Reference number(s)
2585-A

Specialty Guideline Management
Palynziq

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Palynziq	pegvaliase-pqpz

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy

FDA-approved Indications[1]

Palynziq is indicated to reduce blood phenylalanine (Phe) concentrations in adult and pediatric patients 12 years of age and older with phenylketonuria (PKU) who have uncontrolled blood Phe concentrations greater than 600 micromol/L on existing management.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Blood phenylalanine concentration greater than 600 micromol/L or genetic testing results supporting diagnosis.

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Prescriber Specialties

This medication must be prescribed by or in consultation with a physician who specializes in the treatment of metabolic disease and/or phenylketonuria (PKU).

Coverage Criteria

Phenylketonuria (PKU)[1,3]

Authorization of 6 months may be granted for treatment of phenylketonuria (PKU) when all of the following criteria are met:

- Member is 12 years of age or older.
- Member meets either of the following:
  - Baseline blood phenylalanine concentration, prior to initiation of the requested medication, is greater than 600 micromol/L on existing management; or
  - Diagnosis is confirmed by genetic testing results.

Note: If Palynziq is initiated in a member currently receiving Kuvan for phenylketonuria (PKU), then Kuvan will be discontinued after an appropriate period of overlap.

Continuation of Therapy

Phenylketonuria (PKU)[1]

Authorization of 12 months may be granted for members who have achieved a clinical response as evidenced by achieving a blood phenylalanine concentration of less than or equal to 600 micromol/L.

Authorization of 6 months may be granted for members who have not achieved an adequate clinical response to treatment with the requested medication of blood phenylalanine concentration less than or equal to 600 micromol/L and the member meets one of the following requirements:

- Member has not been titrated to the maximum allowed dose of 60 mg once daily.
- Member has received less than 16 weeks of continuous treatment at the maximum allowed dose of 60 mg once daily.

Note: Palynziq should not be used concomitantly with Kuvan for phenylketonuria (PKU).

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References

1. Palynziq [package insert]. Novato, CA: BioMarin Pharmaceutical Inc.; February 2026.
2. ClinicalTrials.gov. *An Open-Label Phase 3 Study of BMN 165 for Adults With PKU Not Previously Treated With BMN 165 (Prism301)*. Identifier NCT01819727. Updated February 26, 2019. Accessed December 9, 2025.
3. Arnold G, Vockley J. Phenylalanine Hydroxylase Deficiency. 2000 Jan 10 [Updated 2025 Nov 20]. In: Adam MP, Bick S, Mirzaa GM, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2025.