Genentech
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Sample Letter of Appeal for GAZYVA® (obinutuzumab) in lupus nephritis

Instructions for use

This letter provides an example of the types of information that may be provided when a patient's insurance company denies coverage or prior authorization (PA) for 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 appeal 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

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

Subject: **Letter of Appeal 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 your reconsideration of the denial of coverage for their treatment with GAZYVA® (obinutuzumab).

As noted in the denial letter, coverage was not approved due to [list reason(s) for the denial]. I would like to address [the reason/those reasons] now. I've listed relevant clinical details below to confirm that this patient meets the standard criteria for biologic therapy in lupus nephritis.

I would appreciate prompt review of the enclosed information demonstrating medical necessity and coverage of GAZYVA.

Patient's Clinical History
[Patient's name] is [a/an] [age]-year-old [male/female/transgender, etc] patient 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.]

Treatment Plan With GAZYVA
Given my patient is experiencing active disease despite standard therapy, the addition of GAZYVA to their treatment regimen is medically necessary.

[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 information above, treatment with GAZYVA is medically necessary, appropriate, and meets the established criteria for biologic therapy for this condition. Denying this therapy would prevent my patient from receiving the current, evidence-based standard of care for this serious and progressive disease.

If you have any further questions, please contact me at [physician's phone number] or [physician's email]. Thank you for your time and reconsideration of this appeal.

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)]