Drug Policy:

Arzerra™ (ofatumumab)

POLICY NUMBER UM ONC_1220	SUBJECT Arzerra™ (ofatumumab)		DEPT/PROGRAM UM Dept	PAGE 1 of 3
DATES COMMITTEE REVIEWED 10/03/12, 12/11/13, 03/16/15, 04/13/16, 02/06/17, 02/14/18, 02/13/19, 12/11/19, 02/12/20, 11/11/20, 10/13/21, 11/15/21, 05/11/22, 07/13/22, 08/09/23, 08/14/24	**APPROVAL DATE** August 14, 2024	**EFFECTIVE DATE** August 30, 2024	**COMMITTEE APPROVAL DATES** 10/03/12, 12/11/13, 03/16/15, 04/13/16, 02/06/17, 02/14/18, 02/13/19, 12/11/19, 02/12/20, 11/11/20, 10/31/21, 11/15/21, 05/11/22, 07/13/22, 08/09/23, 08/14/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Arzerra (ofatumumab) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided:

1. The member has not experienced disease progression on the requested medication AND
2. The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
3. Additional medication(s) are not being added to the continuation request.

B. Chronic Lymphocytic Leukemia (CLL)

1. Arzerra (ofatumumab) may be used in members with ONE of the following criteria:
   a. In combination with chlorambucil for newly diagnosed CLL and the member has no history of prior treatment for CLL
   b. In combination with fludarabine + cyclophosphamide for relapsed/refractory CLL

c. As monotherapy following response to prior therapy or as second line therapy for relapsed/refractory CLL.

NOTE: As of August 20, 2020, Novartis transitioned the availability of Arzerra (ofatumumab) to an oncology patient access program that will provide Arzerra at no cost to chronic lymphocytic leukemia patients in the United States. This program will be through the Patient Access Novartis Oncology (PANO).

III. EXCLUSION CRITERIA

A. Member has disease progression while taking Arzerra (ofatumumab).

B. Dosing exceeds single dose limit of Arzerra (ofatumumab) 1,000 mg (for initial or extended treatment in CLL) or 2,000 mg (for relapsed/refractory CLL).

C. Treatment with Arzerra (ofatumumab) exceeds the maximum duration limit of 12 doses over 24 weeks for previously treated CLL or maximum 12 cycles for previously untreated CLL.

D. Treatment with Arzerra (ofatumumab) exceeds the maximum duration limit of 2 years for extended treatment in CLL.

E. Investigational use of Arzerra (ofatumumab) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Arzerra prescribing information. GSK, Research Triangle Park, NC 2021.

B. Genmab announces plan to transition Arzerra (ofatumumab) to an Oncology Access Program for chronic lymphocytic leukemia patients in the US. News release. Genmab. August 20, 2020. Accessed July 23, 2024. bit.ly/2EYduKS

C. Robak T, et al. Ofatumumab plus fludarabine and cyclophosphamide in relapsed chronic lymphocytic leukemia: results from the COMPLEMENT 2 trial. Leuk Lymphoma. 2017 May;58(5):1084-1093. doi: 10.1080/10428194.2016.1233536

D. Clinical Pharmacology Elsevier Gold Standard 2024.

E. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2024.

F. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2024.

G. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2024.

H. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

I. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.

J. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.