



Nonprofit corporations and independent licensees
of the Blue Cross and Blue Shield Association

Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 02/12/2026

Gazyva® (obinutuzumab)

HCPCS: J9301

Policy:

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

- A. Coverage of the requested drug is provided when all the following are met:
 - a. FDA approved indication
 - b. FDA approved age
 - c. Diagnosis of lupus nephritis
 - i. Must have active disease of the kidney confirmed on biopsy
 - ii. Previous treatment courses of the following have been ineffective unless contraindicated or not tolerated: cyclophosphamide plus glucocorticoids OR mycophenolate mofetil plus glucocorticoids
 - iii. Must not to be used in combination with other biologics for the treatment of lupus nephritis
 - d. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in BCBSM/BCN's prior authorization and step therapy documents
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limits: Align with FDA recommended dosing
 - b. Initial Authorization Period: 1 year
 - 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
 - For the treatment of adult patients with active lupus nephritis (LN) who are receiving standard therapy
- The use of Gazyva in patients with active lupus nephritis was studied in the REGENCY trial, a phase III, randomized, double-blind, placebo-controlled, parallel-group study of 271 patients. The trial included seropositive patients who were stable and maintained on standard therapy of mycophenolate mofetil and corticosteroids. Patients had biopsy-proven lupus nephritis showing active lesions prior to study entry. Patients with a GFR of less than 30 ml/min/1.73 m² of body surface area (BSA) were excluded. The study met its primary endpoint demonstrating that the number of patients treated with Gazyva in combination with standard therapy achieved a complete renal response at week 76 was significantly greater than patients who received placebo plus standard therapy (46.4% vs 33.1% (95% CI: 2.0, 24.8), p-value = 0.0232). Statistical significance compared to placebo across the two major secondary endpoints was achieved, including complete renal response with successful prednisone taper at week 76 and proteinuric response at week 76.
- The 2025 EULAR guidelines recommend kidney biopsy for SLE patients showing any sign of kidney involvement including glomerular hematuria and/or cellular casts, proteinuria greater than 0.5 g/24 hours, spot urine protein-to-creatinine ratio (UPCR) greater than 500 mg/g, or unexplained decrease in glomerular filtration rate. The 2003 International Society of Nephrology/Renal Pathology Society (ISN/RPS) classification still represents the gold standard for assessment of kidney biopsy in LN. Patients with active or active/chronic ISN/RPS 2003 class III or IV, with or without concomitant class V proliferative lupus nephritis determined by kidney biopsy were included in the REGENCY trial.
- The 2025 EULAR/ERA-EDTA guidelines and the 2024 Kidney Disease Improving Global Outcomes (KDIGO) clinical practice guidelines for the management of active lupus nephritis recommend initial treatment with mycophenolate or low-dose intravenous cyclophosphamide in combination with Benlysta ,or mycophenolate with a calcineurin-inhibitor, or mycophenolate with Gazyva. Following renal response, treatment should continue for at least 3 years. Patients should remain on their initial therapy unless they used cyclophosphamide as the initial treatment. If on cyclophosphamide, patients should be switched to mycophenolate or azathioprine alone or in combination with Benlysta. After 3 years if sustained complete renal response is maintained, therapy should be tapered slowly until complete withdrawal.
- Therapy should aim for complete clinical remission, defined as proteinuria less than 0.7 g/24 hours, by 12 months. Evidence of improvement in proteinuria with glomerular filtration rate (GFR) normalization or stabilization should be noted by 3 months and at least a 50% reduction in proteinuria should be seen by 6 months. For patients failing to meet the required clinical endpoints in the designated timeframe, switching of induction therapy is warranted. For patients with nephrotic-range proteinuria at baseline, the aforementioned time frames may be extended by 6 – 12 months due to slower proteinuria recovery.

- Gazyva has not been studied and there is no data to support use in combination with other biologic medications to treat LN.

