STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGVALIASE

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

   APPROVAL TEXT: Renewal requires that 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 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 (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 previously 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.

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PEGVALIASE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of phenylketonuria and meet the following criteria?
   - 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:**
   - **Palynziq 2.5mg/0.5mL: #1mL (2 syringes) per 7 days.**
   - **Palynziq 10mg/0.5mL: #0.5mL (1 syringe) per day.**
   - **Palynziq 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 (Palynziq)** requires the following rules be met for renewal:
   A. You have a diagnosis of phenylketonuria (PKU: type of birth defect that causes buildup of a chemical called phenylalanine)
   B. 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

Part D Effective: N/A
Commercial Effective: 12/12/20
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