PreferredOne® ATION POLICY

POLICY: Oncology (Injectable) – Arzerra® (ofatumumab injection for intravenous use – Novartis)

REVIEW DATE: 10/09/2019

OVERVIEW

Arzerra is a human IgG1 monoclonal antibody that binds to the large and small extracellular loops of the CD20 molecule.[1] The Fab domain of the antibody binds to the CD20 molecule while the Fc domain mediates immune effector function which result in B-cell lysis. Potential mechanisms of cell lysis include complement-mediated cytotoxicity and antibody-dependent, cell-mediated cytotoxicity.

Arzerra is indicated:

- In combination with chlorambucil, for the treatment of previously untreated patients with chronic lymphocytic leukemia (CLL) for whom fludarabine-based therapy is considered inappropriate;
- In combination with fludarabine and cyclophosphamide for the treatment of 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.[1]

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (version 1.2020 – August 23, 2019) recommends Arzerra in combination with bendamustine for the first-line treatment of CLL/small lymphocytic lymphoma (SLL) without del(17p)/TP53 mutation; as a single agent, or in combination with fludarabine and cyclophosphamide for relapsed or refractory CLL/SLL without del(17p)/TP53 mutation; as a single agent for relapsed or refractory disease with del(17p)/TP53 mutation in patients with lymph nodes < 5 cm; and post second-line maintenance therapy following complete or partial response to treatment for relapsed or refractory disease.[2,3]

The NCCN guidelines on Waldenstrom Macroglobulinema/Lymphoplasmacytic Lymphoma (version 2.2019 – September 14, 2018) recommends Arzerra as a single agent or in combination therapy in rituximab (Rituxan, Truxima) intolerant patients for previously treated disease that does not response to primary treatment or for relapsed or progressive disease.[2,4]

The NCCN guidelines on B-Cell Lymphomas (version 4.2019 – June 18, 2019) recommends Arzerra as a substitute for rituximab products and Gazyva (obinutuzumab injection) in patients with B-cell lymphomas experiencing rare complications such as paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, and toxic epidermal necrolysis.[2,5]

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.

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Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

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)** Arzerra 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)** The patient is intolerant to a rituximab product; AND
   - **C)** The patient has relapsed or progressive disease; AND
   - **D)** Arzerra is prescribed by or in consultation with an oncologist.

3. **B-Cell Lymphoma. (Note: Examples include follicular lymphoma, MALT lymphoma, marginal zone lymphoma, mantle cell lymphoma, diffuse large B-cell lymphoma, high-grade B-cell lymphoma).** Approve for 6 months if the patient meets the following criteria (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The patient experienced an adverse event or intolerance to a rituximab product or Gazyva® (obinutuzumab injection).
     (NOTE: Examples of adverse events or intolerance include paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, toxic epidermal necrolysis]; AND
   - **C)** Arzerra is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Arzerra has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

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® [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2016.
2. The NCCN Drugs and Biologics Compendium. © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on November 27, 2018. Search term: ofatumumab.
3. The NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (Version 1.2020 – August 23, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on August 27, 2019.

4. The NCCN Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma Clinical Practice Guidelines in Oncology (Version 2.2019). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on August 27, 2019.
5. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (Version 4.2019 – June 18, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on August 27, 2019.

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PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

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You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

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