

Reference number
2073-A

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. First-line treatment of CLL
2. Small lymphocytic lymphoma (SLL) (managed in the same manner as CLL)
3. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

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

Authorization of 12 months may be granted for the treatment of CD20-positive CLL or SLL.

B. **Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma**

Authorization of 12 months may be granted for the treatment of CD20-positive Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

IV. REFERENCES

1. Arzerra [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2016.

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2. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. <http://www.nccn.org>. Accessed August 06, 2018.