

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) (Label); **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.

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. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. 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.
4. 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.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.

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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