

pegvaliase subcutaneous injection (PALYNZIQ)

Diagnosis Considered for Coverage:

- Phenylketonuria (PKU)

Coverage Criteria:

For diagnosis listed above:

Initial Authorization

- Patient is age 18 years or older, **and**
- Blood phenylalanine (Phe) concentrations greater than 600 micromole per liter (umole/L) while using Kuvan, **and**
- Not being used in combination with Kuvan, **and**
- Dose does not exceed FDA label maximum.

Reauthorization

- Not being used in combination with Kuvan, **and**
- One of the following:
 - Current blood Phe concentration 600 micromole per liter (μmol/L) or less, **or**
 - Recent phenylalanine level is at target range, **or**
 - Patient was previously on less than 60 mg/day and titrating to max dose of 60 mg/day to reach a blood Phe concentration of 600 μmol/L or less.

Coverage Duration: one year

Effective Date: 11/02/2023