References:

1. Gazyva [prescribing information]. South San Francisco, CA: Genentech, Inc.; October 2025.
2. Fanouriakis A, Kostopoulou M, Cheema K, et al. 2025 update of the Joint European League Against Rheumatism and European Renal Association– European Dialysis and Transplant Association (EULAR/ ERA–EDTA) recommendations for the management of lupus nephritis. Ann Rheum Dis. 2025: 1 – 16.
3. Weening JJ, D'Agati VD, Schwartz MM, et al. The classification of glomerulonephritis in systemic lupus erythematosus revisited. Kidney Int. 2004; 65: 521 – 30.
4. KDIGO Executive Committee. Clinical practice guidelines for the management of lupus nephritis. Kidney International. 2024 Jan; 105 (Suppl 1s): S1 – S69.
5. Furie RA, Rovin BH, Garg JP, et al. Efficacy and safety of obinutuzumab in active lupus nephritis. NEJM. 2025 Feb 7; 392: 1471 – 83.

Policy History		
#	Date	Change Description
2.5	Effective Date: 03/04/2026	UM medical management system update for BCN and BCBS
2.4	Effective Date: 02/12/2026	Updated to remove step though Benlysta due to updated EULAR guidelines
2.3	Effective Date: 12/04/2025	Updated to include the new FDA approved indication for lupus nephritis and remove oncology criteria. Policy is now active for both the commercial and Medicare lines of business
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: 04/16/2020	Annual review of criteria was performed, no changes were made

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.

1.6	Effective Date: 12/01/2020	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>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	Yes	BCNA	Yes
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	Yes											
BCN	Yes											
MAPPO	Yes											
BCNA	Yes											
1.5	Effective Date: 01/01/2020	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>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	Yes	MAPPO	Yes	BCNA	Yes
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	No											
BCN	Yes											
MAPPO	Yes											
BCNA	Yes											
1.4	Effective Date: 05/09/2019	Annual review of criteria was performed, no changes were made										
1.3	Effective Date: 05/03/2018	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										
1.2	Effective Date: 11/10/2016	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.										
1.1	Effective Date: 04/01/2015	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>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	Yes	MAPPO	No	BCNA	No
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BCBS	No											
BCN	Yes											
MAPPO	No											
BCNA	No											
1.0	Effective Date: 02/13/2014	New Policy										

* 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>.

Blue Cross Blue Shield/Blue Care Network of Michigan

Medication Authorization Request Form



This form is to be used by participating physicians to obtain coverage for **drugs covered under the medical benefit**. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

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PATIENT INFORMATION	PHYSICIAN INFORMATION
Name	Name
ID Number	Specialty
D.O.B. ☐ Male ☐ Female	Address
Diagnosis	City /State/Zip
Drug Name	Phone/Fax: P: () - F: () -
Dose and Quantity	NPI
Directions	Contact Person
Date of Service(s)	Contact Person Phone / Ext.

STEP 1: DISEASE STATE INFORMATION

- Is this request for: ☐ Initiation ☐ Continuation *Date patient started therapy: _____*
- Administered by patient or a medical professional? ☐ patient (self) ☐ health care professional (physician, nurse, etc.)
- Site of administration? ☐ Provider office/Home infusion ☐ Other: _____
☐ Hospital outpatient facility (go to #4) *Reason for Hospital Outpatient administration: _____*
☐ Hospital inpatient facility for Car-T therapy only (for example: Kymriah, Yescarta, or Tecartus) (go to #5)
- Please specify location of administration if hospital outpatient infusion: _____
- Please specify location of administration if hospital inpatient infusion: _____
- Please provide the NPI number for the place of administration: _____
- Initiation AND Continuation of therapy:**
 - What is the patient's diagnosis? _____
 - What other medication has the patient received for their condition? Please list _____
 - Please describe the response to previous therapies: _____
 - Will the patient be receiving any other treatment for the listed condition while on this medication? Please list: _____
 - Please list any labs values important for diagnosing or monitoring this patient's condition: _____
- Continuation of therapy:**
 - Has the patient progressed while on this medication? ☐ yes ☐ no
 - How has the patient's condition changed while on this medication?

☐ Improved: Please describe: _____
 ☐ Stable: please describe: _____
 ☐ Worsened; Please describe: _____
 ☐ Other; Please describe: _____

Chart notes are required for the processing of all requests. Please add any other supporting medical information necessary for our review (required)

Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.

☐ Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name	Physician Signature	Date
Step 2: Checklist	☐ Form Completely Filled Out ☐ Provide chart notes	☐ Attach test results
Step 3: Submit	By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979	By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320

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7/26/2018, 9/18/2018; 1/31/2020; 3/17/2020; 8/9/2021