SPECIALTY GUIDELINE MANAGEMENT

ARZERRA (ofatumumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
   1. Chronic lymphocytic leukemia (CLL)
      i. In combination with chlorambucil, for the treatment of previously untreated patients with CLL for whom fludarabine-based therapy is considered inappropriate.
      ii. Extended treatment of patients who are in complete or partial response after at least two lines of therapy for recurrent or progressive CLL
      iii. Refractory to fludarabine and alemtuzumab.

B. Compendial Uses
   1. Initial treatment of CLL in combination with chlorambucil
   2. Relapsed or refractory CLL
   3. Small lymphocytic lymphoma (SLL) (managed in the same manner as CLL)
   4. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma

All other indications are considered experimental/investigational and are not a covered benefit.

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review: Results of testing or analysis positive for the CD20 protein on the surface of the B-cell

III. CRITERIA FOR APPROVAL

A. Chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL)
   1. Authorization of 12 months may be granted for previously untreated members prescribed Arzerra in combination with chlorambucil for CD20-positive CLL or SLL

   2. Authorization of 12 months may be granted for extended treatment (maintenance treatment) of CD20-positive CLL or SLL when the member demonstrates complete or partial response after at least two previous therapies for relapsed or refractory disease

   3. Authorization of 12 months may be granted for the treatment of relapsed or refractory CD20-positive CLL/SLL

B. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma
   1. Authorization of 12 months may be granted for the treatment of Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

V. REFERENCES

1. Arzerra [package insert]. Research Triangle Park, NC: GlaxoSmithKline; January 2016.
2. The NCCN Drugs & Biologics Compendium™ © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed August 15, 2016.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Non-Hodgkin's Lymphomas. Version 3.2016. http://www.nccn.org/professionals/physician_gls/pdf/nhl.pdf. Accessed August 15, 2016.
4. Marinus H J van Oers, Kazimierz Kuliczkowski, etc al. Ofatumumab maintenance versus observation in relapsed chronic lymphocytic leukemia (PROLONG): an open label, multicentre, randomized phase 3 study. *Lancet Oncol* 2015; 16: 1370-79.