

**Palynziq**<sup>®</sup>  
(pegvaliase-pqpz) Injection

## BioMarin RareConnections™





### Real support for your PALYNZIQ journey



Kelsey, taking PALYNZIQ







#### Your Case Manager is your one-to-one support to help you:

-  Answer questions you may have about health insurance and coverage
-  Find ways to help you afford treatment, like co-pay\* support and other financial assistance options available for eligible patients
-  Make sure the Specialty Pharmacy gets the prescription and coordinates delivery
-  Work closely with your clinic and other BioMarin teams to ensure you have product support throughout treatment



#### Your Clinical Coordinator is your one-to-one partner to:

-  Provide support and education at any point during your treatment journey — in person or by email, phone, and text
-  Assist you with injection training as often as you need it
-  Help with making PALYNZIQ part of your daily routine
-  Help you avoid interruptions in your treatment

**Personalized support for coverage, financial needs, and education — at every step of your treatment journey**

Please see Important Safety Information throughout, including important warning for risk of anaphylaxis, and full [Prescribing Information and Medication Guide](#).

# With the BioMarin Co-Pay Assistance Program, eligible patients pay as little as \$0 for PALYNZIQ® (pegvaliase-pqpz) prescriptions\*

The BioMarin Co-Pay Assistance Program will cover all co-pay costs related to both your PALYNZIQ® (pegvaliase-pqpz) and epinephrine prescriptions, up to the annual maximum, for as long as you remain on therapy.

Patient must have commercial insurance and not be eligible for reimbursement under a federal or state program. This program is subject to termination or modification at any time.



## To be eligible, you must:

- Have a PALYNZIQ prescription for an FDA-approved indication
- Currently have commercial insurance
- Ensure your prescription is not covered in whole or in part by any federal or state healthcare programs
- Live in the United States or Puerto Rico

You are responsible for any out-of-pocket costs for which your insurance will not allow the use of the co-pay program for such costs



## The program does not cover:

- Any out-of-pocket expenses for PALYNZIQ beyond the annual maximum benefit
- Products, aside from epinephrine, that are not offered by BioMarin
- Insurance premiums
- Transportation costs for clinic visits
- Co-pays related to clinic visits or lab tests



## Co-pay for epinephrine:

Patients may use a specialty pharmacy or any retail pharmacy to obtain their epinephrine

- Patients will need to provide the retail pharmacy with the co-pay program information provided to them by BioMarin RareConnections™ upon enrollment, including member ID
- Co-pay assistance for epinephrine is not available for residents of California or Massachusetts
- Some exclusions may apply; contact 1-866-906-6100 to verify your prescribed epinephrine is covered under the program

Receive up to 3 fills of epinephrine per year at no additional cost (excludes residents of California and Massachusetts)\*

For more information on affording your epinephrine, visit the [Allergy & Asthma Network](http://Allergy & Asthma Network), at [allergyasthmanetwork.org](http://allergyasthmanetwork.org).

## Additional eligibility requirements may apply. Please see below for details.\*

\*Terms and Conditions apply. Valid only for patients with commercial prescription insurance coverage who have a valid prescription for an FDA-approved indication and who meet additional eligibility criteria. Not valid for prescriptions reimbursed, in whole or in part, by any federal, state, or government-funded insurance programs (for example, Medicare, Medicare Advantage, Medigap, Medicaid, VA, DoD, or TRICARE) or where prohibited by law or by the patient's health insurance provider. If at any time a patient begins receiving prescription drug coverage under any federal, state, or government-funded healthcare program, the patient will no longer be able to use the program and patient must notify BioMarin RareConnections at 1-866-906-6100 to stop participation. Patients residing in or receiving treatment in certain states may not be eligible for some or all of the program elements. Patients may not seek reimbursement for value received from the program from any third-party payers. Additional restrictions may apply. Offer subject to change or discontinuance without notice. This assistance offer is not health insurance. See [BioMarin-copay-terms.com](http://BioMarin-copay-terms.com) for full Terms and Conditions.

\*Valid only for those with commercial insurance. Auto-injectable or nasal spray epinephrine co-pay support is not available in California or Massachusetts.

Please see Important Safety Information throughout, including important warning for risk of anaphylaxis, and full [Prescribing Information and Medication Guide](#).



