

Loargys® (pegzilarginase-nbIn) Injection

When requesting Loargys® (pegzilarginase-nbIn), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

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.

Coverage Guidelines

Arginase-1 Deficiency

The individual must meet all of the following criteria for authorization:

- Is 2 years of age or older;
- The diagnosis was confirmed by one of the following:
 - o Genetic testing confirms pathogenic variants in the ARG-1 gene; OR
 - o Enzymatic testing confirms partial or complete loss of arginase 1 activity in red blood cells; OR
 - o Has elevated plasma arginine levels diagnosed with a level above the upper limit of the normal reference range for the reporting laboratory;
- Loargys is prescribed in conjunction with a protein-restricted diet;
- Loargys is prescribed by or in consultation with a geneticist, neurologist or metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases).

Approval Duration: 12 months if diagnosis is confirmed by genetic testing or enzymatic testing; 3 months if diagnosis is confirmed by elevated plasma arginine levels

Dosing Recommendation

The recommended starting dosage of Loargys is 0.1 mg/kg administered via intravenous infusion once weekly. The maximum recommended dosage is 0.2 mg/kg once weekly. After eight weeks of once weekly intravenous Loargys, dose may be switched to once weekly subcutaneous Loargys at the same dosage of intravenous therapy.

References

1. Loargys™ intravenous infusion, subcutaneous injection [prescribing information]. Chicago, IL: Immedica; February 2026.
2. Rudebeck M, Braverman N, Chang R, et al. Clinical characteristics of arginase 1 deficiency: natural history insights from international clinical trials. *J Inherit Metab Dis*. 2026;49(2):e70156.
3. Bin Sawad A, Jackimiec J, Bechter M, et al. Epidemiology, method of diagnosis, and clinical management of patients with arginase 1 deficiency (ARG1-D): a systematic review. *Mol Genet Metab*. 2022;137(1-2):153-163.
4. Bin Sawad A, Pothukuchy A, Badeaux M, et al. Natural history of arginase 1 deficiency and the unmet needs of patients: a systemic review of case reports. *JIMD Rep*. 2022;63(4):330-340.
5. Haberle J, Burlina A, Chakrapani A, et al. Suggested guidelines for the diagnosis and management of Urea cycle disorders: first revision. *J Inherit Metab Dis*. 2019;42(6): 1192-1230.
6. National Institute for Health and Care Excellence (NICE). Pegzilarginase for treating arginase-1 deficiency in people 2 years and over. Published March 4, 2026. Available at: [1 Recommendation | Pegzilarginase for treating arginase-1 deficiency in people 2 years and over | Guidance | NICE](#). Accessed on March 5, 2026.