

pegzilarginase-nbln (Loargys)

HCPCS: J3590 Unclassified biologics (Loargys)

LOB:	MCAL
Duration of Approval:	New: Six months; COC: One year
Quantity Limit:	Per FDA-Approved/Compendia-Supported Dosing
MCG Available:	No
DHCS Drug Policy:	No

Requires Prior Authorization (PA)

Loargys (pegzilarginase-nbln) injection

PA CRITERIA FOR APPROVAL:**New Therapy**

1. The member has a diagnosis for a Food and Drug Administration (FDA)-approved indication (refer to package insert under References) **OR** a compendia-supported (Drugdex or American Hospital Formulary Service [AHFS]) indication **AND**
2. The medication is prescribed by a neurologist, geneticist or metabolic specialist **AND**
3. The diagnosis of arginase-1 deficiency (ARG1D) is confirmed by **ONE** of the following (**a, b or c**):
 - a. Elevated plasma arginine levels above the upper limit of normal reference range
 - b. Genetic test confirming pathogenic variants of ARG-1 gene
 - c. Enzyme assay confirming reduction of arginase activity (i.e., < 1% of normal) in erythrocytes**AND**
4. Requested medication will be used in conjunction with dietary protein restriction

Continuation of Therapy

1. The member has a diagnosis for an FDA-approved indication (refer to package insert under References) **OR** a compendia-supported (Drugdex or AHFS) indication **AND**
2. The medication is prescribed by a neurologist, geneticist or metabolic specialist **AND**
3. Documentation is provided showing positive response to therapy (e.g., decreased plasma arginine levels, reduction in symptoms and/or improvement from baseline) **AND**
4. Requested medication will be used in conjunction with dietary protein restriction

OTHER INFORMATION:

HCPCS	Description	Brand name
J3590	Unclassified biologics	Loargys

REFERENCES:

1. Loargys Prescribing Information:
www.immedicaus.com/sites/default/files/f/prescribing_information_23feb2026_Loargys.pdf. 02/2026.
2. Aeglea Biotherapeutics. Efficacy and Safety of Pegzilarginase in Patients with Arginase 1 Deficiency. NLM Identifier: NCT03921541. clinicaltrials.gov/study/NCT03921541.
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. www.ncbi.nlm.nih.gov/books/NBK1159/

P&T APPROVAL HISTORY:

August 2026 P&T Drug Review.