Drug Therapy Guidelines

<table>
<thead>
<tr>
<th>Applicable*</th>
<th>Arzerra® (ofatumumab)</th>
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<tbody>
<tr>
<td>Medical Benefit</td>
<td>Effective: 5/15/19</td>
</tr>
<tr>
<td>Pharmacy- Formulary 1</td>
<td>Next Review: 3/20</td>
</tr>
<tr>
<td>Pharmacy- Formulary 2</td>
<td>Date of Origin: 9/10</td>
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<td>Pharmacy- Formulary 4/AON</td>
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I. Medication Description

Arzerra (ofatumumab) binds specifically to both the small and large extracellular loops of the CD20 molecule. The CD20 molecule is expressed on normal B lymphocytes (pre-B to mature B-lymphocyte) and on B-cell CLL. The CD20 molecule is not shed from the cell surface and is not internalized following antibody binding. The Fab domain of ofatumumab binds to the CD20 molecule and the Fc domain mediates immune effector functions to result in B-cell lysis in vitro. Data suggest that possible mechanisms of cell lysis include complement-dependent cytotoxicity and antibody-dependent, cell-mediated cytotoxicity.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Arzerra is available when the following criteria have been met:
- Member is at least 18 years of age AND
- The medication is prescribed by a hematologist/oncologist AND
- The requested use is supported by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A.

IV. Quantity Limitations

Coverage is available for a quantity sufficient to allow for FDA-approved dosing.

V. Coverage Duration

- Refractory disease: Coverage will be authorized for 6 months and may not be renewed once doses are administered.
- Previously untreated disease: Coverage will be authorized for 12 months and may not be renewed once doses are administered.
- Extended treatment in CLL: coverage will be authorized for 12 months and may be renewed only once.
- Refractory CLL: Coverage will be authorized for 12 doses (in accordance with FDA-approved dosing schedule) and may not be renewed.
VI. **Coverage Renewal Criteria**

n/a

VII. **Billing/Coding Information**

- Available as 1000 mg/50 ml and 100 mg/5 ml vials
- J9302: 1 billable unit = 10 mg
- Pertinent indications:
  - B-Cell Lymphomas:
    - Follicular Lymphoma: C82.00-C82.09, C82.10-C82.19, C82.20-C82.29, C82.30-C82.39, C82.40-C82.49, C82.50-C82.59, C82.60-C82.69, C82.80-C82.89, C82.90-C82.99
    - Gastric and non-gastric MALT Lymphoma: C83.80-C83.89, C85.80-C85.89, C88.4
    - Nodal Marginal Zone Lymphoma: C83.00, C83.08, C83.80-C83.86, C83.88
    - Splenic Marginal Zone Lymphoma: C83.00-C83.09, C85.80-C85.89
    - Histologic Transformation of Marginal Zone Lymphoma to Diffuse Large B-Cell Lymphoma: C83.30-C83.39, C85.20-C85.29
    - Mantle Cell Lymphoma: C83.10-C83.19
    - Diffuse Large B-Cell Lymphoma: C83.30-C83.39, C85.20-C85.29
    - High-Grade B-Cell Lymphomas: C83.30-C83.39, C85.10 - C85.19
    - Burkitt Lymphoma: C83.70-C83.79
    - AIDS-Related B-Cell Lymphomas: B20, C83.30-C83.39, C83.80-C83.89, C83.90-C83.99, C85.80-C85.89
    - Post-Transplant Lymphoproliferative Disorders: D47.Z1
    - Castleman’s Disease: D36.0, R59.0, R59.1, R59.9, D47.Z2
      - CLL/SLL: C83.00-C83.09, C91.10, C91.12
      - Waldenström’s Macroglobulinemia/ Lymphoplasmacytic Lymphoma:C83.00-C83.09, C88.0, Z85.72, Z85.79

VIII. **Summary of Policy Changes**

- 9/15/12: Moved to own policy from Abbreviated Criteria Policy
- 9/15/13: Removed renewal criteria as this cannot be renewed
- 9/15/14: Previously untreated CLL coverage criteria added to policy
- 12/17/14: updated CLL/SLL criteria to reflect NCCN recommendation updates
- 6/15/15: criteria for coverage in CLL/SLL updated to reflect NCCN guidelines
- 7/1/15: formulary distinctions made
- 6/15/16: Updated coverage to coincide with current NCCN treatment guidelines
- 4/5/17: Policy updated to correspond with current NCCN treatment guidelines
- 5/1/18: coverage criteria updated to allow use as supported by current NCCN guidelines
- 5/15/19: updated coverage duration and billing/coding information
IX. References


*These guidelines are not applicable to benefits covered under Medicare Advantage. Medicare Advantage benefit coverage requests are reviewed in accordance with the guidance set forth in Chapter 15 Section 50 of the Centers for Medicare & Medicaid Services Medicare Benefit Policy Manual.

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.