<td>C90.22</td>
<td>Extramedullary plasmacytoma in relapse</td>
</tr>
<tr>
<td>C90.30</td>
<td>Solitary plasmacytoma not having achieved remission</td>
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<tr>
<td>C90.31</td>
<td>Solitary plasmacytoma in remission</td>
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<tr>
<td>C90.32</td>
<td>Solitary plasmacytoma in relapse</td>
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<tr>
<td>C91.50</td>
<td>Adult T-cell lymphoma/leukemia (HTLV-1-associated) not having achieved remission</td>
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<tr>
<td>C91.52</td>
<td>Adult T-cell lymphoma/leukemia (HTLV-1-associated), in relapse</td>
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<tr>
<td>D36.0</td>
<td>Benign neoplasm of lymph nodes</td>
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<tr>
<td>E85.9</td>
<td>Amyloidosis, unspecified</td>
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<tr>
<td>R59.0</td>
<td>Localized enlarged lymph nodes</td>
</tr>
<tr>
<td>R59.1</td>
<td>Generalized enlarged lymph nodes</td>
</tr>
<tr>
<td>R59.9</td>
<td>Enlarged lymph nodes, unspecified</td>
</tr>
<tr>
<td>Z85.72</td>
<td>Personal history of non-Hodgkin lymphomas</td>
</tr>
<tr>
<td>Z85.79</td>
<td>Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues</td>
</tr>
</tbody>
</table>

**Dual coding requirements:**
- Codes Z85.72 & Z85.79 are secondary codes and must be billed in conjunction with a primary code.
Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

<table>
<thead>
<tr>
<th>Jurisdiction(s):</th>
<th>NCD/LCD Document (s):</th>
<th>Document Link</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Jurisdiction(s):</th>
<th>NCD/LCD Document (s):</th>
<th>Document Link</th>
</tr>
</thead>
</table>

Medicare Part B Administrative Contractor (MAC) Jurisdictions

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Applicable State/US Territory</th>
<th>Contractor</th>
</tr>
</thead>
<tbody>
<tr>
<td>E (1)</td>
<td>CA, HI, NV, AS, GU, CNMI</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>F (2 &amp; 3)</td>
<td>AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>5</td>
<td>KS, NE, IA, MO</td>
<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
</tr>
<tr>
<td>6</td>
<td>MN, WI, IL</td>
<td>National Government Services, Inc. (NGS)</td>
</tr>
<tr>
<td>H (4 &amp; 7)</td>
<td>LA, AR, MS, TX, OK, CO, NM</td>
<td>Novitas Solutions, Inc.</td>
</tr>
<tr>
<td>8</td>
<td>MI, IN</td>
<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
</tr>
<tr>
<td>N (9)</td>
<td>FL, PR, VI</td>
<td>First Coast Service Options, Inc.</td>
</tr>
<tr>
<td>J (10)</td>
<td>TN, GA, AL</td>
<td>Palmetto GBA, LLC</td>
</tr>
<tr>
<td>M (11)</td>
<td>NC, SC, WV, VA (excluding below)</td>
<td>Palmetto GBA, LLC</td>
</tr>
<tr>
<td>L (12)</td>
<td>DE, MD, PA, NJ, DC (includes Arlington &amp; Fairfax counties and the city of Alexandria in VA)</td>
<td>Novitas Solutions, Inc.</td>
</tr>
<tr>
<td>K (13 &amp; 14)</td>
<td>NY, CT, MA, RI, VT, ME, NH</td>
<td>National Government Services, Inc. (NGS)</td>
</tr>
<tr>
<td>15</td>
<td>KY, OH</td>
<td>CGS Administrators, LLC</td>
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</tbody>
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