



An Independent Licensee of the Blue Cross and Blue Shield Association



Gazyva (obinutuzumab)

Line(s) of Business:

HMO; PPO; QUEST Integration
Medicare Advantage

Original Effective Date:

10/01/2015

Current Effective Date:

07/01/2018

POLICY**A. 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.

FDA-Approved Indications**Chronic Lymphocytic Leukemia**

- Gazyva, in combination with chlorambucil, is indicated for the treatment of patients with previously untreated chronic lymphocytic leukemia (CLL).

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.
- 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.

Compendial Uses

- Chronic lymphocytic leukemia/small lymphocytic lymphoma
 - First line therapy in patients with indications for treatment in combination with chlorambucil, or as a single agent, for disease without del(17p)/TP53 mutation
 - Patients greater than, or equal to, 65 years of age
 - Younger patients with significant comorbidities
 - Frail patients unable to tolerate purine analogs
 - First line therapy in patients with indications for treatment in combination with bendamustine for disease without del(17p)/TP53 mutation
 - First line therapy in patients as a single agent for disease with del(17p)/TP53 mutation
 - Relapsed or refractory disease as a single agent in patients with indications for treatment
 - Without del(17p)/TP53 mutation
- Non-Hodgkin's lymphoma
 - Follicular lymphoma

- First-line therapy for stage I, II, III or IV disease in combination with CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone), CVP (cyclophosphamide, vincristine and prednisone) or bendamustine
- Second-line or subsequent therapy for refractory or progressive disease in combination with bendamustine in patients with indications for treatment
- Maintenance therapy as
 - ❖ First-line consolidation or extended dosing
 - ❖ Second-line consolidation or extended dosing if refractory to rituximab
- Gastric/non-gastric MALT lymphoma and nodal/splenic marginal zone lymphoma
 - Second-line or subsequent therapy for recurrent, refractory or progressive disease in combination with bendamustine in patients with indications for treatment
 - Maintenance therapy as second-line consolidation or extended dosing in rituximab-refractory patients treated with obinutuzumab and bendamustine regimen for recurrent disease

B. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:

- Initial therapy
 - Results of testing or analysis positive for the CD20 protein on the surface of the B-cell
 - Cancer type/location, tumor histology and grade, staging, new cancer/recurrence, metastases, prior treatments, treatment intent (e.g., initial chemotherapy, neoadjuvant, adjuvant, or palliative)
 - Treatment plan with treatment regimen including dose, frequency, length of each cycle, number of cycles, and additional therapies (e.g., other medications, radiation)
- Continuation of therapy
 - Documentation demonstrating lack of disease progression on therapy (e.g., clinical notes, laboratory tests, and any pertinent pathology reports and/or imaging studies)

C. PRESCRIBER RESTRICTION

The medication must be recommended by an oncologist or hematologist

D. EXCLUSIONS

- Members who have not been screened for hepatitis B (HBV) infection prior to initiating therapy
- Members whose disease does not possess the CD20 antigen

E. CRITERIA FOR APPROVAL

1. Chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL)

- a. Authorization of 6 months may be granted for members with an indication for treatment (see Appendix A) who are prescribed Gazyva as first line therapy in one of the following regimens:
 - 1) In combination with chlorambucil
 - 2) In combination with bendamustine
 - 3) As single-agent drug therapy

- b. Authorization for 6 months may be granted for members with an indication for treatment (see Appendix A) who are prescribed Gazyva as subsequent therapy for relapsed or refractory disease when the following criteria are met:
 - 1) Member has CLL/SLL without del(17p)/TP53 mutation
 - 2) Gazyva is used as single-agent drug therapy
- 2. Follicular lymphoma**
 - a. Authorization of 6 months may be granted when Gazyva is prescribed as first-line therapy for stage I, II, III or IV disease in combination with bendamustine, CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone), or CVP (cyclophosphamide, vincristine and prednisone).
 - b. Authorization of 6 months may be granted when Gazyva is prescribed as first-line maintenance therapy as first-line consolidation/extended dosing.
 - c. Authorization of 6 months may be granted when Gazyva is prescribed as second-line or subsequent therapy for relapsed, refractory or progressive disease in combination with bendamustine.
 - d. Authorization of 6 months may be granted when Gazyva is prescribed as second-line maintenance therapy as second-line consolidation/extended dosing for lymphoma that has relapsed after or is refractory to a rituximab-containing regimen.
- 3. Gastric/non-gastric MALT and nodal/splenic marginal zone lymphoma**
 - a. Authorization of 6 months may be granted when Gazyva is prescribed as second-line or subsequent therapy for relapsed, refractory or progressive disease in combination with bendamustine
 - b. Authorization of 6 months may be granted when Gazyva is prescribed as second-line maintenance therapy as second-line consolidation/extended dosing for lymphoma that has relapsed after or is refractory to a rituximab-containing regimen and patient received a Gazyva and bendamustine second-line/subsequent regimen.

F. CONTINUATION OF THERAPY

1. No previous authorization/precertification:
All members (including new members and members currently receiving treatment without prior authorization) must meet criteria for initial approval in section E.
2. Reauthorization:
Members who were previously approved for Gazyva by HMSC/PCS may request reauthorization after their initial approval. Approval for an additional 6 months may be granted when the following documentation shows no progression of disease:
 - A current oncology note documenting the patient's response to treatment showing no progression of disease
 - Current laboratory reports or other objective measures showing no progression of disease when compared with previous results

G. DOSING AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

H. APPENDIX A

Indications for therapy include severe fatigue, night sweats, weight loss, progressive anemia, progressive thrombocytopenia, threatened end-organ dysfunction

I. ADMINISTRATIVE GUIDELINES

Precertification is required. Please refer to the [HMSA medical policy web site](#) for the fax form.

J. IMPORTANT REMINDER

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii's Patients' Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA/CVS's determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

K. REFERENCES

1. Gazyva [package insert]. South San Francisco, CA: Genentech, Inc.; November 2017.
2. The NCCN Drugs & Biologics Compendium® © 2017 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed January 31, 2018.

Document History

10/01/2015	Original effective date
03/2016	Added new indication (follicular lymphoma)
12/13/2016	Annual review
06/2017	Annual review
01/01/2018	Revision effective date
02/2018	Annual review
07/01/2018	Revision effective date