Pharmacy Drug Policy & Procedure

Policy Name:	Palynziq (pegvaliase-pqpz)	Policy #:	2652P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Palynziq (pegvaliase-pqpz).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Palynziq (pegvaliase- pqpz) under the specialty pharmacy benefit when the following criteria have been met.

Criteria

1. Coverage Criteria for Phenylketonuria (PKU)

1.1 Documented diagnosis of Phenylketonuria with a phenylalanine level of > 600 micromoles/liter on a PKU diet which includes an average of 65 grams of protein daily (combined natural food and medical food content)

1.2 Age 18 years or older

1.3 Treated by a specialist knowledgeable in the management of PKU

1.4 Documentation that therapy will accompany a strict Phe-restrictive diet

2. Exclusion Criteria

2.1 Palynziq will not be approved if the member is also receiving Kuvan because there is no data available to support the use of concomitant therapy with these medications in the treatment of PKU.

2.2 Documented non-response to Palynziq indicated by a failure to reduce baseline Phe levels by 20%

3. Approval Period

3.1 Initial Approval: 12 months

3.2 Continued Approval: 12 months with recent lab report showing the patient's phenylalanine level is < 600 micromoles/Liter while on treatment

CPT Codes

HCPCS Codes

References

1. Longo N, Dimmock D, Levy H, et al. Evidence- and consensus-based recommendations for the use of pegvaliase in adults with phenylketonuria. Genet Med. 2019 Aug;21(8):1851-1867.
2. Palynziq (pegvaliase-pqpz) [prescribing information]. Novato, CA: BioMarin Pharmaceutical Inc; November 2020.
3. Vockley J, Andersson HC, Antshel KM, et al. Phenylalanine hydroxylase deficiency: diagnosis and management guideline [ACMG Practice Guidelines]. Genet Med. 2014 Feb: 16(2): 188-356.

4. Longo N, Zori R, Wasserstein MP, et al. Long-term safety and efficacy of pegvaliase for the treatment of phenylketonuria in adults: combined phase 2 outcomes through PAL-003 extension study. Orphanet J Rare Dis 2018; 13:108.
5. Thomas J, Levy H, Amato S, et al. Pegvaliase for the treatment of phenylketonuria: Results of a long-term phase 3 clinical trial program (PRISM). Mol Genet Metab 2018; 124:27.
6. Markham A. Pegvaliase: First Global Approval. BioDrugs 2018; 32:391.

Created Date: 10/10/18
Effective Date: 10/10/18
Posted to Website: 01/01/22
Revision Date: 10/02/24