SmartHealth

Ascension

Ofatumumab

(Arzerra®) J9302 (10 mg)

Covered with prior authorization

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

- Adults ≥ 18 years of age; **AND**
- Individual has a diagnosis of chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) (Label; NCCN 2A); **AND**
- Individual is using for one of the following:
    - As first line therapy in combination with chlorambucil; **OR**
    - 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**
    - As maintenance treatment for up to 24 months when the following criteria are met:
        - Treatment is following at least 2 lines of therapy for relapsed or progressive disease; **AND**
        - A complete or partial response has been achieved; **AND**
- Prescribed by hematologist/oncologist provider.

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

- Adults ≥ 18 years of age; **AND**
- Treatment of Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma; **AND**
- Patient had intolerance to rituximab or will be used in combination with rituximab; **AND**
- Prescribed by hematologist/oncologist provider.

Requests for Arzerra® (ofatumumab) may **not** be approved if the above criteria are not met and for all other indications not included above.

Initial and renewal authorizations are for up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Exclusion criteria:

- Arzerra® (ofatumumab) may not be approved when the above criteria are not met and for all other indications.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.
- Treatment of multiple sclerosis.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage. Arzerra® is a monoclonal antibody directed against the surface antigen CD20 and is used to treat chronic lymphocytic leukemia (CLL). Ofatumumab is also available as Kesimpta, a subcutaneous injection approved by the FDA for relapsing multiple sclerosis. Kesimpta is addressed in a separate clinical criteria (ING-CC-0174). The FDA approved indications for Arzerra® in CLL include as a first line agent in combination with chlorambucil for treatment of previously untreated patients for whom fludarabine-based therapy is considered inappropriate. It is also approved in combination with fludarabine and cyclophosphamide for patients with relapsed disease, or as a single agent for those refractory to fludarabine and alemtuzumab. Arzerra® is also approved as extended therapy. For extended therapy, Arzerra® was studied as a maintenance treatment for 24 months in patients who were in complete or partial response after at least 2 lines of prior therapy. Chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) are different manifestations of the same disease and are managed in much the same way.

Other Uses
The National Comprehensive Cancer Network® (NCCN) provides additional recommendations with a category 2A level of evidence for the use of Arzerra®. These include the use as a first line therapy in combination with bendamustine; however, supportive text indicates this recommendation comes from one non-comparative phase 2 study (Flinn 2016). NCCN also recommends the use of Arzerra® in Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma in those intolerant to rituximab, supported by an open-label, single arm phase 2 study. NCCN also lists a 2A recommendation for Arzerra® as a substitute for rituximab in patients experiencing rare mucocutaneous reactions; however, it is unclear if the use of an alternative anti-CD20 antibody poses the same risk of recurrence (Bcell Lymphomas Guideline).

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 Accessed 8/2022:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. 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.
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.; 2022; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™ For additional information visit the NCCN website: http://www.nccn.org/index.asp.
    a. B-Cell Lymphomas. V5.2021.
    b. Chronic Lymphocytic Leukemia/small lymphocytic lymphoma. V1.2022.
    c. Waldenstr̈om Macroglobulinemia/Lymphoplasmacytic Lymphoma. V2.2022.

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.