# Pegzilarginase-nbln (Loargys®) Injection

**Goal(s):**

- Ensure appropriate utilization of pegzilarginase-nbln in FDA-approved indications.

**Length of Authorization:** Up to 12 months

**Requires PA:**

- LOARGYS (pegzilarginase-nbln) for IV or SC administration (pharmacy and provider administered claims)

**Covered Populations:** FFS and CCO patients beginning 5/1/26

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for a patient with a prior FFS approval for the requested drug? | **Yes**: Go to **Renewal Criteria** | **No:** Go to #3 |
| 3. Is this an FDA approved age and indication? | **Yes**: Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Is the drug prescribed by or in consultation with a provider with expertise in managing metabolic disorders (i.e., urea cycle disorders)? | **Yes**: Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Is the request for therapy to treat hyperargininemia in a patient with arginase 1 deficiency? | **Yes**: Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |
| 6. Has the diagnosis been confirmed by genetic testing or documentation of reduced arginase enzyme activity in red blood cells? | **Yes**: Go to #7<br><br>Document date and results____<br>_____ | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Is the patient prescribed a protein restricted diet (below 1.5 g/kg/day at 2 years of age to 0.83 g/kg/day at 18 years of age per World Health Organization guidance)? | **Yes:** Go to #8 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 8. Is there documentation of elevated plasma arginine levels (>200 µmol/L) within the past 3 months? | **Yes:** Go to #9<br><br>Document date and results_____ | **No:** Pass to RPh. Deny; medical appropriateness |
| 9. Does the patient have symptomatic hyperammonemia (ammonia ≥100 µmol/L)? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #10 |
| 10. Is the patient on a stable medication regimen including ammonia scavengers, anti-epileptic drugs, and/or spasticity medications? | **Yes:** Go to #11 | **No:** Pass to RPh. Deny; medical appropriateness |
| 11. Is there a documented plan to evaluate arginine levels within the next 4 weeks to determine need for dose adjustments? | **Yes:** Pass to RPh. Pend; Refer to DMAP for secondary review.<br><br>Duration: Approve for 6 months | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Is the request to renew therapy for treatment of arginase 1 deficiency? | **Yes**: Go to #2 | **No:** Pass to RPh. Deny; medical appropriateness |
| 2. Have arginine levels decreased by at least 25% from baseline assessment? | **Yes**: Pass to RPh. Pend; Refer to DMAP for secondary review.<br><br>Duration: Approvals cover up to 12 months.<br><br>Document results: _____ | **No:** Go to #3. |

| Renewal Criteria | | |
|---|---|---|
| 3. Has the provider assessed adherence to treatment and protein restricted diet with a plan to address any identified barriers to care? | **Yes:** Document treatment plan.<br><br>Pass to RPh.<br>Pend; Refer to DMAP for secondary review.<br><br>Duration: Approvals cover up to 12 months. | **No:** Pass to RPh.<br>Deny; medical appropriateness. Refer to DMAP for secondary review. |