

Palynziq (pegvaliase-pqpz)
Effective 04/01/19

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|------------------------------|---|---------------------|--|
| Plan | <input checked="" type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange | Program Type | <input checked="" type="checkbox"/> Prior Authorization |
| Benefit | <input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX) | | <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy |
| Specialty Limitations | This medication has been designated a specialty medication and must be filled at a contracted pharmacy. | | |
| Contact Information | Specialty Medications | | |
| | All Plans | Phone: 866-814-5506 | Fax: 866-249-6155 |
| | Non-Specialty Medications | | |
| | MassHealth | Phone: 877-433-7643 | Fax: 866-255-7569 |
| | Commercial | Phone: 800-294-5979 | Fax: 888-836-0730 |
| | Exchange | Phone: 855-582-2022 | Fax: 855-245-2134 |
| | Medical Specialty Medications (NLX) | | |
| | All Plans | Phone: 844-345-2803 | Fax: 844-851-0882 |
| Exceptions | N/A | | |

Overview

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 therapy management.

Coverage Guidelines

Member must meet **ALL** the following criteria and documentation has been submitted:

- Member has a diagnosis of uncontrolled PKU on current therapy
- Member is at least 18 years of age
- Member has a baseline phenylalanine level of ≥ 600 micromol/L despite current therapy
- Member has had an inadequate response or adverse reaction or a contraindication to Kuvan
- Member has been educated to recognize signs and symptoms of anaphylaxis, has been prescribed auto-injectable epinephrine and instructed on its appropriate use.

Continuation of Therapy

Reauthorization may be approved upon receipt of documentation evidencing one of the following:

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

Limitations

1. Initial approvals may be granted for 33 weeks to allow for induction and titration to 20mg
2. Reauthorizations will be granted for 12 months

References



1. Palynziq (pegvaliase-pqpz) [prescribing information]. Novato, CA: BioMarin Pharmaceutical Inc; May 2018.
2. Blau N, van Spronsen FJ, Levy HL. Phenylketonuria. *Lancet* 2010; 376:1417.
3. 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.
4. 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.
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. 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.
7. Kuvan (sapropterin) [prescribing information]. Novato, CA: BioMarin Pharmaceutical Inc.; 2016 August.

Review History

02/20/19 – Reviewed

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