AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Loargys		Page:	1 of 3
Effective Date:	7/9/2026		Last Review Date:	6/8/2026
Applies to:	☒Illinois ☒Florida Kids	☒New Jersey ☒Pennsylvania Kids	☒Maryland ☐Virginia	

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Loargys under the patient's prescription drug benefit.

Description:

FDA-Approved Indication
Loargys is indicated for the treatment of hyperargininemia in adult and pediatric patients two years of age and older with Arginase 1 Deficiency (ARG1-D), in conjunction with dietary protein restriction.

This indication is approved under accelerated approval based on reduction of plasma arginine. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Loargys

Policy/Guideline:

Criteria for Initial Approval:

Submission of the following information is necessary to initiate the prior authorization review:

Initial Requests

- Lab results documenting elevated plasma arginine levels (i.e., greater than or equal to 250 micromol/L).
- Chart notes, medical records, or lab results documenting one of the following:
  - Pathogenic (or likely pathogenic) variant in the ARG1 gene.
  - Enzyme assay demonstrating a deficiency of arginase enzyme activity (i.e., <1% of normal) in erythrocytes.

Continuation Requests

- Lab results documenting pre-dose plasma arginine levels.

Prescriber Specialties

This medication must be prescribed by or in consultation with a physician who specializes in the treatment of enzyme or metabolic disorders.

Coverage Criteria

Arginase 1 Deficiency (ARG1-D)

Authorization of 12 months may be granted for treatment of ARG1-D when ALL of the following criteria are met:

- The member is 2 to less than 32 years of age.
- The member has elevated plasma arginine levels (i.e., greater than or equal to 250 micromol/L) prior to initiating therapy with the requested medication.
- The diagnosis of ARG1-D is confirmed by ONE of the following:
  - Pathogenic (or likely pathogenic) variant in the ARG1 gene.
  - Enzyme assay demonstrating a deficiency of arginase enzyme activity (i.e., <1% of normal) in erythrocytes.
- The requested medication will be used in conjunction with dietary protein restriction.
- The member has not had active infection requiring anti-infective therapy within 3 weeks of initiating treatment with the requested medication.
- The member does not have known, active infection with human immunodeficiency virus (HIV), hepatitis B, or hepatitis C.
- The 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.
- The member has not received previous liver or hematopoietic transplant procedure.
- Baseline and subsequent pre-dose plasma arginine levels will be collected and monitored as outlined in the manufacturer's prescribing information.
- The dose of the requested medication 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 micromol/L to 150 micromol/L).
- Initial and subsequent doses of the requested medication will not exceed 0.2 mg/kg once weekly.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when ALL of the following criteria are met:

- The member has not received liver or hematopoietic transplant procedure.
- Either of the following criteria apply:
  - The member has achieved a pre-dose plasma arginine level between 50 micromol/L and 150 micromol/L.
  - The member has not achieved a pre-dose plasma arginine level between 50 micromol/L and 150 micromol/L, and the dose of the requested medication will be adjusted as outlined in the manufacturer's prescribing information.
- The requested dose does not exceed 0.2 mg/kg once weekly

Approval Duration and Quantity Restrictions:

Initial and Renewal Approval: 12 months

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

References:

1. Loargys [package insert]. Chicago, IL: Immedica Pharma US, Inc.; February 2026.
2. Russo RS, Gasperini S, Bubb G, et al. Efficacy and safety of pegzilarginase in arginase 1 deficiency (PEACE): a phase 3, randomized, double-blind, placebo-controlled, multi-centre trial. EClinicalMedicine. 2024;68:102405. Published 2024 Jan 12. doi:10.1016/j.eclinm.2023.102405.
3. Sun A, Crombez EA, Wong D. Arginase Deficiency. 2004 Oct 21 [Updated 2020 May 28]. In: Adam MP, Bick S, Mirzaa GM, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2026. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1159/.
4. Häberle J, Burlina A, Chakrapani A, et al. Suggested guidelines for the diagnosis and management of urea cycle disorders: First revision. J Inherit Metab Dis. 2019;42(6):1192-1230. doi:10.1002/jimd.12100.