SPECIALTY GUIDELINE MANAGEMENT

PALYNZIQ (pegvaliase-pqpz)

POLICY

I. 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 Indication

Palynziq is indicated to reduce blood phenylalanine concentrations in adult patients with phenylketonuria who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management.

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

II. 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.

III. CRITERIA FOR INITIAL APPROVAL

Phenylketonuria (PKU)

Authorization of 6 months may be granted for members when baseline blood phenylalanine concentration, prior to initiation of the requested medication, is greater than 600 micromol/L.

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.

IV. CONTINUATION OF THERAPY

Phenylketonuria (PKU)

- A. 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.
- B. Authorization of 6 months may be granted for members who have not achieved a clinical response to treatment with Palynziq (blood phenylalanine concentration less than or equal to 600 micromol/L) and meets one of the following requirements:
 - 1. Member has not been titrated to the maximum allowed dose of 60mg once daily.
 - 2. Member has received less than 16 weeks of continuous treatment at the maximum allowed dose.

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

V. REFERENCES

Palynziq 2585-A SGM P2021.docx

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Reference	number(s)
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2585-A

1. Palynziq [package insert]. Novato, CA: BioMarin Pharmaceutical Inc.; November 2020.

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