

**LOARGYS (pegzilarginase-nbln),
injection for IV use**

PA Criteria	Criteria Details	
Description	LOARGYS is an arginine specific enzyme.	
Covered Uses (FDA approved indication)	<p>LOARGYS is 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*.</p> <p>*This indication is FDA 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.</p>	
Dosing and Administration	Indication	Dosing Regimen
	ARG1-D	<p>0.1 mg/kg IV once weekly (using actual body weight)</p> <ul style="list-style-type: none"> infuse over 30 minutes <p>To maximize the time within the normal range of 40 to 115 micromolar, dose adjustments should be aimed at achieving a pre-dose level of plasma arginine near the upper limit of normal (ULN).</p> <ul style="list-style-type: none"> After four weeks of administration, measure pre-dose plasma arginine (168 hours after prior dose) to determine the need for dosage adjustment. If two consecutive weekly pre-dose plasma arginine measurements are not in the desired therapeutic range, increase or decrease the weekly LOARGYS dosage as follows: <ul style="list-style-type: none"> >> < 50 micromolar: reduce weekly dose by 0.05 mg/kg >> > 150 micromolar: increase weekly dose by 0.05 mg/kg MAX dose is 0.2 mg/kg IV once weekly <p>After eight weeks of once weekly IV LOARGYS, patients may be switched to once weekly subcutaneous LOARGYS at the same dosage of intravenous therapy.</p> <p>Administer ALL doses of LOARGYS (IV or SQ) under the supervision of a health care provider knowledgeable in the management of hypersensitivity reactions including anaphylaxis.</p>
Billing and Coding Information	10-digit NDC	
	2 mg: 81583-102-01	11-digit NDC
	5 mg: 81583-105-01	2 mg: 81583-0102-01
		5 mg: 81583-0105-01
	HCPCS Code	
	J3590	Description
	C9399	Unclassified biologics
	Unclassified drugs or biologicals	
CPT Procedural Codes		
96365	Description	
96372	Ther/proph/diagn IV infusion, initial	
	Ther/proph/diagn injection, SC/IM	

Product Availability	<i>Single-dose vial:</i> <ul style="list-style-type: none"> • 2 mg/0.4 mL • 5 mg/mL
Contraindications	None.
Recommended Medical Monitoring	BLACK BOX WARNING: Hypersensitivity reactions including anaphylaxis <ul style="list-style-type: none"> • Initiate LOARGYS in a health care setting with appropriate medical monitoring and support measure, including access to cardiopulmonary resuscitation equipment
Approval Criteria	<p>A. Physician administered IV infusion; in-office or HOPD</p> <p>i. Cannot be self-administered</p> <p>B. ARG1-D (must meet all):</p> <p>i. Diagnosis of hyperargininemia associated with Arginase 1 Deficiency (ARG1-D)</p> <p>ii. Age ≥ 2 years old</p> <p>iii. Prescribed by or in consultation with a metabolic geneticist, neurologist and/or pediatric specialist.</p> <p>iv. Dose does not exceed 0.2 mg/kg IV once weekly</p>
Age Restriction	Age ≥ 2 years old
Coverage Duration	<p>Initial: 6 months. Reauthorization: 12 months.</p> <p>Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.</p>
Other Criteria (LCD, NCD, etc.)	None.
Misc Info, Appendix Etc.	None.

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	4/16/26	4/16/26	Tamara Chinarian, PharmD, Clinical Pharmacist	N/A
Approved	N/A	5/14/26	Pharmacy & Therapeutics (P&T) Committee	5/14/26