Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Palynziq (pegvaliase-pqpz)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***August 2018***

Last P & T Committee Approval Date: *August 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Palynziq (pegvaliase-pqpz).

Palynziq (pegvaliase-pqpz) is indicated to reduce blood phenylalanine concentrations in adult patients with phenylketonuria who have concentrations greater than 600 micromol/L on existing management.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

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The drug, Palynziq (pegvaliase-pqpz), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

- Must have a diagnosis of phenylketonuria (PKU)
- Must have a documented baseline serum phenylalanine level of greater than 600 micromol/L on existing management, such as phenylalanine-restricted diets, and/or prior treatment with sapropterin dihydrochloride
- Must be 18 or older

Reauthorization Criteria:

All prior authorization renewals are reviewed after the maintenance dose of 20mg once daily has been continued for at least 24 weeks to determine the Medical Necessity for continuation of therapy. Authorization may be extended on a case-by-case basis, based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

- Members on the maintenance dose of 20 mg once daily 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
    - Dose may be increased to a maximum of 40 mg subcutaneously daily.
    - Approve for 16 weeks at higher dose
- Members on the 40mg once daily dose who have not 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
    - Treatment is discontinued due to lack of response
- Members who respond adequately are approved for 1 year

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	33 weeks (to allow for 4 week induction, 5 week titration, and 24 weeks of maintenance)
Reauthorization	Case-by-case
Quantity Level Limit	
Palynziq 20mg/ mL syringe	2 syringes (max dose) per day; 56 syringes per 28 days

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Palynziq™ [package insert]. BioMarin Pharmaceutical Inc., Novato, CA. 2018

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	*08/18*