**Arzerra® (ofatumumab)**
*(Intravenous)*

Last Review Date: 05/02/2022
Date of Origin: 06/2019
Dates Reviewed: 06/2019, 05/2020, 05/2021, 05/2022

I. **Length of Authorization**

Coverage will be provided for 6 months with renewal subject to the following:

- CLL/SLL (first-line) may be renewed to allow for a total of 12 cycles
- CLL/SLL (relapsed) may not be renewed (unless the provisions for extended treatment have been met)
- CLL/SLL (single agent subsequent therapy) may not be renewed (unless the provisions for extended treatment have been met)
- CLL/SLL (extended treatment) may be renewed to provide for a total of 2 years of therapy
- Waldenström’s Macroglobulinemia/Lymphoplasmacytic lymphoma may be renewed to allow for up to a total of 3 cycles

II. **Dosing Limits**

A. **Quantity Limit (max daily dose) [NDC Unit]:**

- Arzerra 100 mg/5 mL single-use vial: 3 vials Day 1
- Arzerra 1000 mg/50 mL single-use vial: 2 vials weekly x 7 doses, then 2 vials every 4 weeks, then 1 vial every 8 weeks for up to 24 months

B. **Max Units (per dose and over time) [HCPCS Unit]:**

<table>
<thead>
<tr>
<th></th>
<th>First-Line</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CLL/SLL</strong></td>
<td>30 billable units on day 1 and 100 billable units on day 8; then</td>
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<tr>
<td></td>
<td>100 billable units every 28 days for up to 11 doses</td>
</tr>
<tr>
<td><strong>Single agent subsequent therapy</strong></td>
<td>30 billable units on day 1; then</td>
</tr>
<tr>
<td></td>
<td>200 billable units weekly x 7 doses; then</td>
</tr>
<tr>
<td></td>
<td>200 billable units every 28 days x 4 doses</td>
</tr>
<tr>
<td><strong>Relapsed</strong></td>
<td>30 billable units on day 1 and 100 billable units on day 8; then</td>
</tr>
<tr>
<td></td>
<td>100 billable units every 28 days for up to 5 doses</td>
</tr>
<tr>
<td><strong>Extended Treatment</strong></td>
<td>30 billable units on day 1 and 100 billable units on day 8; then</td>
</tr>
</tbody>
</table>
III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; AND

Universal Criteria

- Patient has been screened for the presence of hepatitis B (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; AND
- Must not be administered concurrently with live vaccines; AND

Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) † Φ 1-3,6,12,22,27

- Used as first-line therapy; AND
  - Used in combination with chlorambucil in patients considered inappropriate for fludarabine-based therapy (Note: only applies to CLL); OR
  - Used in combination with bendamustine ‡; AND
    - Patient does not have del(17p)/TP53 mutation (patients ≥ 65 years, or younger patients with or without significant comorbidities; excluding use in frail patients [i.e., creatine clearance (CrCl) <70 mL/min]); OR
- Used as subsequent therapy; AND
  - Used as a single agent; AND
    - Patient is refractory to both fludarabine- and alemtuzumab-containing regimens; OR
    - Patient is refractory to fludarabine and unable to receive treatment with alemtuzumab as a result of bulky (> 5 cm) lymphadenopathy; OR
  - Used in combination with fludarabine and cyclophosphamide (FC) for relapsed disease (Note: only applies to CLL); OR
- Used as extended treatment in patients with complete or partial response after at least 2 lines of therapy for recurrent or progressive disease (Note: only applies to CLL); AND
  - Used as a single agent

Waldenström’s Macroglobulinemia/Lymphoplasmacytic Lymphoma ‡ 2,4,81e

- Used as a single agent; AND
- Patient is intolerant to rituximab; AND
  - Patient has previously failed primary therapy; OR
  - Patient has progressive or relapsed disease
Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria

Coverage may be renewed based on the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; AND
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: Hepatitis B virus reactivation/infection, progressive multifocal leukoencephalopathy, severe infusion reactions, tumor lysis syndrome, cytopenias (neutropenia, anemia, and thrombocytopenia), etc.

V. Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLL/SLL (First-line)</td>
<td>Administer 300 mg on Day 1, then 1,000 mg on Day 8, followed by 1,000 mg on Day 1 of subsequent 28-day cycles for a minimum of 3 cycles until best response or a maximum of 12 cycles</td>
</tr>
<tr>
<td>CLL/SLL (Single agent subsequent therapy)</td>
<td>Administer 300 mg on Day 1, followed 1 week later by 2,000 mg given weekly x 7 doses (infusions 2 through 8), followed 4 weeks later by 2,000 mg every 4 weeks for 4 doses (infusions 9 through 12) for a total of 12 doses</td>
</tr>
<tr>
<td>CLL/SLL (Relapsed)</td>
<td>Administer 300 mg on Day 1, then 1,000 mg on Day 8, followed by 1,000 mg on Day 1 of subsequent 28-day cycles for a maximum of 6 cycles</td>
</tr>
<tr>
<td>CLL/SLL (Extended treatment)</td>
<td>Administer 300 mg on Day 1, then 1,000 mg on Day 8, followed by 1,000 mg 7 weeks later and every 8 weeks thereafter for up to a maximum of 2 years</td>
</tr>
<tr>
<td>Waldenström’s/Lymphoplasmacytic lymphoma</td>
<td><strong>Cycle 1:</strong>&lt;br&gt;• Administer 300 mg on day 1, then 1,000 mg weekly for weeks 2 through 4; OR&lt;br&gt;• Administer 300 mg on day 1, then 2,000 mg weekly for weeks 2 through 5</td>
</tr>
</tbody>
</table>
VI. Billing Code/Availability Information

HCPCS Code:
- J9302 – injection, ofatumumab, 10 mg; 1 billable unit = 10 mg

NDC:
- Arzerra 1000 mg/50 mL single-use vial: 00078-0690-xx
- Arzerra 100 mg/5 mL single-use vial: 00078-0669-xx

VII. References (STANDARD)


2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) ofatumumab. National Comprehensive Cancer Network, 2022. 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 April 2022.


VIII. References (ENHANCED)


### 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>ICD-10</td>
<td>ICD-10 Description</td>
</tr>
<tr>
<td>--------</td>
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<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, intrathoracic 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>
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<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>C88.0</td>
<td>Waldenström macroglobulinemia</td>
</tr>
<tr>
<td>C91.10</td>
<td>Chronic lymphocytic leukemia of B-cell type not having achieved remission</td>
</tr>
<tr>
<td>C91.12</td>
<td>Chronic lymphocytic leukemia of B-cell type in relapse</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), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: [https://www.cms.gov/medicare-coverage-database/search.aspx](https://www.cms.gov/medicare-coverage-database/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/LCA): N/A

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<tr>
<th>Jurisdiction</th>
<th>Applicable State/US Territory</th>
<th>Contractor</th>
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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>
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<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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<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>
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<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>
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</tr>
<tr>
<td>L (12)</td>
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<td>Novitas Solutions, Inc.</td>
</tr>
<tr>
<td>Jurisdiction</td>
<td>Applicable State/US Territory</td>
<td>Contractor</td>
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<tr>
<td>K (13 &amp; 14)</td>
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<td>15</td>
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<td>CGS Administrators, LLC</td>
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