PriorityHealth

Pharmacy Prior Authorization Form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to: ☒ **Commercial (Traditional)** ☒ **Commercial (Individual/Optimized)** ☐ **Medicaid**

This request is: ☐ **Urgent** (life threatening) ☐ **Non-Urgent** (standard review)

Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

Palynziq® (pegvaliase-pqpz)

Member

Last Name: _____ First Name: _____

ID #: _____ DOB: _____ Gender: _____

Primary Care Physician: _____

Requesting Provider: _____ Prov. Phone: _____ Prov. Fax: _____

Provider Address: _____

Provider NPI: _____ Contact Name: _____

Provider Signature: _____ Date: _____

Product Information

☐ New request ☐ Continuation request

Drug product:
- ☐ Palynziq 2.5 mg/0.5 mL syringe
- ☐ Palynziq 10 mg/0.5 mL syringe
- ☐ Palynziq 20 mg/mL syringe

Start date (or date of next dose): _____

Date of last dose (if applicable): _____

Dosing frequency: _____

Drug cost information

The wholesale acquisition cost for Palynziq 40mg daily is $976. The annual cost of treatment with this drug will vary depending on the patient's circumstances, but is estimated to average $351,360.

Precertification Requirements

Before this drug is covered, the patient must meet all of the following requirements (*provide supporting documentation*):

1. Diagnosis of phenylketonuria
2. Age 18 years and older
3. Current adherence to dietary restriction of phenylalanine and continued adherence if approved for Palynziq
    a. Phenylalanine restricted diet defined as:
        i. Adherence to phenylketonuria diet which includes an average of 65 grams of protein per day (from combination of medical foods that supply approximately 75 percent of protein requirements (except phenylalanine) and natural foods)
4. Clinical trial and failure of Kuvan* in combination with phenylalanine restricted diet
    a. Clinical trial defined as 4 weeks treatment with Kuvan 20mg/kg/day
    b. Failure is defined as blood phenylalanine levels greater than 600mcmol/L with combination therapy
    c. Patients with mutation analysis documenting two null mutations in *trans* (i.e. mutations resulting in complete absence of phenylalanine hydroxylase enzyme activity) are not required to trial Kuvan
5. Baseline/current phenylalanine levels provided showing current levels are greater than 600 mcmol/L
6. The prescribing physician is both a metabolic disease specialist and enrolled in and will adhere to REMS (Risk Evaluation and Mitigation Strategy) program requirements for Palynziq

Initial approval is limited to a maximum of one year (includes minimum 9-week titration and maximum of 24-weeks maintenance therapy) at a maximum dose of 20mg daily.

All fields must be complete and legible for review. Your office will receive a response via fax. No changes made since 08/2018

Last reviewed 09/2018

For requests to exceed 20mg Palynziq daily, the patient must meet the following requirements:

1. Must have compliant maintenance therapy on Palynziq 20mg daily for a minimum of 24 weeks
2. Have failed to achieve a 20% reduction in blood phenylalanine concentration from baseline or a blood phenylalanine concentration ≤ 600 micromol/L by week 24 of 20mg daily Palynziq maintenance therapy

Coverage for Palynziq 40mg daily is limited to an initial duration of 16 weeks.

For continuation of coverage after 12-months therapy on an approved dose of Palynziq or after 16-weeks Palynziq 40mg daily, the patient must meet the following requirements:

1. Documented compliant maintenance therapy on Palynziq
2. Continued adherence to a phenylalanine-restricted diet
3. Achieved at least a 20% reduction in blood phenylalanine concentration from baseline or a blood phenylalanine concentration ≤600 micromol/L

Continuation approval is limited to a maximum of one year.

Note: Authorization for indications, dosing, or a route of administration not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the appropriateness of the drug, the dosing of the drug, or the route of administration to be used for the identified indication.

New request
Priority Health Precertification Documentation *(provide supporting documentation)*

A. What condition is this drug being requested for?

☐ phenylketonuria
☐ *Other – the patient's condition is:* _____
Rationale for use: _____

B. Has the patient adhered to a phenylalanine-restricted diet?

☐ Yes
☐ No

C. Has the patient had a clinical trial and failure of Kuvan with a phenylalanine-restricted diet?

☐ Yes
Trial Dates:_____ Kuvan dose (mg/kg/day):_____ Blood Phe level (mcmol/L):_____
☐ No
*Rationale for non-trial:*_____

D. Patient's baseline phenylalanine level

Date:_____ Blood Phe level (mcmol/L):_____

E. The provider is a metabolic disease specialist?

☐ Yes
☐ No

F. The provider is enrolled in and will adhere to REMS (Risk Evaluation and Mitigation Strategy) program requirements for Palynziq?

☐ Yes
☐ No

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Request to continue a previously authorized approval
Priority Health Precertification Documentation *(provide supporting documentation)*

A. Has the patient maintained compliant therapy on Palynziq?
- ☐ Yes
- ☐ No

B. Has the patient adhered to a phenylalanine-restricted diet?
- ☐ Yes
- ☐ No

C. Has the patient achieved at least a 20% reduction in blood phenylalanine concentration from baseline or a blood phenylalanine concentration ≤600 micromol/L?
- ☐ Yes
  Baseline blood Phe level (mcmol/L):_____Date:_____
  Current blood Phe level (mcmol/L):_____Date:_____
- ☐ No

For requests to exceed 20mg Palynziq daily

A. Has the patient maintained compliant therapy on Palynziq 20mg daily for a minimum of 24 weeks?
- ☐ Yes
- ☐ No

B. Has the patient failed to achieve a 20% reduction in blood phenylalanine concentration from baseline or a blood phenylalanine concentration ≤ 600 micromol/L by week 24 of 20mg daily Palynziq maintenance therapy?
- ☐ Yes
  Baseline blood Phe level (mcmol/L):_____Date:_____
  Current blood Phe level (mcmol/L):_____Date:_____
- ☐ No

Additional information

Coverage Limitations:

- Coverage for Palynziq is limited to pharmacy benefit only. Must be ordered from a network specialty pharmacy.
- Dosage Limits:
  The maximum approvable dose of Palynziq is 40mg daily if prior authorization criteria listed above are met.
- Quantity Limits:
  Palynziq 2.5 mg/0.5 mL syringe: 1 syringe per day
  Palynziq 10 mg/0.5 mL syringe: 1 syringe per day
  Palynziq 20 mg/mL syringe: 1 syringe per day*
  *Authorization for Palynziq 40mg daily is subject to Prior Authorization criteria above. If criteria are met, a quantity limit exception may be authorized for the duration specified on this form.
- Dispensing Limits:
  30-day supply per dispensing.
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- Palynziq is not covered in combination with Kuvan. Kuvan treatment must be stopped within 14 days of beginning therapy on Palynziq.

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