UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1248-8
Program	Prior Authorization/Notification
Medication	Palynziq™ (pegvaliase-pqpz)
P&T Approval Date	7/2018, 7/2019, 7/2020, 7/2021, 7/2022, 7/2023, 7/2024, 6/2025
Effective Date	9/1/2025

1. Background:

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.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Palynziq** will be approved based on **all** of the following criteria:

   a. Diagnosis of phenylketonuria (PKU)

   -AND-

   b. Patient has a blood phenylalanine concentration greater than 600 micromol/L

   -AND-

   c. Patient is actively on a phenylalanine-restricted diet

   -AND-

   d. Patient is not receiving Palynziq in combination with sapropterin dihydrochloride

Authorization will be issued for 12 months.

B. Reauthorization

1. **Palynziq** will be approved based on **all** of the following criteria:

   a. Documentation of positive clinical response (e.g., blood phenylalanine concentration less than 600 micromol/L, 20% reduction in blood phenylalanine concentration from pre-treatment baseline)

   -AND-

   b. Patient is actively on a phenylalanine-restricted diet

   -AND-

c. Patient is not receiving Palynziq in combination with sapropterin dihydrochloride

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Medical Necessity and supply limits may also be in place.

4. References:

1. Palynziq [package insert]. Novato, CA: BioMarin Pharmaceutical Inc.; November 2020.
2. Vockley et al. Phenylalanine hydroxylase deficiency: diagnosis and management guideline. American College of Medical Genetics and Genomics Practice Guidelines. Genetics in Medicine 2014;16 (2):188-200.

Program	Prior Authorization/Notification - Palynziq (pegvaliase-pqpz)
Change Control	
7/2018	New program
7/2019	Annual review with no change to coverage criteria.
7/2020	Annual review with no change to coverage criteria.
7/2021	Annual review with no change to coverage criteria. Reference updated.
7/2022	Annual review with no change to coverage criteria. Removed Brand name Kuvan. Added state mandate disclaimer.
7/2023	Annual review with no change to coverage criteria.
7/2024	Annual review. Simplified reauthorization criteria to standard documentation of positive clinical response language.
6/2025	Annual review with no change to coverage criteria.