AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: 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 Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Gazyva® (obinutuzumab) for Lupus Nephritis (J9301) (Medical)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Dosing Limits:

Quantity Limit (max approved dose) [1 billable unit = 10 mg]:

- Maximum of four 1000 mg infusions during year 1 of treatment (Max 4000 mg = 400 units per year)
- Maximum of two 1000 mg infusions during year 2 of treatment (Max 2000 mg = 200 units per year)

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 12 months

- ❑ Prescribed by or in consultation with a Nephrologist or Rheumatologist
- ❑ Member is 18 years of age or older with diagnosis of active lupus nephritis Class III, IV, or V as confirmed by renal biopsy
- ❑ Member has **NOT** received a kidney transplant and is not receiving dialysis
- ❑ Member's diagnosis of active, autoantibody-positive SLE was confirmed by **ONE** of the following **(submit lab results for documentation)**:
  - ❑ anti-nuclear antibody (ANA) titer ≥ 1:80
  - ❑ anti-double stranded DNA (anti-dsDNA) ≥ 30 IU/mL
- ❑ Member has active renal disease and has received standard therapy for the last 90 days with **ONE** of the following **(chart notes documenting established therapy must be submitted)**:
  - ❑ mycophenolate
  - ❑ calcineurin inhibitor (i.e., cyclosporine, tacrolimus, voclosporin) ***voclosporin requires PA***
  - ❑ cyclophosphamide
  - ❑ Benlysta® ***requires PA***
- ❑ Member will initiate or continue daily therapy with **BOTH** of the following **(verified by chart notes and/or pharmacy paid claims)**: mycophenolate and prednisone
- ❑ Baseline measurement of **BOTH** the following must be submitted **(collected within the last 30 days)**:
  - ❑ urine protein:creatinine ratio (uPCR) ≥1 g/g
  - ❑ eGFR >30 mL/min/1.73 m^2
- ❑ Member will **NOT** use obinutuzumab (Gazyva) in combination with any of the following medications: rituximab (i.e., Rituxan, Riabni, Ruxience, Truxima, etc.), belimumab (Benlysta®), or voclosporin (Lupkynis®)

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ All initial authorization criteria continues to be met
- ❑ Member has had improvement from baseline and/or stabilization since last approval of **ONE** of the following **(submit current labs collected within the last 30 days)**:
  - ❑ urine protein:creatinine ratio (UPCR)
  - ❑ eGFR
- ❑ Member has an absence of intolerable side effects such as serious infections, progressive multifocal leukoencephalopathy (PML), or Hepatitis B virus (HBV) reactivation

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Medication being provided by (check applicable box below):

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy**

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee**: 1/22/2026
REVISED/UPDATED/REFORMATTED: 2/16/2026