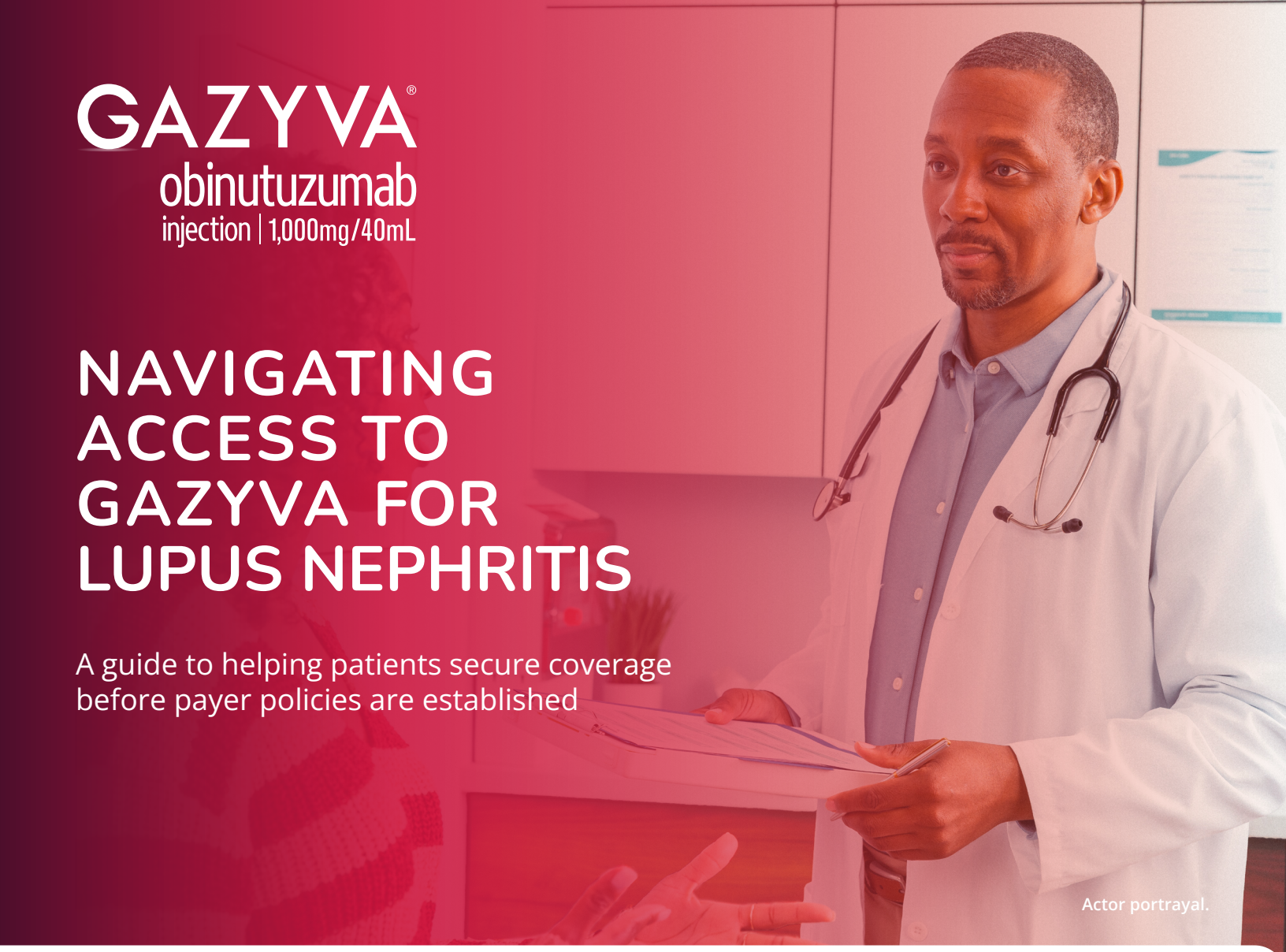
GAZYVA®
obinutuzumab
injection | 1,000mg/40mL

NAVIGATING ACCESS TO GAZYVA FOR LUPUS NEPHRITIS

A guide to helping patients secure coverage before payer policies are established



Indication

GAZYVA® (obinutuzumab) is indicated for the treatment of adult patients with active lupus nephritis (LN) who are receiving standard therapy.

