VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Arzerra Utilization Management Medical 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]

Dosing

The FDA-approved treatment duration varies by the indication for use of Arzerra:
- For the first-line treatment of chronic lymphocytic leukemia/small lymphocytic lymphoma, treatment may continue for up to 12 months (12 cycles).
- For relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma, treatment may continue for up to 6 months or 6 cycles.
- For extended treatment in patients in complete or partial response after $\geq$ 2 lines of therapy, treatment may continue for up to 2 years.[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 medical benefit coverage of Arzerra. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). 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:

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.

   Dosing. Approve ONE of the following dosing regimens (A or B):
   - **A)** Previously Untreated Patients, Relapsed Disease, or Extended Treatment (i, ii, and iii):
     - **i.** Approve up to 1,000 mg administered intravenously; AND
     - **ii.** Patient receives a maximum of two doses in the first cycle (28-day or 8-week); AND
     - **iii.** Patient receives a maximum of one dose in each subsequent cycle (28-day or 8-week); OR
   - **B)** Refractory Disease (i, ii, and iii):
     - **i.** Approve up to 2,000 mg administered intravenously; AND
     - **ii.** Patient receives a maximum of eight weekly doses; AND
     - **iii.** Patient then receives a maximum of one dose in each subsequent 4-week cycle.

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.

   Dosing. Approve up to 2,000 mg administered intravenously for a maximum of five weekly doses.

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.
6. Furman RR, Eradat HA, DiRienzo C, et al. A phase 2 study of ofatumumab in Waldenstrom's macroglobulinemia. *Lancet Haematol*. 2017;4:e24-e34.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	10/20/2021
Annual Revision	**B-Cell Lymphoma:** This condition of approval was removed from policy (the National Comprehensive Cancer Network no longer recommends Arzerra for this indication).	11/16/2022