

# Arzerra (ofatumumab)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Arzerra (ofatumumab)

## **APPROVAL CRITERIA**

Requests for Arzerra (ofatumumab) may be approved if the following criteria are met:

- I. Individual has a diagnosis of chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL); **AND**
- II. Individual is using for one of the following:
  - A. As first-line therapy in combination with chlorambucil; **OR**
  - B. Treatment of relapsed or refractory CLL/SLL, as a single agent and only in one line of therapy, or in combination with fludarabine and cyclophosphamide; **OR**
  - C. As maintenance treatment for up to 24 months when the following criteria are met:
    1. Treatment is following at least two lines of therapy for relapsed or progressive disease; **AND**
    2. A complete or partial response has been achieved;

### **OR**

- III. Individual has a diagnosis of Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma (NCCN 2A); **AND**
  - A. Individual is rituximab-intolerant; **AND**
  - B. Individual is using as a single agent or in combination; **AND**
  - C. Individual is using when previously treated disease did not respond to primary therapy or for progressive or relapsed disease.

Requests for Arzerra (ofatumumab) may not be approved for the following:

- I. Treatment of multiple sclerosis; **OR**
- II. All other indications not included above.

### **Note:**

Arzerra (ofatumumab) has a black box warning for hepatitis B reactivation which, in some cases, results in fulminant hepatitis, hepatic failure, and death. Arzerra also has a black box warning for progressive multifocal leukoencephalopathy which can occur in patients receiving CD20-directed antibodies, including Arzerra.

## **Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: December 28, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Flinn IW, Panayiotidis P, Afanasyev B, et al. A phase 2, multicenter study investigating ofatumumab and bendamustine combination in patients with untreated or relapsed CLL. *Am J Hematol* 2016; 91: 900-906.
5. Furman RR, eradat H, Switzky JC, et al. A phase 2 trial of ofatumumab in subjects with Waldenstrom's macroglobulinemia [abstract]. *Blood* 2010; 116: Abstract 1795.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on December 28, 2022.
  - a. Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma. V2.2024. Revised December 5, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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