Humana. CareSource™

PHARMACY POLICY STATEMENT
Kentucky Medicaid

DRUG NAME	Palynziq (pegvaliase-pqpz)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred product includes Kuvan QUANTITY LIMIT— up to 40 mg SQ once daily
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Palynziq (pegvaliase-pqpz) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

PHENYLKETONURIA

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Member has diagnosis of phenylketonuria and have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management; AND
3. Member's baseline blood phenylalanine concentration submitted with chart notes before initiating treatment; AND
4. Member does **not** have ANY of the following:
   a) Current use of levodopa;
   b) A positive test for HIV antibody, hepatitis B surface antigen, or hepatitis C antibody;
   c) A history of organ transplantation or on chronic immunosuppressive therapy;
   d) A history of substance abuse (as defined by the Diagnostic and Statistical Manual of Mental Disorders [DSM IV]) in the past 12 months or current alcohol or drug abuse;
   e) Alanine aminotransferase (ALT) concentration > 2 times the upper limit of normal;
   f) Creatinine >1.5 times the upper limit of normal.
5. **Dosage allowed:** The recommended initial dosage is 2.5 mg subcutaneously once weekly for 4 weeks. Titrate the dosage in a step-wise manner over at least 5 weeks based on tolerability to achieve a dosage of 20 mg subcutaneously once daily. Consider increasing the dosage to a maximum of 40 mg subcutaneously once daily in patients who have been on 20 mg once daily continuously for at least 24 weeks and who have not achieved either a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration less than or equal to 600 micromol/L.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member achieved at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline **or** a blood phenylalanine concentration less than or equal to 600 micromol/L after 16 weeks of continuous treatment with the maximum dosage of 40 mg once daily; AND

2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Palynziq (pegvaliase-pqpz) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
07/27/2018	New policy for Palynziq (pegvaliase-pqpz) created.

References:

1. Palynziq [package insert]. Novato, CA: BioMarin Pharmaceutical Inc.; May, 2018.
2. U.S. Food and Drug Administration. Media release. FDA approves a new treatment for PKU, a rare and serious genetic disease. Available at: https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm608835.htm. Accessed on July 27, 2018.
3. ClinicalTrials.gov Identifier: NCT01819727. An Open-Label Phase 3 Study of BMN 165 for Adults With PKU Not Previously Treated w/ BMN 165 (Prism301). Available at: https://clinicaltrials.gov/ct2/show/NCT01819727?term=NCT01819727&rank=1. Accessed on July 27, 2018.

Effective date: 10/26/2018
Revised date: 07/27/2018