POLICY NUMBER UM ONC_1220	**SUBJECT** Arzerra™ (ofatumumab)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 2**
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	**APPROVAL DATE** February 12, 2020	**EFFECTIVE DATE** March 01, 2020	**COMMITTEE APPROVAL DATES** (latest version listed last) 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	
PRIMARY BUSINESS OWNER: UM **APPROVED BY:** Dr. Andrew Hertler		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM 1	**NCQA STANDARDS** UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** All	

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.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century 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

1. **Chronic Lymphocytic Leukemia (CLL)**
    a. The member has CLL which in the clinician's judgment requires therapy **AND** Arzerra (ofatumumab) is being used for the following:
        i. In combination with bendamustine as first line therapy **OR**
        ii. As a single agent or in combination with FC (fludarabine, cyclophosphamide) for members with relapsed or refractory disease **OR**
        iii. Maintenance therapy as second-line extended dosing following complete or partial response to treatment for relapsed or refractory disease.
2. **Waldenstrom's Macroglobulemia**
    a. The member has Waldenström Macroglobulinemia and Arzerra (ofatumumab) is being as a single agent or combination therapy for Rituximab – intolerant members who don't respond to primary therapy.

III. EXCLUSION CRITERIA

1. Member has disease progression while taking Arzerra (ofatumumab).
2. Dosing exceeds single dose limit of Arzerra (ofatumumab) 2000 mg.
3. 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

4. Treatment with Arzerra (ofatumumab) exceeds the maximum duration limit of 2 years for extended treatment in CLL
5. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

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

V. APPROVAL AUTHORITY

1. Review – UM Department
2. Final Approval – UM Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Arzerra prescribing information. GSK, Research Triangle Park, NC. 2019.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.