Important Safety Information

BOXED WARNINGS: HEPATITIS B VIRUS REACTIVATION AND PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY

- **Hepatitis B Virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death, can occur in patients receiving CD20-directed cytolytic antibodies, including GAZYVA. Screen all patients for HBV infection before treatment initiation. Monitor HBV-positive patients during and after treatment with GAZYVA. Discontinue GAZYVA and concomitant medications in the event of HBV reactivation**
- **Progressive Multifocal Leukoencephalopathy (PML), including fatal PML, can occur in patients receiving GAZYVA**

Contraindications

- GAZYVA is contraindicated in patients with known hypersensitivity reactions (eg, anaphylaxis) to obinutuzumab or to any of the excipients, or serum sickness with prior obinutuzumab use

Please see additional Important Safety Information throughout and the full Prescribing Information, including BOXED WARNINGS.

Understanding coverage at initial approval for GAZYVA for lupus nephritis

GAZYVA was approved October 2025 for the treatment of adult patients with **active lupus nephritis** who are receiving standard therapy (mycophenolate mofetil + corticosteroids)

Many **payers** may still be **finalizing coverage policies/formularies** and might not have established clear prior authorization (PA) criteria[1]

Healthcare providers may use the payer's **medical/formulary exception process** to secure coverage for GAZYVA[1]

The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and healthcare provider.

Genentech makes no representation or guarantee concerning coverage or reimbursement for any service or item.

The steps on the following pages may help you as you seek to secure patient coverage while insurance companies finalize their policies

Important Safety Information (cont'd)

Warnings and Precautions

Hepatitis B Virus Reactivation

- GAZYVA can cause hepatitis B virus (HBV) reactivation. HBV reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death, can occur in patients treated with anti-CD20 antibodies, including GAZYVA. HBV reactivation has been reported in patients who are hepatitis B surface antigen (HBsAg) positive and in patients who are HBsAg negative but are hepatitis B core antibody (anti-HBc) positive. Reactivation has also occurred in patients who appear to have resolved hepatitis B infection (ie, HBsAg negative, anti-HBc positive, and hepatitis B surface antibody [anti-HBs] positive)
- HBV reactivation is defined as an abrupt increase in HBV replication manifesting as a rapid increase in serum HBV DNA level, or detection of HBsAg in a person who was previously HBsAg negative and anti-HBc positive. Reactivation of HBV replication is often followed by hepatitis, ie, increase in transaminase levels and in severe cases, increase in bilirubin levels, liver failure, and death

Please see additional Important Safety Information throughout and the full Prescribing Information, including BOXED WARNINGS.

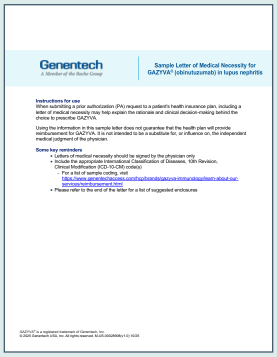
GAZYVA® obinutuzumab injection | 1,000mg/40mL

Securing coverage for GAZYVA for lupus nephritis

1 Perform a benefits investigation (BI) to determine GAZYVA coverage

- To help you understand your patients' coverage, our Specialists can conduct BIs and offer resources as you request a PA for your patient, including considerations for composing a letter of medical necessity
- If the outcome of the BI indicates that GAZYVA is not covered, access may be available by demonstrating medical necessity

2 Establish medical necessity



Genentech
A Member of the Roche Group

Sample Letter of Medical Necessity for GAZYVA® (obinutuzumab) in lupus nephritis

Instructions for use
When submitting a prior authorization (PA) request to a patient's health insurance plan, including a letter of medical necessity may help explain the rationale and clinical decision-making behind the choice to prescribe GAZYVA.

Using the information in this sample letter does not guarantee that the health plan will provide reimbursement for GAZYVA. It is not intended to be a substitute for, or influence on, the independent medical judgment of the physician.

