



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	January 18, 2019

## **PALYNZIQ™ (pegvaliase-pqpz)**

**LENGTH OF AUTHORIZATION:** SIX MONTHS

**REVIEW CRITERIA:**

- Must be  $\geq 18$  years of age.
- Must have phenylketonuria.
- Phenylalanine concentrations are uncontrolled and  $> 600$ micromol/L (baseline levels must be submitted).
- Patient must have documentation of failure to phenylalanine-restricted diet as monotherapy.
- Must provide documentation showing the member has tried and failed, had an intolerance or contraindication to Kuvan® (in conjunction with a phenylalanine-restricted diet).
- Phenylalanine-restricted diet will be in conjunction with Palynziq™.

**CONTINUATION OF THERAPY:**

- Continue to meet the above criteria.
- Patient had at least a 20% decrease in phenylalanine levels from baseline. Discontinue if the patient does not achieve a 20% decrease in baseline phenylalanine, dosed at the maximum of 40mg subcutaneously daily for 16 weeks.

**DOSING AND ADMINISTRATION:**

- Recommended initial induction is 2.5mg subcutaneously once weekly for 4 weeks. Titrate the dosage in a step-wise manner based on tolerability, over at least 5 weeks to 20mg subcutaneously once daily. Maintain a dosage of 20mg subcutaneously once daily for at least 24 weeks.