



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

PEGVALIASE-PQPZ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGVALIASE-PQPZ	PALYNZIQ	44944		GPI-10 (3090855040)	

**GUIDELINES FOR USE**

**INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)**

1. Does the patient have a diagnosis of phenylketonuria and meet **ALL** of the following criteria?
  - The patient is 18 years of age or older
  - The patient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management, as confirmed by a measurement in the last 30 days
  - The patient has had a trial of Kuvan (sapropterin)
  - The patient is not concurrently receiving Kuvan (sapropterin)

If yes, **approve for 6 months by GPID or GPI-14 for all strengths with the following quantity limits:**

- **2.5mg/0.5mL: #1mL (2 syringes) per 7 days.**
- **10mg/0.5mL: #0.5mL (1 syringe) per day.**
- **20mg/mL: #3mL (3 syringes) per day.**

If no, do not approve.

**INITIAL DENIAL TEXT: \*Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **PEGVALIASE-PQPZ (Palynziq)** requires the following rules be met for approval:

- A. You have phenylketonuria (PKU: a type of birth defect that causes buildup of a chemical called phenylalanine)
- B. You are 18 years of age or older
- C. You have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management, as confirmed by a measurement in the last 30 days
- D. You have tried Kuvan (sapropterin)
- E. You are NOT receiving Kuvan (sapropterin) at the same time as Palynziq (pegvaliase)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

**CONTINUED ON NEXT PAGE**



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PEGVALIASE-PQPZ

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

- Does the patient have a diagnosis of phenylketonuria **AND** meet the following criterion?
  - The patient has demonstrated a reduction in phenylalanine levels, compared to baseline, by at least 20% or to a level below 600 micromol/L

If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**

- 2.5mg/0.5mL: #1mL (2 syringes) per 7 days.**
- 10mg/0.5mL: #0.5mL (1 syringe) per day.**
- 20mg/mL: #3mL (3 syringes) per day.**

If no, do not approve.

**RENEWAL DENIAL TEXT: \*Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **PEGVALIASE-PQPZ (Palynziq)** requires the following rules be met for renewal:

- You have phenylketonuria (PKU: a type of birth defect that causes buildup of a chemical called phenylalanine)
- Your phenylalanine levels have dropped by at least 20% from baseline or to a level under 600 micromol/L

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

**RATIONALE**

For further information, please refer to the Prescribing Information and/or Drug Monograph for Palynziq.

**REFERENCES**

- Palynziq [Prescribing Information]. Novato, CA: BioMarin Pharmaceutical, Inc.; November 2020.

Library	Commercial	NSA
Yes	Yes	No

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