Mass General Brigham
Health Plan

Palynziq (pegvaliase-pqpz)
Effective 03/01/2025

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview
Palynziq (pegvaliase-pqpz) is a phenylalanine (Phe)-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 therapy management.

Coverage Guidelines
Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted all of the following criteria are met:

1. Member has a diagnosis of phenylketonuria (PKU)
2. Member is 18 years of age or older
3. Member has a baseline phenylalanine level of ≥600 micromol/L
4. Member has had an inadequate response or adverse reaction or a contraindication to Kuvan

Continuation of Therapy
Requests for reauthorization will be approved when the member meets ONE of the following:

1. ≥ 20% reduction from baseline in blood phenylalanine
2. Blood phenylalanine concentrations are ≤ 600 micromol/L

Limitations

1. Initial approvals will be granted for 9 months to allow for induction and titration to 20mg
2. Reauthorizations will be granted for 12 months

References

1. Bernegger C, Blau N. High frequency of tetrahydrobiopterin-responsiveness among hyperphenylalaninemias: a study of 1,919 patients observed from 1988 to 2002. Mol Genet Metab 2002; 77:304.

2. Blau N, van Spronsen FJ, Levy HL. Phenylketonuria. Lancet 2010; 376:1417.
3. Palynziq (pegvaliase-pqpz) [prescribing information]. Novato, CA: BioMarin Pharmaceutical Inc; November 2020.
4. Harding CO, Amato RS, Stuy M et al. Pegvaliase for the treatment of phenylketonuria: a pivotal, double-blind randomized discontinuation phase 3 clinical trial. Mol Genet Metab. 2018; 124(1):20-6.
5. van Wegberg AMJ, MacDonald A, Ahring K, et al. The complete European guidelines on phenylketonuria: diagnosis and treatment. Orphanet J Rare Dis 2017; 12:162.
6. Kuvan (sapropterin) [prescribing information]. Novato, CA: BioMarin Pharmaceutical Inc.; 2016 August.
7. 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.

Review History

02/20/2019 – Reviewed.

12/11/2024 – Reviewed at December P&T. Updated initial criteria to remove “on current therapy” from diagnosis and lab requirements. Removed requirement regarding anaphylaxis education for member. Updated initial approval period from 33 weeks to 9 months. Effective 03/01/2025.