

Specialty Guideline Management

Arzerra

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Arzerra	ofatumumab

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹

Chronic lymphocytic leukemia (CLL)

Arzerra is indicated:

- in combination with chlorambucil, for the treatment of previously untreated patients with CLL for whom fludarabine-based therapy is considered inappropriate.
- in combination with fludarabine and cyclophosphamide for the treatment of patients with relapsed CLL.
- for extended treatment of patients who are in complete or partial response after at least two lines of therapy for recurrent or progressive CLL.
- for the treatment of patients with CLL refractory to fludarabine and alemtuzumab.

Compendial Uses²

- CLL

Reference number(s)
2073-A

- Small lymphocytic lymphoma (SLL) (managed in the same manner as CLL)

Note: Arzerra is only available through the manufacturer's oncology patient access program.

All other indications are considered experimental/investigational and not medically necessary.

Coverage Criteria

Chronic Lymphocytic Leukemia (CLL), Small Lymphocytic Lymphoma (SLL)¹⁻²

Authorization of 6 months may be granted for the treatment of CLL or SLL.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Arzerra [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2016.
2. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. Version 3.2025. Available at: <http://www.nccn.org>. Accessed June 9, 2025.