I. Medication Description

Arzerra (ofatumumab) is a fully human monoclonal antibody that binds specifically to the CD20 antigen on B-cells which causes cell lysis and death. The binding site used by Arzerra is different than that targeted by current CD20 antibodies such as rituximab and it also binds more stably with CD20 which may explain its efficacy against cells with low CD20 antigen density and high expression of complement inhibitory molecules.

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.

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:
  - CLL/SLL: 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

IX. References

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.