obinutuzumab (Gazyva)

Commercial Medical Benefit Drug Policy

For oncology-related indications, medical necessity criteria can be found here: Blue Shield Oncology-Related Medication Policies.

For PPO, Direct Contract HMO, and when applicable, ASO, and Shared Advantage: Please access Evolent's CarePro Provider Portal to submit your request.

Place of Service
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: ANTINEOPLASTICS
Mechanism of Action: Anti-CD20 monoclonal antibody
HCPCS:
J9301:Injection, obinutuzumab, 10 mg
How Supplied:
1000 mg/40 ml (single-use vial)

Condition(s) listed in policy *(see coverage criteria for details)*

- Lupus Nephritis

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Lupus Nephritis
Meets medical necessity if all the following are met:
Initial
1. Prescribed by or in consultation with a rheumatologist or nephrologist
2. Age is consistent with the FDA-approved indication (18 years of age and older)

3. Being used in combination with standard therapy (e.g., corticosteroids, mycophenolate, cyclophosphamide, azathioprine)
4. Not being used in combination with Benlysta, Lupkynis, or rituximab
5. Dose does not exceed the FDA-approved maximum

Reauthorization
1. Patient is responding to therapy (e.g., proteinuria reduction, stable kidney function)
2. Not being used in combination with Benlysta, Lupkynis, or rituximab, and
3. Dose does not exceed the FDA-approved maximum

Covered Doses:
Not to exceed 1,000 mg given intravenously at Week 0, 2, 24, 26, and every 6 months thereafter

Coverage Period:
One year

ICD-10:
M32.14

References

1. Gazyva (obinutuzumab) [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 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.
3. Fanouriakis A, Kostopoulou M, Anders HJ, et al. EULAR recommendations for the management of systemic lupus erythematosus with kidney involvement: 2025 update. *Ann Rheum Dis*. 2025 Oct 16:S0003-4967(25)04412-7. doi: 10.1016/j.ard.2025.09.007.
4. No Authors. KDIGO 2024 Clinical Practice Guideline for the Management of Lupus Nephritis. *Kidney Int*. 2024 Jan;105(1S):S1-S69. doi: 10.1016/j.kint.2023.09.002.

Review History

Date of Last Annual Review: 1Q2026
Changes from previous policy version:

- Lupus nephritis: Added coverage for new FDA indication (Rationale: In October 2025, FDA approved Gazyva for the treatment of adult patients with active lupus nephritis who are receiving standard therapy; EULAR (2025); KDIGO (2024))

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee