Updated: 11/2020
DMMA Approved: 11/2020

Request for Prior Authorization for Phenylketonuria Medications
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

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 must have Phe levels greater than 6mg/dL (360 mm/L) for neonates through 12 years of age.
- Phe levels must be greater than 10mg/dL (600 mmol/L) on average after the age of 12.
- 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.
- **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, 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:** 16 weeks
- **Reauthorization criteria**
    - Documentation of baseline (pre-treatment) blood Phe levels.
    - Documentation of Phe levels decreased by 20% or greater from baseline.
- **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.

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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 Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (844) 325-6251 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:
Health Options 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)

Please provide pre-treatment blood Phe levels (please also attach clinical documentation): _____
Has the member tried and failed a Phe restricted diet(please attach clinical documentation)? ☐ Yes ☐ No
If requesting Palynziq, does the member have a genotype known to be non-responsive to Kuvan? ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

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

REAUTHORIZATION

Has Phe levels decreased by 20% or greater from baseline? ☐ Yes ☐ No
Please provide pre-treatment and post-treatment blood Phe levels (please also attach clinical documentation):
Pre-treatment: _____ Post-treatment: _____

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date