Genentech
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# 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.genentech-access.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

[Date]
[Payer name]
Attention: [Contact title/Medical Director]
[Payer address]
[City, State, ZIP]

Subject: **Medical Necessity for GAZYVA® (obinutuzumab) - Active Lupus Nephritis**

Patient: [Patient's first and last name]
Date of Birth: [MM/DD/YYYY]
Insurance ID Number: [Insurance ID number]
Insurance Group Number: [Insurance group number]
Case ID Number: [Case ID number (if available)]
Dates of Service: [Dates]

Dear [Contact title/Medical Director],
I am writing on behalf of my patient, [patient's first and last name], to [request prior authorization for/document the medical necessity of] treatment with GAZYVA® (obinutuzumab). This letter provides information about the patient's medical history and diagnosis and a summary of the treatment plan.

**Patient's Clinical History**
[Patient's name] is [a/an] [age]-year-old [male/female/transgender, etc] under my care for active lupus nephritis, diagnosed on [date of lupus nephritis diagnosis].

[Brief summary of rationale for treatment with GAZYVA. This includes a brief description of the patient's diagnosis, including the ICD-10-CM code(s), the severity of the patient's condition, prior treatments and the duration of each, responses to those treatments, the rationale for discontinuation, as well as other factors (eg, underlying health issues, age) that have affected your treatment selection.]

My patient's disease remains active, creating significant risk for irreversible kidney damage. GAZYVA is not contraindicated with the therapies my patient is currently on.

**Treatment Plan With GAZYVA**
[In 2025, the US Food and Drug Administration approved GAZYVA for the treatment of adult patients with active lupus nephritis who are receiving standard therapy.]

[Insert plan of treatment: The plan is to add GAZYVA to the patient's current standard therapy, consistent with its FDA-approved indication and the pivotal Phase III REGENCY trial. The prescribed dosage is 1,000 mg intravenously on Day 1, Week 2, Week 24, Week 26, and every 6 months thereafter.]

**Summary**
Based on the above facts, I believe GAZYVA is not only indicated but also medically necessary for this patient. If you have any further questions, please contact me at [physician's phone number] or [physician's email]. Thank you for your consideration.

Sincerely,
[Physician's signature]
[Physician's typed name, credentials]
[Title]
[Practice name/institution]
[NPI number]

**Enclosures**
Enclosed are [List enclosures, which may include the following:

- **GAZYVA Prescribing Information**
  https://www.gene.com/download/pdf/gazyva_prescribing.pdf
- **FDA approval letter available at:**
  https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125486
- **Current/recent chart notes, including:**
  - Initial diagnosis date
  - Disease severity markers (eg, UPCR, eGFR, serology)
  - Prior therapy history (eg, medication, dose, dates, and clinical outcome/reason for discontinuation)
  - Relevant comorbidities
  - Relevant history, prior to care
- **Renal biopsy/pathology report**
- **Relevant diagnostic test results** (eg, labs showing ANA, anti-dsDNA, UPCR, serum creatinine)
- **Patient's narrative** (if applicable)]