Mass General Brigham
Health Plan

Enzyme and Metabolic Disorder Therapies
Loargys (pegzilarginase-nbln)
Effective 01/04/2027

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 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. Medical records or a copy of testing to support **ONE** of the following:
    a. Genetic testing confirming mutation in the ARG1 gene
    b. Laboratory testing confirming reduced erythrocyte arginase activity
5. Baseline/pre-treatment plasma arginine level ≥250 µmol/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 (use to verify correct dosing)
8. Appropriate dosing

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

1. Plasma arginine level < 200 µmol/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
11/4/26 – Reviewed and updated for P&T. Updated formatting. Effective 1/4/27