Updated: 10/2018
PARP Approved: 10/2018

Prior Authorization Criteria

Phenylketonuria Medications - Palynziq (pegvaliase-PQPZ) and Kuvan (sapropterin)

All requests for Phenylketonuria Medications - Palynziq (pegvaliase-PQPZ) and Kuvan (sapropterin) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

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 must have Phe levels greater than 6mg/dL (360 mm/L) for neonates through 12 years of age.
- Phe levels must be greater than 6mg/dL (360 mm/L) on average after the age of 12.
- Tetrahydorbiopterin (BH4) deficiency has been ruled out
- 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 360 mm/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 (600mm/L)
- Member must have documentation of failure to Phe restricted diet as monotherapy.
- Must provide documentation showing the member has tried and failed, or had an intolerance or contraindication to Kuvan* (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:** 16 weeks
- **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 360 mmol/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

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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: _____pounds or _____kg

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)

1) Please provide baseline (pre-treatment) blood Phe levels (please attach clinical documentation)

2) Has tetrahydorbiopterin (BH4) deficiency has been ruled out?
☐ Yes ☐ No

3) Is there documentation of failure to Phe restricted diet as monotherapy (please attach clinical documentation)?
☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

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

REAUTHORIZATION

Please provide baseline (pre-treatment) blood Phe levels (please attach clinical documentation):

Has Phe levels decreased by 20% or greater from baseline?

☐ Yes ☐ No

Please provide blood Phe levels after treatment (please attach clinical) documentation:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date

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Palynziq (pegvaliase-PQPZ)
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
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PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

MEDICAL HISTORY (Complete for ALL requests)

1) Please provide baseline (pre-treatment) blood Phe levels (please attach clinical documentation)

2) Is there documentation of failure to Phe restricted diet as monotherapy (please attach clinical documentation)?
☐ Yes ☐ No

3) Has member tried and failed, had an intolerance, or contraindication to Kuvan (in conjunction with a phenylalanine-restricted diet)?
☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

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

REAUTHORIZATION

Please provide baseline (pre-treatment) blood Phe levels (please attach clinical documentation):

Has Phe levels decreased by 20% or greater from baseline?
☐ Yes ☐ No

Please provide blood Phe levels after treatment (please attach clinical) documentation:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date