Original Effective Date: 03/13/2026
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Last P&T Approval/Version: 01/28/2026
Next Review Due By: 10/2026
Policy Number: C30345-A

Gazyva (obinutuzumab)

PRODUCTS AFFECTED

Gazyva (obinutuzumab)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Lupus Nephritis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. LUPUS NEPHRITIS:
1. Documentation of systemic lupus erythematosus (SLE)
   OR
2. Documentation of kidney biopsy with a histologic diagnosis of lupus nephritis Classes III, IV, V to confirm diagnosis of active lupus nephritis [DOCUMENTATION REQUIRED]
   AND
3. Gazyva (obinutuzumab) will be used concurrently with standard therapy (i.e., corticosteroids, hydroxychloroquine, and/or immunosuppressive agents [e.g., oral cyclophosphamide, azathioprine, methotrexate, mycophenolate mofetil])
   AND
4. Documentation that member is not receiving dialysis and has not received kidney transplant
   AND
5. Documentation the member does not have baseline eGFR <30 mL/min/1.73 m2
   AND
6. Documentation of pretreatment UPCR ≥ 1 g/g
   AND
7. Prescriber attests member does not have an active or latent untreated infection (e.g., Hepatitis B), including clinically important localized infections, according to the FDA label
   AND
8. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).
   MOLINA REVIEWER NOTE: For Illinois Marketplace, please see Appendix.

B. ONCOLOGY INDICATIONS: SEE STANDARD ONCOLOGY CRITERIA

CONTINUATION OF THERAPY:

A. LUPUS NEPHRITIS:
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation of positive clinical response as demonstrated by:
   (a) Improvement in proteinuria: UPCR of < 0.5 g/g AND UPCR has not increased more than 50% from baseline
   AND
   (b) Improvement or stabilization of eGFR OR eGFR has not decreased more than 30% from baseline
   AND
4. Prescriber attests to ongoing monitoring for development of infection (e.g., Hepatitis B reactivation) according to the FDA label
   AND
5. Member is currently treated with and adherent to standard therapy for SLE

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of Therapy: 12 months
MOLINA REVIEWER NOTE: For Texas Marketplace, please see Appendix.

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a board-certified nephrologist or rheumatologist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
1,000 mg IV once, then 1,000 mg IV at Week 2, 24, and 26, followed by 1,000 mg IV every 6 months

PLACE OF ADMINISTRATION:
The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous

DRUG CLASS:
Antineoplastic - Anti-CD20 Antibodies

FDA-APPROVED USES:
Gazyva (obinutuzumab) is indicated:

- in combination with chlorambucil, for the treatment of patients with previously untreated chronic lymphocytic leukemia (CLL)
- in combination with bendamustine followed by GAZYVA monotherapy, for the treatment of patients with follicular lymphoma (FL)who relapsed after, or are refractory to, a rituximab-containing regimen
- in combination with chemotherapy followed by GAZYVA monotherapy in patients achieving at least a partial remission, for the treatment of adult patients with previously untreated stage II bulky, III or IV follicular lymphoma
- for the treatment of adult patients with active lupus nephritis (LN) who are receiving standard therapy

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information

State Marketplace

Illinois (Source: Illinois General Assembly)
"(215 ILCS 134/45.1) Sec. 45.1. Medical exceptions procedures required. (c) An off-formulary exception request shall not be denied if: (1) the formulary prescription drug is contraindicated; (2) the patient has tried the formulary prescription drug while under the patient's current or previous health insurance or health benefit plan and the prescribing provider submits evidence of failure or intolerance; or (3) the patient is stable on a prescription drug selected by his or her health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan. (d) Upon the granting of an exception request, the insurer, health plan, utilization review organization, or other entity shall authorize the coverage for the drug prescribed by the enrollee's treating health care provider, to the extent the prescribed drug is a covered drug under the policy or contract up to the quantity covered. (e) Any approval of a medical exception request made pursuant to this Section shall be honored for 12 months following the date of the approval or until renewal of the plan."

Texas (Source: Texas Statutes, Insurance Code)
"Sec. 1369.654. PROHIBITION ON MULTIPLE PRIOR AUTHORIZATIONS.
(a) A health benefit plan issuer that provides prescription drug benefits may not require an enrollee to receive more than one prior authorization annually of the prescription drug benefit for a prescription drug prescribed to treat an autoimmune disease, hemophilia, or Von Willebrand disease.
(b) This section does not apply to:
(1) opioids, benzodiazepines, barbiturates, or carisoprodol;
(2) prescription drugs that have a typical treatment period of less than 12 months;
(3) drugs that:
(A) have a boxed warning assigned by the United States Food and Drug Administration for use; and
(B) must have specific provider assessment; or
(4) the use of a drug approved for use by the United States Food and Drug Administration in a Manner other than the approved use."

