Gateway Health It's Wholecare.

Updated: 11/2021
PARP Approved: 11/2021

Gateway Health
Prior Authorization Criteria

Phenylketonuria Medications – Palynziw (pegvaliase-PQPZ) and Kuvan (Sapropterin)

All requests for Phenylketonuria Medications require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Phenylketonuria Medications Prior Authorization Criteria:

For all requests for Kuvan (sapropterin) all of the following criteria must be met:

Coverage may be provided with a diagnosis of phenylketonuria and the following criteria is met:

- Member who are neonates through 12 years of age must have Phe levels greater than or equal to 6mg/dL (360 micromol/L)
- Members who are 12 years of age or older must have Phe levels greater than or equal to 10 mg/dL (600 micromol/L)
- Member must have documentation of failure to Phe restricted diet as monotherapy.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines.
- **Initial Duration of Approval:** 8 weeks
- **Reauthorization criteria**
    - Documentation of baseline (pre-treatment) blood Phe levels.
    - Documentation of Phe levels decreased by 20% or greater from baseline or Phe levels between 120 and 600 micromol/L.
- **Reauthorization Duration of approval:** 12 months

For all requests for Palynziq (pegvaliase-PQPZ) all of the following criteria must be met:

Coverage may be provided with a diagnosis of phenylketonuria and the following criteria is met:

- Member must be 18 years of age or older
- Member must have Phe levels greater than 10mg/dL (600micromol/L)
- Member must have documentation of failure to Phe restricted diet as monotherapy.
- Must provide documentation showing the member has tried and failed, had an intolerance or contraindication, or has a genotype that is known to be non-responsive to Kuvan (prior authorization required, in conjunction with a phenylalanine-restricted diet).
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines.
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
    - Documentation of baseline (pre-treatment) blood Phe levels.
    - Documentation of Phe levels decreased by 20% or greater from baseline or greater from baseline or Phe levels between 120 and 600 micromol/L.
- **Reauthorization Duration of approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

Gateway Health℠

It's Wholecare.

Updated: 11/2021
PARP Approved: 11/2021

Phenylketonuria Medications – Palynziq (pegvaliase-PQPZ) and Kuvan (Sapropterin)
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Gateway ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No

BILLING INFORMATION

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

PLACE OF SERVICE INFORMATION

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Has the member failure a Phe restricted diet as monotherapy (please attach clinical documentation)? ☐ Yes ☐ No

If requesting Palynziq, does the member have a genotype known to be non-responsive to Kuvan? ☐ Yes ☐ No

REFERENCE VALUES

Lab	Baseline (Pre-Treatment) Value	Units (circle one)	Date	Post-Therapy Value (Reauthorization only)	Units (circle one)	Date
Blood Phenylalanine (Phe) Levels		**mg/dL or micromol/L**			**mg/dL or micromol/L**	

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

Gateway Health℠

It's Wholecare.

Updated: 11/2021
PARP Approved: 11/2021

Phenylketonuria Medications – Palynziq (pegvaliase-PQPZ) and Kuvan (Sapropterin) **PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 of 2**	
Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049 If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (800) 392-1147 Monday through Friday 8:30am to 5:00pm	
MEMBER INFORMATION	
Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg
SUPPORTING INFORMATION or CLINICAL RATIONALE	
Prescribing Provider Signature	**Date**