Jace (right) – taking PALYNZIQ and his mom, Holly (left)

more than  
**92%**

of insured patients have secured coverage  
for PALYNZIQ® (pegvaliase-pqpz)<sup>1</sup>

More than **97%** of eligible commercial  
insured patients paid \$0 out-of-pocket<sup>2</sup>

**Learn about eligibility and enrollment now!  
Call 1-866-906-6100 to speak with a  
BioMarin RareConnections Case Manager.**

<sup>1</sup>BioMarin RareConnections Data on File. Patients included are eligible PALYNZIQ patients who have enrolled in BioMarin RareConnections and are on commercial therapy. BioMarin RareConnections data 2022-2024.

<sup>2</sup>BioMarin RareConnections Data on file. Patients included are eligible PALYNZIQ patients who have enrolled in BioMarin RareConnections and are on commercial therapy. BioMarin RareConnections co-pay program data from 2022-2024.

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## IMPORTANT SAFETY INFORMATION

### What is PALYNZIQ?

PALYNZIQ® (Pal-lin-zeek) (pegvaliase-pqpz) is a prescription medication used to lower blood levels of phenylalanine (Phe) in people 12 years and older with PKU (phenylketonuria) who have uncontrolled blood Phe levels above 600 micromol/L (10 mg/dL) on their current treatment. You should discuss the potential benefits and risks of PALYNZIQ with your healthcare provider.

### What is the most important information I should know about PALYNZIQ?

**PALYNZIQ can cause a severe allergic reaction (anaphylaxis) that may be life-threatening and may happen any time during treatment.** Severe allergic reactions are a serious and common side effect of PALYNZIQ.

- You will get your first injection under the supervision of a healthcare provider prepared to manage a severe allergic reaction. You will be watched for at least 1 hour after your injection for a severe allergic reaction.
- If you have a severe allergic reaction during treatment with PALYNZIQ, you will need to receive an immediate administration of epinephrine and get emergency medical help right away.
- Your healthcare provider will decide if you (or your caregiver) are able to give PALYNZIQ injections, to recognize the signs and symptoms of a severe allergic reaction, and how to use your epinephrine and call for medical help, if needed.
- Your healthcare provider may ask an adult observer (or your caregiver) to be with you during and for at least 1 hour after each injection to watch for signs of a severe allergic reaction. If needed, they should be ready to give you epinephrine and call 911 to get medical help right away.

**Stop PALYNZIQ and get emergency medical care right away if you have any of the following signs or symptoms of a severe allergic reaction during treatment with PALYNZIQ:** fainting (passing out); dizziness or lightheadedness; sudden confusion; trouble breathing or wheezing; chest discomfort or chest tightness; fast heart rate; swelling of your face, lips, eyes, or tongue; throat swelling or tightness; flushed or red skin; skin rash, itching, or raised bumps on skin; nausea, vomiting, or diarrhea; losing control of urine or stools.

- Your healthcare provider will give you a prescription for epinephrine and teach you (or your caregiver) and your observer, if needed, how to use it if you have a severe allergic reaction. **Keep epinephrine with you at all times during treatment with PALYNZIQ.** Read the Patient Information that comes with epinephrine for more details.
- **If you have a severe allergic reaction, stop taking PALYNZIQ** until you talk with your healthcare provider. Tell them that you had a severe allergic reaction. They will decide if it is safe for you to keep using it.
  - Your healthcare provider may prescribe other medicines to take before your PALYNZIQ injection to help reduce the symptoms of an allergic reaction.
  - If your healthcare provider decides you can keep taking PALYNZIQ, you will receive your next injection under the supervision of a healthcare provider prepared to manage a severe allergic reaction, where you will be closely watched for at least 1 hour after your injection for signs of a severe allergic reaction.
- **Your healthcare provider will give you a PALYNZIQ Patient Wallet Card** that lists the signs and symptoms of a severe allergic reaction. You (or your caregiver), or your observer, should call 911 right away if any of these signs or symptoms occur. **Keep this card with you at all times while using PALYNZIQ.** Show this card to any other healthcare provider who treats you.

**PALYNZIQ REMS:** PALYNZIQ is only available through a restricted program called the PALYNZIQ REMS (Risk Evaluation and Mitigation Strategy). Before you can receive PALYNZIQ, you must:

- enroll in the program.
- learn about the risk of a severe allergic reaction (anaphylaxis) from a healthcare provider certified in the PALYNZIQ REMS so you can understand the risks and benefits of treatment.
- fill a prescription of epinephrine and carry it with you at all times while using PALYNZIQ.
- keep the PALYNZIQ Patient Wallet Card with you at all times.

