

Arzerra® (ofatumumab) (Intravenous)

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I. Length of Authorization

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

- CLL/SLL (1st-line) may be renewed to allow for a total of 12 cycles
- CLL/SLL (relapsed or refractory) 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/Lymphoplasmacytic lymphoma may not be renewed

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Arzerra 100 mg/5 mL: 3 vials Day 1
- Arzerra 1000 mg/50 mL: 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) [Medical Benefit]:

CLL/SLL	<p>1st Line</p> <ul style="list-style-type: none"> ▪ 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 <p>Refractory</p> <ul style="list-style-type: none"> ▪ 30 billable units on day 1; then ▪ 200 billable units weekly x 7 doses; then ▪ 200 billable units every 28 days x 4 doses <p>Relapsed</p> <ul style="list-style-type: none"> ▪ 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 <p>Extended Treatment</p> <ul style="list-style-type: none"> ▪ 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
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III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is at least 18 years old; **AND**
- Patient must be screened for HBV infection (i.e., HBsAg and anti-HBc) prior to initiating therapy; **AND**
- Must not be administered concurrently with live vaccines; **AND**

Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) †

- Used as first-line therapy in combination with chlorambucil; **OR**
- Used for relapsed or refractory disease; **AND**
 - Used as a single agent; **OR**
 - Used in combination with fludarabine and cyclophosphamide (FC); **OR**
- Used as extended treatment in patients with complete or partial response after 2 or more lines of therapy; **AND**
 - Used as a single agent for recurrent or progressive disease
- Used as first-line therapy in combination with bendamustine ‡; **AND**
 - Patient does not have del(17p)/TP53 mutation

Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma ‡

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

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s)

IV. Renewal Criteria

Authorizations can be renewed based on the following criteria:

- Patient continues to meet criteria 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. Examples of unacceptable toxicity include the following: Hepatitis B virus reactivation/infection, progressive multifocal leukoencephalopathy, severe infusion reactions, tumor lysis syndrome, cytopenias (neutropenia, anemia, and thrombocytopenia), etc.

V. Dosage/Administration

Indication	Dose
CLL/SLL (1 st line)	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 or a maximum of 12 cycles
CLL/SLL (Refractory)	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)	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)	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	300 mg on day 1, then 1,000 mg weekly for 4 doses

VI. Billing Code/Availability Information

Jcode:

- 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

1. Arzerra [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation, August 2016. Accessed March 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium[®]) ofatumumab. National Comprehensive Cancer Network, 2018. 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 2018.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium[®]) Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. Version 4.2018. National Comprehensive Cancer Network, 2018. 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 2018.

4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Waldenstrom’s Macroglobulinemia/Lymphoplasmacytic Lymphoma. Version 1.2018. National Comprehensive Cancer Network, 2018. 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 2018.
5. Furman RR, Eradat H, Switzky JC, et al. A phase II trial of ofatumumab in subjects with Waldenstrom's macroglobulinemia. *Blood*. 2011;118:3701
6. Wierda WG, Kipps TJ, Mayer J, et al. Ofatumumab as single-agent CD20 immunotherapy in fludarabine-refractory chronic lymphocytic leukemia. *J Clin Oncol* 2010;28:1749-1755

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
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse
Z85.72	Personal history of non-Hodgkin lymphomas
Z85.79	Personal history of other malignant neoplasm of lymphoid hematopoietic and related tissues

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 Biologics. 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): 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