



UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2023 P 3156-3
Program	Step Therapy
Medication	Palynziq™ ( pegvaliase-pqpz)
P&T Approval Date	6/2021, 6/2022, 6/2023
Effective Date	9/1/2023; Oxford only: N/A

**1. Background:**

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try sapropterin dihydrochloride before providing coverage for Palynziq.

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.

Sapropterin dihydrochloride (generic Kuvan) is a phenylalanine hydroxylase activator indicated to reduce blood phenylalanine levels in adult and pediatric patients one month of age and older with hyperphenylalaninemia due to tetrahydrobiopterin-responsive Phenylketonuria and is to be used in conjunction with a phenylalanine-restricted diet.

Members currently on Palynziq as documented in claims history will be allowed continued coverage of their current therapy. Members new to therapy will be required to meet the coverage criteria below.

**2. Coverage Criteria<sup>a</sup>:**

<p><b>A. Palynziq</b> will be approved based on the following criteria:</p> <ol style="list-style-type: none"><li>1. History of failure, contraindication, or intolerance to sapropterin dihydrochloride (document date of trial and list reason for therapeutic failure, contraindication, or intolerance)</li></ol> <p><b>Authorization will be issued for 12 months.</b></p> <p><sup>a</sup> 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.</p>
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**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, Supply Limits and/or Notification may be in place.

**4. References:**

1. Palynziq [package insert], Novato, CA: BioMarin Pharmaceutical Inc.; November 2020.
2. Kuvan [package insert], Novato, CA: BioMarin Pharmaceutical Inc.; February 2021.
3. Sapropterin Dihydrochloride [package insert], Chestnut Ridge, NY: Par Pharmaceutical; March 2020.

Program	Step Therapy – Palynziq ( pegvaliase-pqpz)
<b>Change Control</b>	
6/2021	New program.
6/2022	Annual review with no change to coverage criteria.
6/2023	Annual review with no change to coverage criteria.