SmartPA Criteria Proposal

Drug/Drug Class:	Palynziq™ Clinical Edit
First Implementation Date:	April 18, 2019
Proposed Date:	June 18, 2020
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐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 black box warning. Doses should be administered under the supervision of a health care provider, and epinephrine should be available during treatment.

Program-Specific Information:

Date Range FFS 4-1-2019 to 3-31-2020				
Drug	**Claims**	**Spend**	**Cost per unit**	**Cost per month**
PALYNZIQ 2.5 MG/0.5 ML SYR	0	-	$515.10 MAC	$15,453.00 to $30,906.00 MAC
PALYNZIQ 10 MG/0.5 ML SYR	1	$6,909.87		
PALYNZIQ 20 MG/ML SYR	3	$44,387.85		

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 in 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 no approval crieria are met
- **Claim quanitity exceeds 2ml per day**

Required Documentation

Laboratory Results:	X	Progress Notes:	
MedWatch Form:		Other:	X

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.; May 2018.
- IPD Analytics. Endocrine and Metabolic Agents: Phenylketonuria. Accessed May 14, 2020.
- Clinical Pharmacology. Pegvaliase: PALYNZIQ. Accessed May 14, 2020.