Some key reminders
- Letters of medical necessity should be signed by the physician only
- Include the appropriate International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) code(s)
  - For a list of sample coding, visit https://www.genentechaccess.com/hcp/brands/gazyva-immunology/learn-about-our-services/reimbursement.html
- Please refer to the end of the letter for a list of suggested enclosures

A. Complete the payer's medical/formulary exception form (if available)
  - **Genentech Immunology Access Solutions** can help you identify these forms and offer resources as you request medical/formulary exception for your patient

B. Compose a letter of medical necessity. Be sure to include:
  - A description of the diagnosis (including ICD-10-CM codes)
  - The severity of the condition
  - Prior treatments
  - Rationale for discontinuation
  - Other factors (eg, underlying health issues, age) that have affected treatment selection

A sample letter of medical necessity can be found at **gazyva-hcp.com/lupus-nephritis/resources/practice-forms-and-documents.html**

C. Attach relevant documentation, including:
  - Renal biopsy/pathology reports
  - Relevant diagnostic test results (eg, labs showing ANA, anti-dsDNA, UPCR, serum creatinine)
  - Current/recent chart notes
  - A copy of the US Prescribing Information
  - A copy of the FDA approval letter, which can be found at **accessdata.fda.gov/drugsatfda_docs/appletter/2025/125486Orig1s037,s038ltr.pdf**

Important Safety Information (cont'd)
Warnings and Precautions (cont'd)
Hepatitis B Virus Reactivation (cont'd)

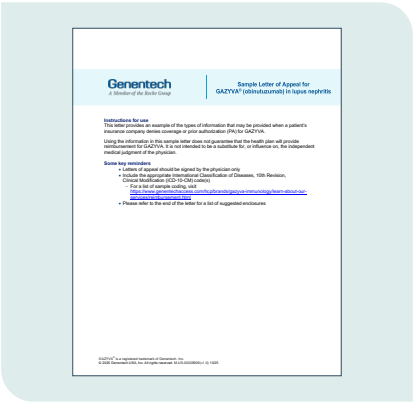
- Screen all patients for HBV infection by measuring HBsAg and anti-HBc before initiating treatment with GAZYVA. For patients who show evidence of hepatitis B infection (HBsAg positive [regardless of antibody status] or HBsAg negative but anti-HBc positive), consult healthcare providers with expertise in managing hepatitis B regarding monitoring and consideration for HBV antiviral therapy

Please see additional Important Safety Information throughout and the full Prescribing Information, including BOXED WARNINGS.

GAZYVA® obinutuzumab injection | 1,000mg/40mL

Securing coverage for GAZYVA for lupus nephritis (cont'd)

3 If denial persists, you may file an appeal*



- Review the denial letter to help you understand the reason for the denial
  - **A sample appeal letter** can be found at **gazyva-hcp.com/lupus-nephritis/resources/practice-forms-and-documents.html**
- Provide additional information and documentation as needed
  - **Genentech Immunology Access Solutions** can provide resources as you prepare an appeal submission, per your patient's plan requirements
- Submit the appeal
  - **Genentech Immunology Access Solutions** can follow up with a patient's health insurance plan about the status of the appeal

We are here to help you navigate coverage for GAZYVA

Visit **genentech-access.com/gazyva-immunology**

Fax **(866) 681-3288**

Call **(866) 681-3261**
Monday through Friday,
9 AM to 8 PM ET

Contact your **Field Reimbursement Manager**

*Appeals cannot be completed or submitted by Genentech Immunology Access Solutions on your behalf.

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

Hepatitis B Virus Reactivation (cont'd)

- 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

Please see additional Important Safety Information throughout and the full Prescribing Information, including BOXED WARNINGS.

