Reference number(s)
2585-A

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

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