

Enzyme and Metabolic Disorder Therapies
Loargys (pegzilarginase-nbln)
Effective 10/01/2026

Plan	☒ MassHealth UPPL ☐ Commercial/Exchange		Program Type	☒ Prior Authorization
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit			☐ Quantity Limit ☐ Step Therapy
Specialty Limitations	N/A			
Contact Information	Medical Benefit	Phone: 833-895-2611	Fax: 888-656-6671	
	Pharmacy Benefit	Phone: 800-711-4555	Fax: 844-403-1029	
Notes	Loargys is also available on the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria. Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.			

Overview

Loargys (pegzilarginase-nbln) 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.

Coverage Guidelines

If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted when all of the following criteria are met:

1. Diagnosis of Arginase 1 Deficiency (ARG1-D)
2. Member is ≥ 2 years of age
3. Prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided
4. **ONE** of the following:
 - a. Medical records or a copy of genetic testing confirming mutation in the ARG1 gene
 - b. Copy of laboratory testing confirming reduced erythrocyte arginase activity
5. Baseline/pre-treatment plasma arginine level ≥ 250 $\mu\text{mol/L}$ (dated within the last 90 days if treatment-naïve)
6. Requested agent will be used in combination with a low-protein, arginine-restricted diet
7. Member's current weight
8. Appropriate dosing

Continuation of Therapy

Submission of medical records for **ALL** of the following:

1. Plasma arginine level < 200 $\mu\text{mol/L}$
2. Member's current weight

3. Appropriate dosing

Limitations

1. Initial approvals will be granted for 6 months
2. Reauthorizations will be granted for 6 months

References

1. Loargys [package insert]. Chicago (IL): Immedica Pharma US, Inc.; 2026 Feb.
2. Immedica overcomes prior FDA rebuke for ultrarare disease med to score new approval [press release on the Internet]. New York (NY): Fierce Pharma; 2026 Feb 24 [cited 2026 Mar 10]. Available from: <https://www.fiercepharma.com/pharma/immedica-cashes-after-fda-gives-ultra-rare-disease-drug-loargys-2nd-chance>

Review History

9/9/26 – Created for P&T. New drug added requiring PA under both pharmacy and medical benefits. Effective 10/1/26

