

## SPECIALTY QUANTITY LIMIT PROGRAM

### PALYNZIQ (pegvaliase-pqpz)

#### I. PROGRAM DESCRIPTION

The standard limit is designed to allow a quantity sufficient for the most common uses of the medication. The recommended dosing parameters for the treatment of phenylketonuria (PKU) fall within the standard limits. Coverage of an additional quantity may be reviewed on a case-by-case basis upon request.

#### II. COVERED QUANTITIES

Medication	Standard Limit	FDA-recommended dosing
Palynziq (pegvaliase-pqpz) 2.5 mg/0.5 mL single-dose prefilled syringe for subcutaneous injection	90 per 30 days	Induction: 2.5 mg once weekly for 4 weeks. Titration: 2.5 mg twice weekly for 1 week, 10 mg once weekly for 1 week, 10 mg twice weekly for 1 week, 10 mg four times per week for 1 week, 10 mg once daily for 1 week. Maintenance: 20mg once daily for 24 weeks Maximum: 40 mg once daily for 16 weeks Discontinue: Patients who have not achieved a response after 16 weeks of continuous treatment with the maximum dosage of 40 mg once daily.
Palynziq (pegvaliase-pqpz) 10 mg/0.5 mL single-dose prefilled syringe for subcutaneous injection	30 per 30 days	
Palynziq (pegvaliase-pqpz) 20 mg/mL single-dose prefilled syringe for subcutaneous injection	60 per 30 days	

#### III. REFERENCE

1. Palynziq [package insert]. Novato, CA: BioMarin Pharmaceutical Inc.; May 2018.