

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

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.

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

- I. All other indications not included above; **OR**
- II. Treatment of Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma.

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.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. 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: June 14, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on April 12, 2019.
 - B-Cell Lymphomas. V2.2019. Revised March 6, 2019.
 - Chronic Lymphocytic Leukemia/small lymphocytic lymphoma. V4.2019. Revised March 15, 2019.

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