Reference number
2075-A

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
      a. 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. Gazyva, in combination with chemotherapy followed by Gazyva monotherapy in patients achieving at least a partial remission, is indicated for the treatment of adult patients with previously untreated stage II bulky, III or IV follicular lymphoma.

B. Compendial Uses
   1. Chronic lymphocytic leukemia, relapsed or refractory disease
   2. Small lymphocytic lymphoma (SLL) (managed in the same manner as CLL)
   3. Gastric MALT lymphoma, recurrent or progressive disease
   4. Non-gastric MALT lymphoma, refractory or progressive disease
   5. Nodal and splenic marginal zone lymphoma, refractory or progressive disease
   6. Primary cutaneous B-cell lymphomas: primary cutaneous marginal zone or follicle center lymphoma

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

II. CRITERIA FOR INITAL APPROVAL

A. Chronic Lymphocytic Leukemia (CLL) and Small Lymphocytic Lymphoma (SLL)
Authorization of 12 months may be granted for the treatment of CD20-positive CLL/SLL.

B. Follicular Lymphoma
Authorization of 30 months total may be granted for the treatment of CD20-positive follicular lymphoma.

C. Gastric MALT Lymphoma, Non-gastric MALT Lymphoma, Nodal and Splenic Marginal Zone Lymphoma
Authorization of 30 months total may be granted for the treatment of recurrent, refractory, or progressive CD20-positive gastric MALT lymphoma, non-gastric MALT lymphoma, nodal marginal zone lymphoma, or splenic marginal zone lymphoma.

D. Primary Cutaneous Marginal Zone or Follicle Center Lymphoma
Authorization of 30 months total may be granted for the treatment of CD20-positive primary cutaneous marginal zone or follicle center lymphoma.

III. CONTINUATION OF THERAPY

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

IV. REFERENCES

1. Gazyva [package insert]. South San Francisco, CA: Genentech, Inc.; November 2017.
2. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. http://www.nccn.org. Accessed August 23, 2017.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. Version 1.2018. https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed August 23, 2017.
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas. Version 3.2017. https://www.nccn.org/professionals/physician_gls/pdf/b-cell_blocks.pdf. Accessed August 23, 2017.
5. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Primary Cutaneous B-Cell Lymphomas. Version 2.2017. https://www.nccn.org/professionals/physician_gls/pdf/pcbcl.pdf. Accessed August 30, 2017.