Corporate Medical Policy: Obinutuzumab (Gazyva®) **"Notification"** **POLICY EFFECTIVE JANUARY 1, 2026**

Restricted Product(s):

- obinutuzumab (Gazyva®) intravenous infusion for administration by a healthcare professional

FDA Approved Use:

- For the treatment of adults with active lupus nephritis (LN) who are receiving standard therapy

Criteria for Medical Necessity:

The restricted product(s) may be considered medically necessary when the following criteria are met:

Initial Criteria for Approval:

1. The patient is 18 years of age or older; **AND**
2. The patient has a clinical diagnosis of systemic lupus erythematosus (SLE) according to American College of Rheumatology classification criteria **[medical record documentation required]**; **AND**
3. The patient has biopsy-proven active lupus nephritis (LN) Class III or IV (with or without Class V LN) **[medical record documentation required]**; **AND**
4. The patient is autoantibody positive with ONE of the following **[medical record documentation required]**:
    a. ANA (anti-nuclear antibody) above the laboratory reference range; **OR**
    b. Anti-dsDNA (double stranded DNA antibody) above the laboratory reference range, or greater than two-fold the reference range if tested by ELISA; **AND**
5. ONE of the following:
    a. The patient is currently being treated with hydroxychloroquine AND the patient will continue therapy in combination with the requested agent **[medical record documentation required]**; **OR**
    b. The patient will be initiated on concurrent therapy with hydroxychloroquine **[medical record documentation required]**; **OR**
    c. The patient has a clinical intolerance/contraindication to hydroxychloroquine **[medical record documentation required]**; **AND**
6. The patient will be receiving the requested agent in combination with a standard immunosuppressive therapy regimen for active LN (e.g., azathioprine, cyclophosphamide, glucocorticoids, mycophenolic acid analogs) **[medical record documentation required]**; **AND**
7. The patient will NOT be using the requested agent in combination with another biologic immunomodulator agent; **AND**
8. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist, nephrologist) or has consulted with a specialist in the area of the patient's diagnosis; **AND**

9. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below).

   Duration of Approval: 365 days (1 year)

Continuation Criteria for Approval:

1. The patient was approved through Blue Cross NC initial criteria for approval; **OR**
2. The patient would have met initial criteria for approval at the time they started therapy; **AND**
3. The patient has achieved a complete renal response as indicated by BOTH of the following **[medical record documentation required]**:
   a. Reduction in proteinuria (i.e., urine protein:creatinine ratio [UPCR] < 0.5 g/g); **AND**
   b. Stabilization or improvement in kidney function (i.e., an estimated glomerular filtration rate [eGFR] at least 80% of baseline [no decrease in eGFR more than 20% from baseline]); **AND**
4. The patient is currently being treated with and will continue receiving standard immunosuppressive LN therapy (e.g., azathioprine, cyclophosphamide, glucocorticoids, mycophenolic acid analogs) **[medical record documentation required]**; **AND**
5. The patient will NOT be using the requested agent in combination with another biologic immunomodulator agent; **AND**
6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist, nephrologist) or has consulted with a specialist in the area of the patient's diagnosis; **AND**
7. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below).

   Duration of Approval: 365 days (1 year)

Note: This product may require authorization for oncology related indications; please refer to our Prior Review and Limitations Page https://www.bluecrossnc.com/members/health-plans/drug-search

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
obinutuzumab (Gazyva®) intravenous (IV) infusion	Active lupus nephritis in adults receiving standard therapy	IV: 1,000 mg at the initial infusion (1st dose), then on week 2 (2nd dose), week 24 (3rd dose), week 26 (4th dose), and every 6 months thereafter (beginning 6 months after 4th dose)	J9301	Initial: 500 Continuation: 200

***Maximum units allowed for duration of approval**

References: all information referenced is from FDA package insert unless otherwise noted below.

1. Sammaritano LR, Askanase A, Bermas BL, et al. 2024 American College of Rheumatology (ACR) Guideline for the Screening, Treatment, and Management of Lupus Nephritis. *Arthritis & Rheumatology*. 2025;77(9):1115-1135.

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q2 annually.

January 2026: Original medical policy criteria issued for non-oncologic indications. **Policy notification given 11/1/2025 for effective date 1/1/2026**.