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Section:	Prescription Drugs	**Effective Date:**	July 1, 2026
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	March 27, 2026
Subject:	Loargys	**Page:**	1 of 3

Last Review Date: June 11, 2026

Loargys

Description

Loargys (pegzilarginase-nbln)

Background
Arginase-1 deficiency (ARG1-D) is a rare inherited disorder characterized by complete or partial lack of the enzyme arginase in the liver and red blood cells. Arginase is one of six enzymes that play a role in the breakdown and removal of nitrogen from the body, a process known as the urea cycle. The lack of arginase enzyme results in excessive accumulation of nitrogen, in the form of ammonia (hyperammonemia), in the blood and arginine (hyperarginemia) in the blood and cerebrospinal fluid. Untreated children may exhibit seizures, progressive spasticity, short stature, and intellectual disability. Most affected infants can now be identified at birth through newborn screening. Arginase-1 deficiency is inherited as an autosomal recessive genetic disorder (1).

Loargys provides an exogenous source of the deficient human arginase 1 enzyme activity in patients with ARG1-D and reduces plasma arginine by converting it to urea and ornithine (2).

Regulatory Status
FDA-approved indication: Loargys is an arginine specific enzyme indicated for the treatment of hyperargininemia in adult and pediatric patients 2 years of age and older with Arginase 1 Deficiency (ARG1-D), in conjunction with dietary protein restriction (2).

Loargys contains a boxed warning regarding hypersensitivity reactions including anaphylaxis. Loargys should be initiated in a healthcare setting with appropriate medical monitoring and support measures, including access to cardiopulmonary resuscitation equipment. If a severe

hypersensitivity reaction occurs, Loargys should be discontinued, and appropriate medical treatment initiated immediately, including the use of epinephrine (2).

The safety and effectiveness of Loargys in pediatric patients less than 2 years of age have not been established (2).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Loargys may be considered **medically necessary** if the conditions indicated below are met.

Loargys may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 2 years of age or older

Diagnosis

Patient must have the following:

Arginase 1 Deficiency (ARG1-D)

AND ALL the following:

1. Used in conjunction with dietary protein restriction
2. Patient will be monitored for hypersensitivity reactions including anaphylaxis

Prior–Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 2 years

Prior–Approval *Renewal* Limits

Same as above

Rationale

Summary

Loargys is an arginine specific enzyme indicated for the treatment of hyperargininemia in adult and pediatric patients 2 years of age with Arginase 1 Deficiency (ARG1-D), in conjunction with dietary protein restriction. Loargys contains a boxed warning regarding hypersensitivity reactions including anaphylaxis. The safety and effectiveness of Loargys in pediatric patients less than 2 years of age have not been established (2).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Loargys while maintaining optimal therapeutic outcomes.

References

1. Arginase-1 Deficiency: National Organization for Rare Disorders. April 11, 2023. https://rarediseases.org/rare-diseases/arginase-deficiency/.
2. Loargys [package insert]. Chicago, IL: Immedica Pharma US Inc.; February 2026.

Policy History

Date	Action
March 2026	Addition to PA
June 2026	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 11, 2026 and is effective on July 1, 2026.