Blue Cross Blue Shield Blue Care Network of Michigan

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P&T Date: 04/10/2025

Gazyva® (obinutuzumab)

HCPCS: J9301

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

Note: This policy pertains to Medicare Part B only

A. Coverage of the requested drug is provided when all the following are met:
   a. FDA approved age
   b. Treatment-naïve chronic lymphocytic leukemia (CLL) patients
      i. Must be receiving concurrent chlorambucil therapy
      OR
   c. Follicular lymphoma (FL) patients relapsed/refractory to rituximab-containing regimen
      i. Must be receiving concurrent bendamustine therapy, followed by Gazyva monotherapy
      OR
   d. Treatment-naïve FL patients
      i. Must be receiving concurrent chemotherapy (bendamustine, CHOP, or CVP), followed by Gazyva monotherapy

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing
   b. Initial Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time
   c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Gazyva is a CD20-directed cytolytic antibody indicated:
    - In combination with chlorambucil, for the treatment of patients with previously untreated chronic lymphocytic leukemia.
    - In combination with bendamustine followed by Gazyva monotherapy for the treatment of patients with follicular lymphoma who relapsed after, or are refractory to, a rituximab-containing regimen.
    - In combination with chemotherapy followed by Gazyva monotherapy in patients achieving at least a partial remission, for the treatment of adult patients with previously untreated stage II bulky, III or IV follicular lymphoma.

References:

1. Gazyva [prescribing information]. South San Francisco, CA: Genentech, Inc.; July 2022.
2. National Comprehensive Cancer Network. Chronic lymphocytic leukemia/small lymphoctic leukemia (Version 2.2025). 2025 Feb 7. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed on February 11, 2025.
3. National Comprehensive Cancer Network. B-cell lymphomas (Version 2.2025). 2025 Feb 10. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed on February 11, 2025.
4. Sehn L, Chua N, Mayer J, et al. Obinutuzumab plus bendamustine versus bendamustine monotherapy in patients with rituximab-refractory indolent non-Hodgkin lymphoma (GADOLIN): a randomized, controlled, open-label, multicenter, phase 3 trial. Lancet Oncol. 2016 Aug; 17 (8): 1081 - 93.
5. Marcus R, Davies A, Ando K, et al. Obinutuzumab for the first-line treatment of follicular lymphoma. NEJM. 2017 Oct 5; 377: 1331 – 44.
6. Goede V, Fischer K, Busch R, et al. Obinutuzumab plus chlorambucil in patients with CLL and coexisting conditions. NEJM. 2014 March 20; 370: 1101 – 10.

Policy History		
#	Date	Change Description
2.2	Effective Date: 04/10/2025	Annual review of criteria was performed, no changes were made
2.1	Effective Date: 04/11/2024	Annual review of criteria was performed, no changes were made
2.0	Effective Date: 04/06/2023	Updated approval length to allow for FDA recommended dosing or up to 6 months at a time. Policy will now only be active for the Medicare Part B line of business only
1.9	Effective Date: 04/16/2022	Updated approval length to allow for FDA recommended dosing or up to 6 months at a time
1.8	Effective Date: 04/08/2021	Annual review of criteria was performed, no changes were made
1.7	Effective Date: 4/16/2020	Annual review of criteria was performed, no changes were made

<table>
<tr><td>1.6</td><td>Effective Date: 12/01/2020</td><td>UM medical management system update for BCBS
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table></td></tr>
<tr><td>1.5</td><td>Effective Date: 01/01/2020</td><td>UM medical management system update for BCNA and MAPPO
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table></td></tr>
<tr><td>1.4</td><td>Effective Date: 05/09/2019</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>1.3</td><td>Effective Date: 05/03/2018</td><td>Criteria updated for: New indication for use in treatment-naïve patients with follicular lymphoma (FL) stage II bulky, III, or IV, with chemotherapy (CHOP, CVP, or bendamustine), followed by Gazyva monotherapy.
Added efficacy for FL relapsed/refractory to Rituxan
Updated formatting for dosing & administration</td></tr>
<tr><td>1.2</td><td>Effective Date: 11/10/2016</td><td>Criteria updated for: New indication for use in combination with bendamustine followed by Gazyva monotherapy, for the treatment of patients with follicular lymphoma (FL) relapse or refractory to rituximab-containing regimens.</td></tr>
<tr><td>1.1</td><td>Effective Date: 04/01/2015</td><td>UM medical management system update for BCN
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table></td></tr>
<tr><td>1.0</td><td>Effective Date: 02/13/2014</td><td>New Policy</td></tr>
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** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*