



STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES



Office of Pharmacy Service
Prior Authorization Criteria

Palynziq® (pegvaliase-pqpz)
Effective 10/01/2019

Prior Authorization Request Form

Palynziq is a phenylalanine-metabolizing enzyme indicated to reduce blood phenylalanine concentrations in adult patients with phenylketonuria who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management.

Criteria for Approval

- 1) Diagnosis of phenylketonuria; **AND**
- 2) The patient must be within the age range recommended by the FDA label and indication; **AND**
- 3) Patient has been prescribed an epinephrine autoinjector (as recommended by the manufacturers label in case of anaphylaxis); **AND**
- 4) Documentation is submitted indicating that the patient is currently adhering to a Phe-restricted diet, and has failed to reduce PHE levels below 600 µmol/L after a minimum 60-day trial of Kuvan with at least 30 days of therapy at a dose of ≥ 20 mg/kg/day (unless a contraindication/intolerance to Kuvan is documented); **AND**
- 5) Palynziq will **not** be authorized for concurrent use with Kuvan.

NOTE: Prescriber must submit the patient's current weight and phenylalanine levels at initiation of therapy. Initial prior authorization will be for 6 months.

Reauthorization Criteria

- Patient must have experienced at least a 20% reduction in Phe after 6 months of therapy.
- The maximum approvable dose is 40 mg/day.
- Patient must continue to adhere to therapy as well as a Phe-restricted diet.

References

- 1) Lexi-Comp Clinical Application 09/20/2019
- 2) Palynziq [package insert]. 05/2018
- 3) Vockley J, Andersson HC, Antshel KM, et al. "Phenylalanine Hydroxylase Deficiency: Diagnosis and Management Guideline" *ACMG Practice Guideline*. 2014. Accessed 4/20/2015.