GAZYVA® obinutuzumab injection | 1,000mg/40mL

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

Hepatitis B Virus Reactivation (cont'd)

- In patients who develop reactivation of HBV while receiving GAZYVA, immediately discontinue GAZYVA and any concomitant chemotherapy and institute appropriate treatment. Resumption of GAZYVA in patients whose HBV reactivation resolves should be discussed with healthcare providers with expertise in managing hepatitis B. Insufficient data exist regarding the safety of resuming GAZYVA in patients who develop HBV reactivation

Progressive Multifocal Leukoencephalopathy (PML)

- John Cunningham (JC) virus infection resulting in PML, which can be fatal, occurred in patients treated with GAZYVA in chronic lymphocytic leukemia (CLL) and non-Hodgkin lymphoma (NHL). Consider the diagnosis of PML in any patient presenting with new onset or changes to, preexisting neurologic manifestations. Evaluation of PML includes, but is not limited to, consultation with a neurologist, brain MRI, and lumbar puncture. Discontinue GAZYVA therapy and consider discontinuation or reduction of any concomitant chemotherapy or immunosuppressive therapy in patients who develop PML

Infusion-Related Reactions

- GAZYVA can cause severe and life-threatening infusion-related reactions (IRRs).
- In patients with LN, IRRs occurred predominantly during infusion of the first 1,000 mg. IRRs were generally mild to moderate and could be managed by slowing or temporarily halting the infusion. Severe and life-threatening IRRs requiring symptomatic treatment were also reported. The most common IRR signs/symptoms reported in the REGENCY study included headache, nausea, and vomiting. In the NOBILITY study, the most common IRR symptoms were pyrexia and tachycardia
- Premedicate patients with acetaminophen, an antihistamine, and a glucocorticoid. Closely monitor patients during the entire infusion. Reduce infusion rate, interrupt infusion, or permanently discontinue GAZYVA for IRRs based on severity. Institute medical management (eg, glucocorticoids, epinephrine, bronchodilators, and/or oxygen) for IRRs as needed
- For patients with preexisting cardiac or pulmonary conditions, monitor more frequently throughout the infusion and the post-infusion period, since they may be at greater risk of experiencing more severe reactions. Hypotension may occur as part of the IRR to GAZYVA. Consider withholding antihypertensive treatments for 12 hours prior to, during each GAZYVA infusion, and for the first hour after administration until blood pressure is stable. For patients at increased risk of hypertensive crisis, consider the benefits versus the risks of withholding their antihypertensive medication

Hypersensitivity Reactions Including Serum Sickness

- Hypersensitivity reactions have been reported in patients treated with GAZYVA. Signs of immediate-onset hypersensitivity included dyspnea, bronchospasm, hypotension, urticaria, and tachycardia. Late-onset hypersensitivity diagnosed as serum sickness has also been reported, with symptoms that include chest pain, diffuse arthralgia, and fever. Hypersensitivity reactions may be difficult to clinically distinguish from IRRs. However, hypersensitivity very rarely occurs with the first infusion and, when observed, often occurs after previous exposure
- If a hypersensitivity reaction is suspected during or after an infusion, stop the infusion and permanently discontinue treatment. GAZYVA is contraindicated in patients with known hypersensitivity reactions to GAZYVA, including serum sickness with prior GAZYVA use

Please see additional Important Safety Information throughout and the full Prescribing Information, including BOXED WARNINGS.

GAZYVA® obinutuzumab injection | 1,000mg/40mL

Important Safety Information (cont'd)

Serious, Including Fatal, Infections

- Fatal and serious bacterial, fungal, and new or reactivated viral infections can occur during and following GAZYVA therapy
- In the pooled double-blind periods of REGENCY (Week 76) and NOBILITY (Week 52), the incidence of Grade 3-5 infections was 11% (22/200) in patients treated with GAZYVA and standard therapy compared to 9% (18/193) in patients receiving placebo and standard therapy, corresponding to an exposure-adjusted incidence rate (EAIR) of 8.9 and 7.9 per 100 patient years, respectively. The incidence of fatal infections was 1% (2/200) in patients treated with GAZYVA and 0.5% (1/193) in patients receiving placebo, corresponding to an EAIR of 0.8 and 0.4 per 100 patient years, respectively
- In 40 patients who crossed-over from placebo to GAZYVA and standard therapy at Week 76 in the REGENCY study, and patients who continued treatment with GAZYVA and standard therapy, including additional treatment after Week 76, the EAIR of Grade 3-5 infections for the GAZYVA arm was 9.0 per 100 patient years while the EAIR of fatal infections for the GAZYVA arm was 1.8 per 100 patient years
- 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. Consider the risk and benefit of resuming treatment with GAZYVA following resolution of serious infections

