I. Medication Description

Ofatumumab (Arzerra®) is a targeted anti-CD20 human monoclonal antibody that binds to the CD20 molecule on normal B lymphocytes and on B-cell chronic lymphocytic leukemia (CLL). Possible mechanisms of action, based on in-vitro data, include both 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 is provided for the following indications:

- Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)
  - For previously untreated patients in combination with chlorambucil who are unable to tolerate purine analogs in combination with chlorambucil OR
  - For relapsed or refractory disease OR
  - As first line therapy in combination with chlorambucil, without del (17p)/TP53 mutation and with or without del(11q) in patients aged 65 years or older or in younger patients with significant comorbidities who have indication for treatment

- Waldenstrom’s Macroglobulinemia/Lymphoplasmacytic Lymphoma where:
  - Patient is intolerant to rituximab AND
  - Disease has not responded to primary therapy or disease is progressive or relapsed

IV. Quantity Limitations

Up to 2,230 units (equal to 22,300mg) will be covered to accommodate maximum 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

- J9302 – 1 billable unit is 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

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.

Drug therapy initiated with samples will not be considered as meeting medical necessity for coverage for non-preferred or prior authorized medications.

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.