

PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Arzerra Prior Authorization Policy

- Arzerra® (ofatumumab intravenous infusion – Novartis)

REVIEW DATE: 11/16/2022

OVERVIEW

Arzerra is indicated for the treatment of **chronic lymphocytic leukemia (CLL)** in the following situations:

- Previously untreated patients, in combination with chlorambucil, in patients for whom fludarabine-based therapy is considered inappropriate.
- Recurrent or progressive CLL, in patients who are in complete or partial response after at least two lines of therapy.
- Refractory CLL, in patients with disease refractory to fludarabine and alemtuzumab.
- Relapsed CLL, in combination with fludarabine and cyclophosphamide.¹

Guidelines

Arzerra is addressed in the National Comprehensive Cancer Network (NCCN) guidelines:

- **B-cell lymphomas:** Guidelines (version 5.2022 – July 12, 2022) no longer recommend Arzerra for the treatment of B-cell lymphomas.^{2,5}
- **Chronic lymphocytic leukemia/small lymphocytic lymphoma:** NCCN has removed Arzerra from the guidelines (version 1.2023 – August 30, 2022) due to limited clinical use and availability.^{2,3}
- **Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma:** Guidelines (version 1.2023 – July 6, 2022) recommend Arzerra in rituximab-intolerant patients, anywhere that rituximab (Rituxan, biosimilars) is given, for previously treated disease that does not respond to primary treatment or for relapsed or progressive disease.^{2,4}

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Arzerra. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Arzerra as well as the monitoring required for adverse events and long-term efficacy, approval requires Arzerra to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Arzerra is recommended in those who meet one of the following criteria:

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FDA-Approved Indication

- 1. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma.** Approve for 6 months if the patient meets the following criteria (A and B):
 - A) Patient is ≥ 18 years of age; AND
 - B) The medication is prescribed by or in consultation with an oncologist.

Other Uses with Supportive Evidence

- 2. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma.** Approve for 6 months if the patient meets the following criteria (A, B, C, and D):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient is intolerant to a rituximab product; AND
Note: Examples of rituximab products include Rituxan and biosimilars.
 - C) Patient has relapsed or progressive disease; AND
 - D) The medication is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Arzerra is not recommended in the following situations:

- 1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Arzerra® intravenous infusion [prescribing information]. East Hanover, NJ: Novartis; August 2016.
2. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on November 11, 2022. Search term: ofatumumab.
3. The NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (version 1.2023 – August 30, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on November 11, 2022.
4. The NCCN Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma Clinical Practice Guidelines in Oncology (version 1.2023 – July 6, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on November 11, 2022.
5. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 5.2022 – July 12, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on November 11, 2022.