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Lupus nephritis (LN) is a severe manifestation of systemic lupus erythematosus (SLE) characterized by immune complex-mediated inflammation of the kidneys. Its pathogenesis is driven by the formation of anti-double-stranded DNA immune complexes that deposit in glomerular structures, activating the complement system and triggering neutrophilic and macrophage-mediated injury. Genetic predisposition plays a substantial role, with more than 100 implicated loci influencing B-cell signaling, interferon pathways, and immune complex clearance, while HLA-DR2, DR3, and DR15 confer increased risk. Environmental factors such as ultraviolet exposure, Epstein–Barr virus infection, psychosocial stress, smoking, and certain medications promote loss of self-tolerance and autoimmune activation. Hormonal effects, particularly estrogen-driven enhancement of type I interferon activity and B-cell survival, contribute to the marked female predominance.

Epidemiologically, lupus nephritis develops in approximately 50–60% of individuals with SLE,

making it one of the condition's most clinically significant complications. Incidence estimates average around 1 per 100,000 person-years, with the highest rates occurring between ages 30 and 39. The disease disproportionately affects females and is more common and severe among Black, Asian, and Hispanic populations. Pediatric SLE accounts for roughly 20% of all SLE cases, and kidney involvement occurs early and aggressively in this group, with 50–75% developing LN within two years of diagnosis. These disparities reflect a combination of genetic, hormonal, and socioeconomic factors influencing disease severity and outcomes.

Current therapeutic strategies have shifted from the traditional induction-then-maintenance model toward continuous, combination immunosuppression aimed at preserving renal function while minimizing treatment-related toxicity. Guidelines from the American College of Rheumatology (2024-2025) strongly emphasize routine screening for proteinuria every six to twelve months in patients with SLE, with more frequent testing in active LN. Kidney biopsy remains critical for diagnosis, classification, and treatment planning, particularly in patients with proteinuria exceeding 0.5 g/g or unexplained renal dysfunction. For active Class III or IV (±V) disease, "triple therapy" is now conditionally recommended, combining glucocorticoids with either (1) mycophenolate plus belimumab, (2) mycophenolate plus a calcineurin inhibitor such as voclosporin or tacrolimus, or (3) low-dose cyclophosphamide plus belimumab. Pure Class V LN with proteinuria ≥1 g/g is also best managed with glucocorticoid-based triple therapy incorporating mycophenolate and a calcineurin inhibitor. Corticosteroid minimization is critical, with targets of tapering to ≤5 mg/day within four to six months following initial intravenous pulse therapy. EULAR's 2025 update further supports combination regimens – sometimes quadruple therapy including hydroxychloroquine and a biologic or calcineurin inhibitor – reflecting robust evidence favoring multi-agent approaches. Continuous therapy for three to five years is recommended to sustain remission and prevent relapse. Adjunctive measures such as blood pressure control, renin-angiotensin-aldosterone system blockade, infection prevention, and cardiovascular risk reduction remain key components of comprehensive LN management.

Gazyva (obinutuzumab), a type II anti-CD20 monoclonal antibody, has emerged as a new, guideline-supported biologic option for adults with active lupus nephritis (LN) who are receiving standard therapy. Its approval was driven by robust phase II (NOBILITY) and phase III (REGENCY) data showing superior renal outcomes compared with standard therapy alone. In the REGENCY trial, 46.4% of patients receiving Gazyva plus mycophenolate mofetil (MMF) and glucocorticoids achieved a complete renal response (CRR) at 76 weeks, versus 33.1% on standard therapy alone – representing a statistically and clinically meaningful improvement in kidney function, proteinuria reduction, complement normalization, and anti-dsDNA reduction.

Because it is the only anti-CD20 antibody to demonstrate CRR benefit in a randomized phase III LN trial, Gazyva is now considered a validated B-cell depletion option in the LN therapeutic landscape. Emerging guidelines, including EULAR 2025 expert guidance, recognize Gazyva as an early combination therapy option, particularly for patients with poor prognostic features or those at high risk of progression. Its benefit is consistent across LN subtypes (ISN/RPS Class III/IV ± V), highlighting utility in a broad patient population.

