

Market Applicability															
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

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# Arzerra (ofatumumab)

DRUG.00063

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Arzerra (ofatumumab)

## APPROVAL CRITERIA

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

- I. Individual is using Arzerra (ofatumumab) as first-line therapy for chronic lymphocytic leukemia /small lymphocytic lymphoma in combination with chlorambucil; **OR**
- II. Treatment of relapsed or refractory chronic lymphocytic leukemia /small lymphocytic lymphoma as a single agent and only in one line of therapy; **OR**

Requests for maintenance treatment for up to 24 months for relapse or progressive chronic lymphocytic leukemia /small lymphocytic lymphoma may be approved when the following criteria are met:

- I. Individual has achieved a complete or partial response; **AND**
- II. Treatment is following at least two lines of therapy.

Arzerra (ofatumumab) may not be approved when the criteria above are not met and for all other indications, including, but not limited to, Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma.

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

## Key References:

Arzerra [Product Information]. Research Triangle Park, NC. GlaxoSmithKline; Revised August 30, 2016. Available at: [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2016/125326s063lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125326s063lbl.pdf). Accessed on October 10, 2016.

Bauer K, Rancea M, Roloff V, et al. Rituximab, ofatumumab and other monoclonal anti-CD20 antibodies for chronic lymphocytic leukaemia. Cochrane Database Syst Rev. 2012;(11):CD008079.

National Comprehensive Cancer Network®. NCCN® Drugs & Biologic Compendium™ (electronic version). For additional information visit the NCCN website: <http://www.nccn.org/index/asp>. Accessed on October 06, 2016.

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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Applicable	X	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

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NCCN Clinical Practice Guidelines in Oncology®. © 2016 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on October 06, 2016.

Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia (V.1.2017). September 28, 2016.

Non-Hodgkin's Lymphoma (V.2 2016). March 17, 2016.

Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma (V.2 2016). September 06, 2015.

Ofatumumab: DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated March 18, 2016. Available at: <http://www.micromedexsolutions.com>. Accessed on October 06, 2016.

Ofatumumab Monograph. Lexicomp® Online, American Hospital Formulary Service® (AHFS®) Online, Hudson, Ohio, Lexi-Comp., Inc. Last revised June 30, 2014. Accessed on October 06, 2016.

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