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: Loargys (pegzilarginase-nbln) **(C9399/J3590) 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.

Recommended Dosing:

- Starting dosage is 0.1 mg/kg administered via intravenous infusion once weekly. For the recommended dosage use actual body weight
- The maximum recommended dosage is 0.2 mg/kg once weekly.

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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: 6 months

- ❑ Member is 2 to less than 32 years of age
- ❑ Prescribed by or in consultation with a neurologist or physician experienced in treating metabolic disorders
- ❑ Member has elevated plasma arginine levels (i.e., greater than or equal to 250 mcmol/L) prior to initiating therapy with the requested medication **(submit documentation)**
- ❑ Diagnosis of ARG1-D has been confirmed by **ONE** of the following **(submit documentation)**:
  - ❑ Genetic confirmation of an ARG1 pathogenic variant
  - ❑ Documentation of reduced arginase enzyme activity in red blood cells
- ❑ Provider attests that member is currently adherent to a protein-restricted diet and will continue this diet during treatment with Loargys
- ❑ Documentation of plasma arginine level from within the last 3 months has been submitted with request
- ❑ Documentation of member's current weight in kg has been submitted with request
- ❑ Member does **NOT** have known active infection with human immunodeficiency virus (HIV), hepatitis B, or hepatitis C
- ❑ Member does **NOT** have a history of hypersensitivity to polyethylene glycol that, in the opinion of the provider, puts the member at unacceptable risk for adverse events
- ❑ Member has **NOT** received previous liver or hematopoietic transplant procedures
- ❑ Provider attests baseline and subsequent pre-dose plasma arginine levels will be collected and monitored as outlined in the manufacturer's prescribing information
- ❑ Requested dose will be adjusted as outlined in the manufacturer's prescribing information if the member's pre-dose plasma arginine levels fall outside of the therapeutic range (i.e., 50 mcmol/L to 150 mcmol/L).
- ❑ Initial and subsequent doses of the requested medication will **NOT** exceed 0.2 mg/kg once weekly.

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.

- ❑ Member continues to meet the initial indication-specific relevant criteria
- ❑ Member has demonstrated a beneficial response to therapy compared to pretreatment baseline as evidence by stabilization or improvement in plasma arginine levels and/or complications of disease manifestations **(submit documentation)**
- ❑ Provider attests pre-dose arginine will be measured after four weeks of therapy (168 hours after prior dose)

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- ❑ Member must meet **ONE** of the following **(submit documentation)**:
  - ❑ Member plasma arginine levels are within the normal range (i.e., 40-115 micromolar)
  - ❑ Member plasma arginine levels are outside the normal range and require a dose adjustment
- ❑ If an additional dose adjustment is required, at least 2 weeks have elapsed since the previous dose adjustment **(Note: Dose adjustments are permitted only if two consecutive weekly pre-dose plasma arginine levels are outside the therapeutic target)**
- ❑ Member has **NOT** experienced unacceptable toxicity from the drug

Medication being provided by: Please 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**: 5/28/2026
REVISED/UPDATED/REFORMATTED: 6/15/2026