Priority Health Medicare prior authorization form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to: ☐ **Medicare Part B** ☐ **Medicare Part D**

This request is: ☐ **Expedited request** ☐ **Standard request**

Your request will be expedited if you haven't gotten the prescription and Priority Health Medicare determines, or your prescriber tells us, that your life or health may be at risk by waiting.

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: _____

Prior authorization criteria

The following requirements need to be met before this drug is covered by Priority Health Medicare. These requirements have been approved by the Centers for Medicare and Medicaid Services (CMS), but you may ask us for an exception if you believe one or more of these requirements should be waived.

For this drug to be covered, the patient must meet the following criteria:

1. Diagnosis of phenylketonuria
2. Age 18 years and older
3. Current and continued adherence to dietary restriction of phenylalanine
4. Failure to achieve blood phenylalanine levels 600mcmol/L or less with phenylalanine-restricted diet in combination with 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 duration is 12 months.

For continuation of subsequent 12-month approvals, 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

All fields must be complete and legible for review. Your office will receive a response via fax.

Updated 08/2018
Last reviewed 09/2018

Medically accepted indication

This drug is only covered under Medicare Part D when it is used for a medically accepted indication. A medically accepted indication is a use of the drug that is *either*:

- approved by the Food and Drug Administration. (That is, the Food and Drug Administration has approved the drug for the diagnosis or condition for which it is being prescribed.)
- — *or* — supported by certain reference books. (These reference books are the American Hospital Formulary Service Drug Information and the DRUGDEX Information System)

New request
Priority Health Precertification 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

Continuation
Priority Health Precertification 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

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Updated 08/2018
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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

Note:
Kuvan trial is not required for patients with two null mutations in trans resulting in complete absence of phenylalanine hydroxylase enzyme activity. Palynziq is not covered in combination with Kuvan and Kuvan must be stopped at least 14 days prior to starting Palynziq. Requests to cover Palynziq 40mg daily require patient to have 24-weeks maintenance therapy on Palynziq 20mg daily with failure to achieve a 20% reduction in blood phenylalanine concentration from baseline or a blood phenylalanine concentration ≤ 600 micromol/L.

Priority Health Medicare plans

Note: Priority Health Medicare applies CMS national and local coverage determination criteria when available for Part B drugs. If no national determination criteria or local coverage determination criteria is available for the state in which the member is receiving the services, the above prior authorization criteria must be met.

Priority Health Medicare exception request

Do you believe one or more of the prior authorization requirements should be waived? ☐ Yes ☐ No
If yes, you must provide a statement explaining the medical reason why the exception should be approved.

Would _____ likely be the most effective option for this patient?

☐ No
☐ Yes, because:_____

_____

_____

If the patient is currently using _____, would changing the patient's current regimen likely result in adverse effects for the patient?

☐ No
☐ Yes, because:_____

_____

_____

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Updated 08/2018
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