UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Palynziq

Program	Prior Authorization
Medication	Palynziq (pegvaliase-pqpz)
Markets in Scope	Arizona, Hawaii, Nevada, Maryland, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, California, South Carolina
Issue Date	7/2018
Pharmacy and Therapeutics Approval Date	7/2020
Effective Date	9/2020

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.

Palynziq has a black boxed warning for risk of serious hypersensitivity reactions or anaphylaxis. Please see full prescribing information for additional details

2. Coverage Criteria:

A. <u>Initial Authorization</u>

1. Palynziq will be approved based on **<u>all</u>** of the following criteria:

a. Diagnosis of phenylketonuria (PKU)

-AND-

b. Patient is actively on a phenylalanine-restricted diet

-AND-

c. Physician attestation that the patient will not be receiving Palynziq in combination with Kuvan (sapropterin dihydrochloride)

-AND-

d. Submission of medical records (e.g. chart notes, laboratory values) documenting that the patient has a blood phenylalanine concentration greater than 600 micromol/L

Authorization will be issued for 6 months.

B. Reauthorization

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

a. Patient is actively on a phenylalanine-restricted diet

-AND-

b. **One** of the following:

(1) Submission of medical records (e.g. chart notes, laboratory values) documenting that the patient has a blood phenylalanine concentration less than 600 micromol/L

-OR-

(2) Submission of medical records (e.g. chart notes, laboratory values) documenting that the patient has achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline

-OR-

(3) **Both** of the following:

(a) Patient is in initial titration/maintenance phase of dosing regimen (week 1-33)

-AND-

(b) Patient will receive maximum labeled dosage of 40 mg once daily if response has not been obtained after 24 weeks of 20 mg once daily maintenance dosing

-AND-

c. Submission of medical records (e.g. chart notes, laboratory values) documenting that the patient is not receiving Palynziq in combination with Kuvan (sapropterin dihydrochloride) [Prescription claim history that does not

show any concomitant Kuvan claim within 60 days of reauthorization request may be used as documentation]

Authorization will be issued for 6 months.

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.
- Supply limits may be in place.

4. References:

1. Palynziq [package insert], Novato, CA: BioMarin Pharmaceutical Inc.; May 2018.
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 –Palynziq (pegvaliase-pqpz)
Change Control	
Date	Change
7/2018	New Program
9/2018	Revised program from notification to medical necessity. Added prescriber attestation and submission of medical records to initial authorization. Added submission of medical records to reauthorization criteria with additional criteria for initial/maintenance dosing and maximum dosing requirements as options for reauthorization approval. Changed authorization durations to 6 months.
7/2019	Annual review. No changes to the program.
7/2020	Annual review. No changes to coverage criteria. Added Clinical Rules section.