

Gazyva® (obinutuzumab) Injection

When requesting Gazyva® (obinutuzumab) for non-oncology indication, the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Non-oncology Indication

Gazyva is indicated for the treatment of adult patients with active lupus nephritis who are receiving standard therapy.

Coverage Guidelines

Lupus Nephritis

The individual must meet all of the following criteria for initial authorization:

- Is 18 years of age or older;
- Diagnosis of lupus nephritis has been confirmed on biopsy;
- Gazyva is being used concurrently with an immunosuppressive regimen (e.g., azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate mofetil, systemic corticosteroid);
- Gazyva is prescribed by, or in consultation with a nephrologist or rheumatologist.

The individual must meet all of the following criteria for re-authorization:

- Gazyva is being used concurrently with an immunosuppressive regimen (e.g., azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate mofetil, systemic corticosteroid);
- Has responded to Gazyva treatment (e.g., improvement in organ dysfunction, reduction in flares, reduction in corticosteroid dose, reduction in proteinuria, decrease in anti-dsDNA titers, or improvement in complement levels [i.e., C3, C4]);
- Gazyva is prescribed by, or in consultation with a nephrologist or rheumatologist.

Approval Duration (initial): 6 months

Approval Duration (renewal): 12 months

Dosing Recommendation

The recommended dose of Gazyva is 1,000 mg administered intravenously at the initial infusion, on Week 2, 24, 26, and every 6 months thereafter.

References

1. Gazyva® intravenous infusion [prescribing information]. South San Francisco, CA: Genentech; October 2025.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Lupus Nephritis Work Group. KDIGO 2024 Clinical Practice Guideline for the management of Lupus Nephritis. *Kidney Int.* 2024;105(1S):S1-S69.
3. Sammaritano L, Askanase A, Bermas B, et al. 2024 American College of Rheumatology (ACR) Guidelines for the Screening, Treatment, and Management of Lupus Nephritis. Published: May 7, 2025. Available at: <https://rheumatology.org/lupus-guideline>. Accessed: October 21, 2025