

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Pegvaliase-pqpz (Palynziq)

Notes:

- The FDA requires enrollment in the Risk Evaluation and Mitigation Strategy (REMS) program called the Palynziq REMS Program.
- The REMS program requires that persons be educated about the risk of anaphylaxis by a certified prescriber to ensure they understand the risks and benefits of treatment with Palynziq.
- The product labeling states that the initial subcutaneous injection must be administered under supervision of a healthcare provider who has completed training on Palynziq.

Initiation (new start) criteria: Non-formulary **pegvaliase-pqpz (Palynziq)** will be covered on the prescription drug benefit for 6 months when the following criteria are met:

- The prescriber is a metabolic disease specialist or geneticist
- Patient is at least 18 years of age
- Diagnosis of phenylketonuria (PKU)
- Pre-treatment baseline phenylalanine (Phe) level is more than 600 micromol/L, on existing treatment of sapropterin (Kuvan) AND phenylalanine-restricted diet.
- Sapropterin (Kuvan) will not be used in combination with pegvaliase
- Patient is not pregnant or breast feeding

Criteria for members already taking the medication who have not been reviewed previously (e.g., new members): Non-formulary **pegvaliase-pqpz (Palynziq)** will be covered on the prescription drug benefit for 6 months when the following criteria are met:

- The prescriber is a metabolic disease specialist or geneticist
- Patient is at least 18 years of age
- Diagnosis of phenylketonuria (PKU)
- Phenylalanine (Phe) level was more than 600 micromol/L, on existing treatment of sapropterin (Kuvan) AND phenylalanine-restricted diet.
- Sapropterin (Kuvan) will not be used in combination with pegvaliase
- Patient is not pregnant or breast feeding

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Continued use criteria after initial approval:

- 1) Non-formulary **pegvaliase-pqpz (Palynziq)** will continue to be covered on the prescription drug benefit when the following criteria are met:
 - Patient has responded to pegvaliase defined as either: a 20% reduction or more in Phe level from pre-treatment baseline or Phe level is 600 micromol/L or lower.
 - Patient is not receiving sapropterin (Kuvan) in combination with pegvaliase
- 2) Non-formulary **pegvaliase-pqpz (Palynziq)** will continue to be covered for 4 months on the prescription drug benefit when the following criteria are met:
 - The patient has not responded (as defined above) to pegvaliase 20 mg/day for 24 weeks and dose is being titrated up to the maximum dose of 60 mg/day; or the patient has been receiving pegvaliase 40 to 60 mg/day for less than 16 weeks.
 - Patient is not receiving sapropterin (Kuvan) in combination with pegvaliase