SPECIALTY GUIDELINE MANAGEMENT

GAZYVA (obinutuzumab)

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)
      Gazyva, in combination with chlorambucil, is indicated for the treatment of patients with previously untreated CLL.
   2. Follicular lymphoma
      Gazyva, in combination with bendamustine followed by Gazyva monotherapy, is indicated for the treatment of patients with follicular lymphoma who relapsed after, or are refractory to, a rituximab-containing regimen.

B. Compendial Uses
   1. Chronic lymphocytic leukemia
      i. Therapy for those who are unable to tolerate purine analogs in combination with chlorambucil
      ii. Therapy for relapsed or refractory disease
   2. Small lymphocytic lymphoma (SLL) (managed in the same manner as CLL)

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 to members who are prescribed Gazyva in combination with chlorambucil for the initial treatment of CD20-positive CLL/SLL
   2. Authorization of 12 months may be granted to members who are prescribed Gazyva for the treatment of relapsed or refractory CD20-positive CLL/SLL.

B. Follicular lymphoma
   Authorization of up to 30 months total may be granted when both of the following criteria are met:
   1. Follicular lymphoma has relapsed after, or is refractory to, a rituximab-containing regimen
   2. Gazyva is used in combination with bendamustine during the initial 6 cycles of treatment (i.e., induction therapy), followed by use as monotherapy (i.e., maintenance therapy).

IV. CONTINUATION OF THERAPY

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

V. REFERENCES

1. Gazyva [package insert]. South San Francisco, CA: Genentech, Inc.; February 2016.
2. The NCCN Drugs & Biologics Compendium™ © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed August 16, 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 16, 2016.