Neighborhood Health Plan OF RHODE ISLAND™
910 Douglas Pike, Smithfield, RI 02917 : 1-800-963-1001 : nhpri.org

Gazyva® (obinutuzumab) NON-ONCOLOGY Policy
(Intravenous)

Effective Date: 09/01/2026
Review Date: 06/30/2026
Scope: Medicaid, Commercial, Medicare

I. Length of Authorization for Lupus Nephritis:

Initial: Prior authorization validity will be provided initially for 12 months.

Renewal: Prior authorization validity may be renewed every 12 months thereafter.

II. Dosing Limits
Max Units (per dose and over time) [HCPCS Unit]:

Lupus Nephritis:

- Initial: 100 billable units weeks 0, 2, 24, and 26
- Maintenance: 100 billable units every 6 months

III. Summary of Evidence:

Gazyva is an anti-CD20 monoclonal antibody indicated for the treatment of adult patients with active lupus nephritis (LN) who are receiving standard therapy. Clinical efficacy is based on positive results from Phase III REGENCY studies. REGENCY is a randomized, double-blind, placebo-controlled, parallel-group, multicenter study in 271 patients with ISN/RPS 2003 Class III or IV, with or without concomitant Class V lupus nephritis (LN), treated with standard therapy consisting of mycophenolate mofetil (MMF) and corticosteroids. Patients were randomized 1:1 to receive GAZYVA 1,000 mg (N=135) or placebo (N=136) intravenously, in combination with MMF 2-2.5 g/day and a tapering course of corticosteroids and were evaluated over 76 weeks. In REGENCY, data showed that nearly half of the participants (46.4%) on Gazyva in combination with standard therapy achieved a complete renal response (CRR) compared to 33.1% on standard therapy alone. This was accompanied by clinically meaningful improvements in complement levels and reductions in anti-dsDNA, corticosteroid use, and proteinuria, all signaling improved disease control. The most common adverse reactions are infusion-related reactions, neutropenia, fatigue, and upper respiratory tract infections.

IV. **Initial Criteria**

Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Universal Criteria [1]

- Member is at least 18 years of age; **AND**
- The medication is prescribed by or in consultation with a nephrologist or rheumatologist; **AND**
- Member does not have an active infection, including clinically important localized infections; **AND**
- Member has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Member has been screened for the presence of hepatitis B virus (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and members with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**

Lupus Nephritis (LN) † [1,25-26]

- Member has a diagnosis of active class III, IV, or V lupus nephritis as confirmed via kidney biopsy; **AND**
- Member will be using background immunosuppressive LN therapy (e.g., corticosteroids plus mycophenolate, azathioprine, or cyclophosphamide) in combination; **AND**
- Member does not have severe active central nervous system (CNS) lupus; **AND**
- Will not be used in combination with Benlysta (belimumab) or Lupkynis (voclosporin); **AND**
- Documentation that the member has baseline urine proteincreatinine ratio (UPCR) ≥1 g/g and eGFR >30 ml/min/1.73 m2

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); **Φ** Orphan Drug

V. Renewal Criteria [1]

Authorizations will be based on the following criteria:

- Member continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section IV; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe neutropenia/febrile neutropenia, severe thrombocytopenia, severe infusion-related reactions, hypersensitivity reactions including serum sickness, tumor lysis syndrome (TLS), disseminated intravascular coagulation (DIC), etc.; **AND**
- Member has been evaluated for the presence of progressive multifocal leukoencephalopathy (PML) and has been found to be negative; **AND**
- The member has experienced a clinical benefit with the requested agent as evidenced by low disease activity or general improvement in signs/symptoms of disease

VI. Dosage and Administration

<table>
<tr><th>Indication</th><th>Dose</th></tr>
<tr><td>Lupus Nephritis</td><td>The recommended dose is 1,000 mg intravenously according to the table below:
<table>
<tr><th>Dose Number</th><th>Timing of treatment</th><th>Dose of obinutuzumab</th></tr>
<tr><td>1</td><td>Initial infusion</td><td>1,000 mg</td></tr>
<tr><td>2</td><td>Week 2 (two weeks after Dose 1)</td><td>1,000 mg</td></tr>
<tr><td>3</td><td>Week 24</td><td>1,000 mg</td></tr>
</table></td></tr>
</table>

	4	Week 26 (two weeks after Dose 3)	1,000 mg
	5* and thereafter	Every 6 months	1,000 mg

***Dose 5 should be administered six months after Dose 4**

Refer to Prescribing Information for rates of infusion and modifications for infusion-related reactions.

VII. Billing Code/Availability Information

HCPCS Code:

- J9301 – Injection, obinutuzumab, 10 mg; 1 billable unit = 10 mg

NDC:

- Gazyva 1000 mg/40 mL single-dose vial: 50242-0070-xx

VIII. References

1. Gazyva [package insert]. South San Francisco, CA; Genentech, Inc; December 2025. Accessed June 2026.
2. Rovin BH, Ayoub IM, Chan TM, et al. KDIGO 2024 Clinical Practice Guideline for the Management of Lupus Nephritis. Kidney International. 2024;105(1):S1-S69. doi:10.1016/j.kint.2023.09.002
3. 2024 American College of Rheumatology (ACR) Guideline for the Screening, Treatment, and Management of Lupus Nephritis: Guideline Summary. American College of Rheumatology. Published online November 18, 2024. https://rheumatology.org/lupus-guideline
4. Parikh SV, Almaani S, Brodsky S, Rovin BH. Update on Lupus nephritis: Core Curriculum 2020. *American Journal of Kidney Diseases*. 2020;76(2):265-281. doi:10.1053/j.ajkd.2019.10.017
5. Furie R, Rovin BH, Houssiau F, et al. Two-Year, Randomized, Controlled Trial of Belimumab in Lupus Nephritis. *N Engl J Med*. 2020;383(12):1117-1128. doi:10.1056/nejmoa2001180

6. Weening JJ, D'agati VD, Schwartz MM, et al. The classification of glomerulonephritis in systemic lupus erythematosus revisited. *Kidney International.* 2004;65(2):521-530. doi:10.1111/j.1523-1755.2004.00443.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
M32.14	Glomerular disease in systemic lupus erythematosus
M32.15	Tubulo-interstitial nephropathy in systemic lupus erythematosus

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: **https://www.cms.gov/medicare-coverage-database/search.aspx.** Additional indications, including any preceding information, may be applied at the discretion of the health plan**.**

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY,	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Policy Rationale: Gazyva was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Gazyva according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.