



## SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Palynziq Clinical Edit
<b>First Implementation Date:</b>	April 18, 2019
<b>Revised Date:</b>	November 18, 2021
<b>Prepared for:</b>	MO HealthNet
<b>Prepared by:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

### Executive Summary

**Purpose:** Ensure appropriate utilization and control of Palynziq® (pegvaliase-pqpz)

**Why Issue Selected:** Palynziq® (pegvaliase-pqpz) is a phenylalanine-metabolizing enzyme indicated to reduce blood phenylalanine concentrations in adult patients with phenylketonuria (PKU) who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management. PKU results from a deficiency of phenylalanine hydroxylase, leading to elevated blood and urine concentrations of phenylalanine and its metabolites. If untreated, PKU can cause neurological problems such as mental disability and seizures. PKU affects about 1 in 10,000-15,000 people in the United States, and it is estimated that there are about 11,000 adult PKU patients in the United States. Current therapies available for PKU, such as Kuvan® (sapropterin dihydrochloride) require patients to adhere to a restricted diet; Palynziq does not have a dietary requirement. Palynziq reduces blood phenylalanine concentrations by converting phenylalanine to ammonia and trans-cinnamic acid. Due to a high risk of hypersensitivity reactions, Palynziq comes with a REMS program and boxed warning. Doses should be administered under the supervision of a health care provider, and epinephrine should be available during treatment. Due to the high cost, possible adverse events, and specific approved indication, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Palynziq.

**Program-Specific Information:**

Date Range FFS 4-1-2020 to 3-31-2021			
Drug	Claims	Cost per syringe	Cost per year at maximum dose
PALYNZIQ 2.5 MG/0.5 ML SYR	0	\$536.81 MAC	\$587,806.95 MAC
PALYNZIQ 10 MG/0.5 ML SYR	0		
PALYNZIQ 20 MG/ML SYR	0		

**Type of Criteria:** ☐ Increased risk of ADE  
☒ Appropriate Indications

☐ Preferred Drug List  
☒ Clinical Edit

**Data Sources:** ☐ Only Administrative Databases

☒ Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Palynziq™ (pegvaliase-pqpz)
- Age range: All appropriate MO HealthNet participants aged 18 years or older

## Approval Criteria

### Initial Therapy:

- Documented diagnosis of phenylketonuria (PKU) in the past year **AND**
- Documented adequate therapeutic trial of Kuvan (sapropterin) defined as 180 days of therapy in the past year or ADE/ADRs to Kuvan therapy **AND**
- Documented baseline blood phenylalanine concentrations > 600 micromol/L

### Continuation of Therapy:

- Initial approval of prior authorization is 1 year
- Renewal of prior authorization may be given following documentation of blood phenylalanine concentrations < 600 micromol/L or at least 20% less than baseline level

## Denial Criteria

- Therapy will be denied if all approval criteria are not met
- **Lack of an adequate response to therapy after 16 weeks of continuous treatment at the maximum dose of 60 mg daily**
- **Participant is currently pregnant**
- Claim quantity exceeds **3 syringes** per day

## Required Documentation

Laboratory Results:  
MedWatch Form:

<b>X</b>

Progress Notes:  
Other:

<b>X</b>

## Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)  
Rule Type: CE

## Default Approval Period

1 year

## References

- PALYNZIQ (pegvaliase-pqpz) injection [package insert]. Novato, CA: BioMarin Pharmaceutical Inc.; November 2020.
- IPD Analytics. Endocrine and Metabolic Agents: Phenylketonuria. Accessed May 6, 2021.
- Clinical Pharmacology. Pegvaliase: PALYNZIQ. Accessed May 6, 2021.

*SmartPA Clinical Proposal Form*

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