PHARMACY POLICY STATEMENT
TRICARE

DRUG NAME	Gazyva (obinutuzumab)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Gazyva, approved by the FDA in 2013, is a type II CD20-directed cytolytic antibody indicated for the treatment of chronic lymphocytic leukemia (CLL) and follicular lymphoma (FL). It is also indicated for the treatment of adult patients with active lupus nephritis (LN) who are receiving standard therapy.
LN is a complication of systemic lupus erythematosus (SLE) and can progress to end stage renal disease (ESRD). Proteinuria is often the first sign of LN, which is evident by an elevated urine protein creatinine ratio (UPCR). Diagnosis is confirmed by a kidney biopsy, which reveals the classification of disease and is used to guide treatment.

Gazyva (obinutuzumab) will be considered for coverage when the following criteria are met:

Lupus Nephritis (LN)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a nephrologist or rheumatologist; AND
3. Member has a documented diagnosis of active class III or IV lupus nephritis (with or without class V disease) as confirmed by kidney biopsy; AND
4. Medication must be prescribed in combination with standard therapy (e.g., mycophenolate mofetil and oral prednisone); AND
5. Member's eGFR is at least 30 mL/min/1.73 m^2; AND
6. Member's urine protein to creatinine ratio is at least 1 on a 24-hour collection; AND
7. Member has been screened for hepatitis B (HBV) infection; AND
8. Member is not on dialysis and has not had a kidney transplant.
9. **Dosage allowed/Quantity limit:** 1,000 mg at the initial IV infusion, on Week 2, 24, 26, and every 6 months thereafter.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must show the member has a reduced UPCR from baseline (goal is 0.5 mg/mg or less); AND
2. eGFR has improved or stabilized.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Chronic Lymphocytic Leukemia (CLL), Follicular Lymphoma (FL)

Any request for cancer must be submitted through NantHealth/Eviti portal.

TRICARE Prime® Demo by CareSource Military & Veterans™ considers Gazyva (obinutuzumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
10/27/2025	New policy created for Gazyva.

References:

1. Gazyva [prescribing information]. Genentech, Inc.; 2025.
2. Furie RA, Rovin BH, Garg JP, et al. Efficacy and Safety of Obinutuzumab in Active Lupus Nephritis. *N Engl J Med*. 2025;392(15):1471-1483. doi:10.1056/NEJMoa2410965
3. Rovin BH, Ayoub IM, Chan TM, et al. Executive summary of the KDIGO 2024 Clinical Practice Guideline for the Management of Lupus Nephritis. *Kidney Int*. 2024;105(1):31-34. doi:10.1016/j.kint.2023.09.001
4. Fanouriakis A, Kostopoulou M, Andersen J, et al. EULAR recommendations for the management of systemic lupus erythematosus: 2023 update. *Ann Rheum Dis*. 2024;83(1):15-29. Published 2024 Jan 2. doi:10.1136/ard2023-224762
5. 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 Rheumatol*. 2025;77(9):1115-1135. doi:10.1002/art.43212

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Revised date: 10/27/2025