CareSource

PHARMACY POLICY STATEMENT
Georgia 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.

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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