Polivy™ (polatuzumab vedotin-piiq) (Intravenous)

I. Length of Authorization

Coverage will be provided for six months (up to 6 cycles of therapy) and may NOT be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:
   • Polivy 140 mg SDV vial: 1 vial per 21 days*

B. Max Units (per dose and over time) [HCPCS Unit]:
   • 140 billable units every 21 days*

III. Initial Approval Criteria

Coverage is provided in the following conditions:

• Patient is 18 years or older; AND
• Patient will receive prophylaxis for Pneumocystis jiroveci pneumonia and herpesvirus; AND
• Patient does not currently have Grade ≥ 2 peripheral neuropathy; AND
• Patient has not had a prior allogeneic stem-cell transplant; AND
• Patient has not had an autologous stem-cell transplant within 100 days prior to start of therapy, or is not a candidate; AND
• Patient has not had chimeric antigen receptor T-cell (CAR-T) therapy within 100 days prior to start of therapy; AND
• Patient has relapsed or refractory disease; AND
• Used in combination with bendamustine and rituximab; AND
• Used as subsequent treatment after at least two prior therapies (Note: For patients with relapsed disease who received prior bendamustine, response duration must have been >1 year)
IV. Renewal Criteria

Coverage cannot be renewed.

V. Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>DLBCL</td>
<td>The recommended dose of Polivy is 1.8 mg/kg administered as an intravenous infusion every 21 days for 6 cycles in combination with bendamustine and rituximab product. Administer Polivy, bendamustine, and rituximab products in any order on Day 1 of each cycle. <strong>Note</strong>: patients in excess of 77 kg will require a dose greater than one 140 mg vial. The Genentech Temporary POLIVY Vial Supplement Program must be used if the second vial meets the eligibility criteria. This program will terminate once a 30 mg vial of POLIVY is available.</td>
</tr>
</tbody>
</table>

VI. Billing Code/Availability Information

HCPCS code:
• J9999 – Not otherwise classified, antineoplastic drugs
• J9309 – Injection, polatuzumab vedotin-piiq 1 mg; 1 mg = 1 billable unit (effective 1/1/2020)

NDC:
• Polivy 140 mg lyophilized powder for injection, single-use vial: 50242-0105-xx

VII. References


2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for polatuzumab vedotin. National Comprehensive Cancer Network, 2019. 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 June 2019.

Appendix 1 – Covered Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C83.30</td>
<td>Diffuse large B-cell lymphoma unspecified site</td>
</tr>
<tr>
<td>C83.31</td>
<td>Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck</td>
</tr>
<tr>
<td>C83.32</td>
<td>Diffuse large B-cell lymphoma intrathoracic lymph nodes</td>
</tr>
<tr>
<td>ICD-10</td>
<td>ICD-10 Description</td>
</tr>
<tr>
<td>--------</td>
<td>-----------------------------------------------------------------------</td>
</tr>
<tr>
<td>C83.33</td>
<td>Diffuse large B-cell lymphoma intra-abdominal lymph nodes</td>
</tr>
<tr>
<td>C83.34</td>
<td>Diffuse large B-cell lymphoma lymph nodes of axilla and upper limb</td>
</tr>
<tr>
<td>C83.35</td>
<td>Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb</td>
</tr>
<tr>
<td>C83.36</td>
<td>Diffuse large B-cell lymphoma intrapelvic lymph nodes</td>
</tr>
<tr>
<td>C83.37</td>
<td>Diffuse large B-cell lymphoma, spleen</td>
</tr>
<tr>
<td>C83.38</td>
<td>Diffuse large B-cell lymphoma lymph nodes of multiple sites</td>
</tr>
<tr>
<td>C83.39</td>
<td>Diffuse large B-cell lymphoma extranodal and solid organ sites</td>
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<tr>
<td>C85.10</td>
<td>Unspecified B-cell lymphoma, unspecified site</td>
</tr>
<tr>
<td>C85.11</td>
<td>Unspecified B-cell lymphoma, lymph nodes of head, face, and neck</td>
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<tr>
<td>C85.12</td>
<td>Unspecified B-cell lymphoma, intrathoracic lymph nodes</td>
</tr>
<tr>
<td>C85.13</td>
<td>Unspecified B-cell lymphoma, intra-abdominal lymph nodes</td>
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<tr>
<td>C85.14</td>
<td>Unspecified B-cell lymphoma, lymph nodes of axilla and upper limb</td>
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<tr>
<td>C85.15</td>
<td>Unspecified B-cell lymphoma, lymph nodes of inguinal region and lower limb</td>
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<tr>
<td>C85.16</td>
<td>Unspecified B-cell lymphoma, intrapelvic lymph nodes</td>
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<tr>
<td>C85.17</td>
<td>Unspecified B-cell lymphoma, spleen</td>
</tr>
<tr>
<td>C85.18</td>
<td>Unspecified B-cell lymphoma, lymph nodes of multiple sites</td>
</tr>
<tr>
<td>C85.19</td>
<td>Unspecified B-cell lymphoma, extranodal and solid organ sites</td>
</tr>
</tbody>
</table>

### 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](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): N/A

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Applicable State/US Territory</th>
<th>Contractor</th>
</tr>
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<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>
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<tr>
<td>6</td>
<td>MN, WI, IL</td>
<td>National Government Services, Inc. (NGS)</td>
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<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>
</tbody>
</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>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>
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<tr>
<td>15</td>
<td>KY, OH</td>
<td>CGS Administrators, LLC</td>
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