

Policy Name:	Palynziq (pegvaliase-pqpz)	Policy #:	2652P
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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 and Health Alliance Northwest 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

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HCPCS Codes

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References

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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.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.