### What should I tell my healthcare provider BEFORE starting PALYNZIQ?

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, or herbal supplements.

**Tell your healthcare provider about all of your medical conditions, including if you:**

- cannot or do not want to use epinephrine to treat a severe allergic reaction.
- are pregnant or plan to become pregnant. It is not known whether PALYNZIQ will harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think you might be pregnant while taking PALYNZIQ.
  - If your Phe levels are too high or too low during pregnancy, this may also affect your unborn baby. You and your healthcare provider can decide the best way for you to manage your blood Phe levels and if taking PALYNZIQ is right for you and your unborn baby.
- It is very important to keep your Phe at the levels your healthcare provider recommends during pregnancy.
  - **Pregnancy Surveillance Program.** There is a pregnancy surveillance program for females who take PALYNZIQ during pregnancy, or who become pregnant while taking PALYNZIQ or within 1 month after their last dose of PALYNZIQ. This program collects information about the health of you and your baby while taking PALYNZIQ. To join, talk to your healthcare provider or call BioMarin at 1-866-906-6100.
- are breastfeeding or plan to breastfeed. It is not known if PALYNZIQ passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take PALYNZIQ.

### What are the possible side effects of PALYNZIQ?

**PALYNZIQ may cause serious side effects, including:**

- Serious allergic reactions. See **"What is the most important information I should know about PALYNZIQ?"**
- **Other allergic reactions to PALYNZIQ** can happen during treatment. **Call your healthcare provider right away if you have any of the following symptoms of an allergic reaction including:** rash, itching, or swelling of the face, lips, eyes, or tongue. Your healthcare provider may change your dose of PALYNZIQ, pause your treatment, or give you medicine for you to take before your injection to help reduce the symptoms of an allergic reaction.
- **Injection site infections.** Serious infections at the injection site have happened in people during treatment with PALYNZIQ. Some of these injection site infections required hospitalization, surgery, treatment with antibiotics given through the vein, or stopping treatment with PALYNZIQ. Change (rotate) your injection site and check your injection site for redness, swelling, or tenderness before each injection. Tell your healthcare provider right away if you develop signs or symptoms of an infection at your injection site that are new, do not go away, or get worse, including: pain, redness, swelling, or tenderness; the area feels hard; fluid or pus; blisters; a dark scab; an open wound.
  - **Do not** inject PALYNZIQ into the affected area until the infection has cleared.
- **Low levels of Phe in your blood (hypophenylalaninemia, or HypoPhe).** Your healthcare provider will monitor your blood Phe levels during treatment.

**The most common side effects of PALYNZIQ include:** injection site reactions: redness, itching, pain, bruising, rash, swelling, tenderness; joint pain; allergic reactions; headache; skin reactions that spread and last at least 14 days, such as itching, rash, redness; nausea; stomach pain; vomiting; cough; mouth and throat pain; itching; diarrhea; stuffy nose; feeling very tired; dizziness; anxiety; low levels of Phe in your blood.

**The most common side effects of PALYNZIQ in people 12 years to less than 18 years of age include:** injection site reactions: redness, itching, pain, bruising, rash, swelling, tenderness; joint pain; headache; fever; allergic reactions; dizziness; nausea; vomiting; feeling very tired; pain in your arms or legs.

These are not all the possible side effects of PALYNZIQ. Call your healthcare provider for medical advice about side effects.

You may report side effects to FDA at 1-800-FDA-1088 or

[www.fda.gov/medwatch](http://www.fda.gov/medwatch).

### Important notes

#### Blood Phe testing and diet

- Your healthcare provider will monitor your blood Phe levels during PALYNZIQ treatment.
- Monitor the amount of protein and Phe you eat or drink. Your healthcare provider may change your diet based on the amount of Phe in your blood. Follow your healthcare provider's instructions about the amount of protein and Phe you should have in your diet.

#### Missed dose

- If a dose is missed, take the next dose at the regular time. Do not take 2 doses of PALYNZIQ to make up for the missed dose.

Please see full [Prescribing Information](#), including Important Warning, and the [Medication Guide](#).