Neutropenia

- Severe and life-threatening neutropenia, including febrile neutropenia, has been reported during treatment with GAZYVA. Monitor patients with Grade 3 to 4 neutropenia frequently with regular laboratory tests until resolution. Anticipate, evaluate, and treat any symptoms or signs of developing infection. Consider dose delays for Grade 3 or 4 neutropenia. Consider administration of granulocyte colony-stimulating factors (GCSFs) in patients with Grade 3 or 4 neutropenia
- Neutropenia can also be of late onset (occurring more than 28 days after completion of treatment) and/or prolonged (lasting longer than 28 days)
- 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. Consider antiviral and antifungal prophylaxis

Thrombocytopenia

- Severe and life-threatening thrombocytopenia has been reported during treatment with GAZYVA in combination with chemotherapy. Fatal hemorrhagic events have been reported in patients with CLL treated with GAZYVA in combination with chemotherapy
- Monitor patients frequently for thrombocytopenia and hemorrhagic events, and if clinically indicated, evaluate laboratory coagulation parameters. In patients with Grade 3 or 4 thrombocytopenia, monitor platelet counts more frequently until resolution and consider dose delays of GAZYVA and chemotherapy or dose reductions of chemotherapy. Transfusion of blood products (ie, platelet transfusion) may be necessary. Consider withholding concomitant medications that may increase bleeding risk (platelet inhibitors or anticoagulants), especially during the first cycle

Please see additional Important Safety Information throughout and the full Prescribing Information, including BOXED WARNINGS.

GAZYVA® obinutuzumab injection | 1,000mg/40mL

Important Safety Information (cont'd)

Disseminated Intravascular Coagulation (DIC)

- Fatal and severe DIC has been reported in patients receiving GAZYVA for CLL and NHL. The majority of DIC cases have involved changes in platelets and laboratory coagulation parameters following the first infusion, with spontaneous resolution usually occurring by Day 8. In some cases, DIC was associated with IRRs
- In patients with suspected DIC, evaluate potential causes and monitor coagulation parameters, platelet counts, and for signs and symptoms of bleeding or thrombosis. Manage according to standard guidelines for DIC. Supportive care, including transfusion of blood products and other medical management, may be necessary

Immunization

- The safety and efficacy of immunization with live or attenuated viral vaccines during or following GAZYVA therapy have not been studied. Immunization with live virus vaccines is not recommended during treatment with GAZYVA and until B-cell recovery

Embryo-Fetal Toxicity

- 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. Mothers who have been exposed to GAZYVA during pregnancy should discuss the safety and timing of live virus vaccinations for their infants with their child's healthcare providers. Advise females of reproductive potential to use effective contraception while receiving GAZYVA and for 6 months after the last dose

Lactation

- Human IgG is known to be present in human milk. Because of the potential of serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment with GAZYVA and for 6 months after the last dose

Additional Important Safety Information

- The most common adverse reactions (incidence ≥5%) observed in patients with LN in the GAZYVA arm were upper respiratory tract infection, COVID-19, urinary tract infection, bronchitis, pneumonia, infusion-related reactions, and neutropenia
- The most common serious adverse reactions in the GAZYVA arm were: COVID-19 (5.5%), pneumonia (4.5%), neutropenia (3.5%), urinary tract infections (2.5%), and infusion-related reactions (0.5%). No serious adverse reactions were reported for bronchitis, herpes simplex and upper respiratory tract infections. Two fatal adverse reactions of COVID-19 were reported in the GAZYVA arm

You are encouraged to report side effects to Genentech and the FDA. You may contact Genentech by calling 1-888-835-2555. You may contact the FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088.

Please see the full Prescribing Information for additional Important Safety Information, including BOXED WARNINGS.

Reference: 1. Patient Advocate Foundation. Filing a formulary exception. Accessed September 2, 2025. https://www.patientadvocate.org/wp-content/uploads/Filing-a-Formulary-Exception-1.pdf

Genentech
A Member of the Roche Group

GAZYVA® obinutuzumab injection | 1,000mg/40mL