Clinically, Gazyva is positioned as an addition to standard therapy, not a replacement. It is given as four infusion doses in year 1, followed by twice-yearly maintenance dosing, offering a relatively convenient long-interval schedule. Reduced corticosteroid exposure was observed in REGENCY, supporting its role in modern steroid-sparing LN regimens. Safety aligns with known risks of anti-CD20 agents, including hepatitis B reactivation and PML, necessitating appropriate screening and monitoring.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Gazyva (obinutuzumab) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Gazyva include: known hypersensitivity reactions (e.g., anaphylaxis) to obinutuzumab or any of the excipients, including serum sickness with prior obinutuzumab use, avoid administration of live virus vaccines during Gazyva treatment and until B-cell recovery.

Exclusions/Discontinuation:
Gazyva (obinutuzumab) was not studied in patients with:

- sclerosis in > 50% of glomeruli on kidney biopsy
- presence of rapidly progressive glomerulonephritis

Based on its mechanism of action and findings in animals, Gazyva can cause B-cell depletion in infants exposed to obinutuzumab in-utero. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception while taking Gazyva and for 6 months after the last dose.
Do not take concurrently with Benlysta (belimumab) or Lupkynis (voclosporin).

OTHER SPECIAL CONSIDERATIONS:
Gazyva (obinutuzumab) has a Black Box Warning for hepatitis B virus (HBV) reactivation and progressive multifocal leukoencephalopathy. Monitor patients with evidence of current or prior HBV infection for clinical and laboratory signs of hepatitis or HBV reactivation during and for several months following treatment with Gazyva. In patients who develop reactivation of HBV while receiving Gazyva, immediately discontinue Gazyva and institute appropriate treatment.

Gazyva (obinutuzumab) can cause severe and life-threatening infusion-related reactions (IRRs). In patients with lupus nephritis, IRRs occurred predominantly during infusion of the first 1,000 mg. The most common IRR signs or symptoms include: headache, nausea, vomiting, pyrexia and tachycardia. Premedicate patients with acetaminophen, anti-histamine, and a glucocorticoid. Closely monitor patients during the entire infusion. Reduce infusion rate, interrupt infusion or permanently discontinue Gazyva for IRRs based on severity.

Fatal and serious bacterial, fungal, and new or reactivated viral infections can occur during and following Gazyva (obinutuzumab) therapy. Do not administer Gazyva to patients with an active infection. Patients with a history of recurring or chronic infections may be at increased risk of

infection. In patients who develop a serious infection while receiving Gazyva, immediately discontinue Gazyva and institute appropriate treatment.

Severe and life-threatening neutropenia, including febrile neutropenia, has been reported during treatment with Gazyva (obinutuzumab). Monitor patients with Grade 3 to 4 neutropenia frequently with regular laboratory tests until resolution. Patients with severe and long lasting (> 1 week) neutropenia are strongly recommended to receive antimicrobial prophylaxis until resolution of neutropenia to Grade 1 or 2.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
J9301	Injection, obinutuzumab, 10 mg

AVAILABLE DOSAGE FORMS:
Gazyva SOLN 1000MG/40ML single-dose vial

REFERENCES

1. Gazyva (obinutuzumab) injection, for intravenous use [prescribing information]. San Francisco, CA: Genentech, Inc.; December 2025.
2. Rovin, B. H., Adler, S. G., Barratt, J., Caster, D. J., Glassock, R. J., Jayne, D. R. W., Parikh, S. V., Reich, H. N., Rovin, J. S., & Floege, J. (2024). KDIGO 2024 clinical practice guideline for the management of lupus nephritis. Kidney International, 105(1), S1–S69. https://doi.org/10.1016/j.kint.2023.09.001
3. American College of Rheumatology. (2024). 2024 American College of Rheumatology (ACR) guideline for the screening, treatment, and management of lupus nephritis [Clinical practice guideline]. https://rheumatology.org/lupus-guideline#2024-lupus-nephritis-guideline
4. Fanouriakis, A., Kostopoulou, M., Anders, H. J., Andersen, J., Aringer, M., Beresford, M. W., Doria, A., Frangou, E., Furie, R., Gladman, D. D., Houssiau, F., Karras, A., Kouloumas, M., Madenidou, A. V., Malvar, A., Marinaki, S., Mok, C. C., Moroni, G., Parodis, I., Rednic, S., Sieiro Santos, C., Scirè, C. A., Smolen, J. S., Tamirou, F., Tanaka, Y., Teng, Y. K. O., Welin, E., Bertsias, G., & Boumpas, D. T. (2025). EULAR recommendations for the management of systemic lupus erythematosus with kidney involvement: 2025 update. Annals of the Rheumatic Diseases, 1–16. https://doi.org/10.1016/j.ard.2025.09.007

SUMMARY OF REVIEW/REVISIONS	DATE
NEW CRITERIA CREATION	Q1 2026