Arzerra® (ofatumumab)
(Intravenous)

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I. Length of Authorization [1,10]

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]:

CLL/SLL	**First-Line** ▪ 30 billable units on day 1 and 100 billable units on day 8; then ▪ 100 billable units every 28 days for up to 11 doses **Single agent subsequent therapy** ▪ 30 billable units on day 1; then ▪ 200 billable units weekly x 7 doses; then ▪ 200 billable units every 28 days x 4 doses **Relapsed** ▪ 30 billable units on day 1 and 100 billable units on day 8; then ▪ 100 billable units every 28 days for up to 5 doses **Extended Treatment** ▪ 30 billable units on day 1 and 100 billable units on day 8; then ▪ 100 billable units 7 weeks later and every 8 weeks thereafter

Waldenström's Macroglobulinemia / Lymphoplasmacytic Lymphoma	▪ 30 billable units on day 1; then ▪ 200 billable units every 7 days x 4 doses

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria [1]

- 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]

- 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; **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)*

Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma ‡ [2,4]

- Used as a single agent OR as part of combination therapy; **AND**
- Patient is intolerant to rituximab; **AND**
  - Patient has previously failed primary therapy; **OR**
  - Patient has progressive or relapsed disease

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

IV. Renewal Criteria [1]

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 [1,10]

Indication	Dose
CLL/SLL (First-line)	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
CLL/SLL (Single agent subsequent therapy)	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
CLL/SLL (Relapsed)	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
CLL/SLL (Extended treatment)	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
Waldenström's/ Lymphoplasmacytic lymphoma	<u>Cycle 1:</u> • Administer 300 mg on day 1, then 1,000 mg weekly for weeks 2 through 4; **OR** • Administer 300 mg on day 1, then 2,000 mg weekly for weeks 2 through 5 <u>Cycle 2-3:</u> • Patients with stable disease or a minor response at week 16 of cycle 1 are eligible to receive a re-dosing cycle of 300 mg on day 1, then 2,000 mg for weeks 2 through 5. • Patients responding to cycle 1 or the redosing cycle who developed disease progression within 36 months can receive treatment with 300 mg on day 1, then 2,000 mg for weeks 2 through 5.

VI. Billing Code/Availability Information

<u>HCPCS Code:</u>

- J9302 – Injection, ofatumumab, 10 mg; 1 billable unit = 10 mg

<u>NDC:</u>

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

VII. References

1. Arzerra [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation, August 2016. Accessed March 2022.
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 March 2022.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. Version 2.2022. 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 March 2022.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma. Version 2.2022. 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 March 2022.
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11. Hillmen P, Robak T, Janssens A, et al. Chlorambucil plus ofatumumab versus chlorambucil alone in previously untreated patients with chronic lymphocytic leukaemia (COMPLEMENT 1): a randomised, multicentre, open-label phase 3 trial. Lancet. 2015 May 9;385(9980):1873-83. doi: 10.1016/S0140-6736(15)60027-7. Epub 2015 Apr 14.
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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C83.00	Small cell B-cell lymphoma, unspecified site
C83.01	Small cell B-cell lymphoma, lymph nodes of head, face and neck
C83.02	Small cell B-cell lymphoma, intrathoracic lymph nodes
C83.03	Small cell B-cell lymphoma, intra-abdominal lymph nodes
C83.04	Small cell B-cell lymphoma, lymph nodes of axilla and upper limb
C83.05	Small cell B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.06	Small cell B-cell lymphoma, intrapelvic lymph nodes
C83.07	Small cell B-cell lymphoma, spleen
C83.08	Small cell B-cell lymphoma, lymph nodes of multiple sites
C83.09	Small cell B-cell lymphoma, extranodal and solid organ sites
C88.0	Waldenström macroglobulinemia
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission

ICD-10	ICD-10 Description
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse

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 Article (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. Additional indications may be covered at the discretion of the health plan.

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

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

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Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

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Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

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PreferredOne Insurance Company
PO Box 59212
Minneapolis, MN 55459-0212
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013)។

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013). 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).