AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Palynziq™ (pegvaliase-pqpz) **Injection**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Approval: 6 months

- ❑ Patient must be at least 18 years old
- ❑ Patient must have a diagnosis of phenylketonuria **(chart notes must be attached for documentation)**
- ❑ Provider must be a metabolic geneticist or physician knowledgeable in the management of phenylketonuria
- ❑ Baseline current phenylalanine levels must be >600 µmol/L **OR** average phenylalanine levels must have been >600 µmol/L for the last 6 months on existing management **(lab results from within the last 30 days must be attached)**
- ❑ Initial dose must be administered under the supervision of a healthcare provider and auto-injectable epinephrine must be prescribed

(Continued on next page)

- ❑ Medication will **NOT** be used in combination with Kuvan®
- ❑ Patient must **NOT** have taken Kuvan® within 14 days of last phenylalanine lab **or** within 14 days of initial therapy with Palynziq™

Reauthorization Approval: 6 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Patient must be at least 18 years old
- ❑ Patient must have a diagnosis of phenylketonuria (chart notes must be attached for documentation)
- ❑ Provider must be a metabolic geneticist or physician knowledgeable in the management of phenylketonuria
- ❑ Phenylalanine levels must have decreased by at least 20% from baseline OR phenylalanine blood levels must have decreased to ≤ 600 µmol/L and continue to be maintained at those levels while on maintenance therapy (labs completed within the last 30 days must be attached)
- ❑ Medication will **NOT** be used in combination with Kuvan®

Medication being provided by a Specialty Pharmacy - PropriumRx

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous Therapies will be verified through pharmacy paid claims or submitted chart notes.

***Approved by Pharmacy and Therapeutics Committee**: 7/19/2018
REVISED/UPDATED: ~~9/29/2018;05/22/2019;~~ **10/27/2023**