

SPECIALTY GUIDELINE MANAGEMENT

ARZERRA (ofatumumab)

POLICY

I. 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.

A. FDA-Approved Indications

Chronic lymphocytic leukemia (CLL):

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

B. Compendial Uses

1. CLL
2. Small lymphocytic lymphoma (SLL) (managed in the same manner as CLL)
3. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma

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

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

II. CRITERIA FOR INITIAL APPROVAL

A. **Chronic Lymphocytic Leukemia (CLL) and Small Lymphocytic Lymphoma (SLL)**

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

B. **Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL)**

Authorization of 6 months may be granted for the treatment of Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma when all of the following criteria are met:

1. The disease is relapsed, refractory, or progressive, and
2. The member is intolerant to rituximab.

III. CONTINUATION OF THERAPY

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

Reference number
2073-A

IV. REFERENCES

1. Arzerra [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2016.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed June 2, 2023.