

PALYNZIQ Co-Pay Assistance Program

Eligible, commercially-insured patients pay as little as \$0 for PALYNZIQ prescriptions*†

Receive up to 3 fills of auto-injectable epinephrine per year at no additional cost (excludes residents of California and Massachusetts)‡

Learn about eligibility and enrollment now!

Call 1-833-PKU-CARE

(1-833-758-2273)

and speak with a BioMarin RareConnections™ Case Manager.

What is PALYNZIQ? PALYNZIQ® (Pal-lin-zeek) (pegvaliase-pqpz) is a prescription medication used to lower blood levels of phenylalanine (Phe) in adults 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.

BOXED WARNING: RISK OF ANAPHYLAXIS

Anaphylaxis has been reported after administration of PALYNZIQ and may occur at any time during treatment with PALYNZIQ.

Please visit PALYNZIQ.com for more information.

Please see **Important Safety Information** below, and full [Prescribing Information](#) and [Medication Guide](#).



Eligible patients pay as little as \$0 for PALYNZIQ prescriptions*†

The PALYNZIQ Co-Pay Assistance Program will cover all co-pay costs related to both your PALYNZIQ (pegvaliase-pqpz) and auto-injectable 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.

BOXED WARNING: RISK OF ANAPHYLAXIS

Anaphylaxis has been reported after administration of PALYNZIQ and may occur at any time during treatment with PALYNZIQ.

For eligible patients, the program covers:

- Up to \$16,500 per year in co-pay assistance for PALYNZIQ

Co-pay related to auto-injectable epinephrine:

- Patients may use a specialty pharmacy or any retail pharmacy to obtain their auto-injectable 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 auto-injectable epinephrine is not available for residents of California or Massachusetts
- Some exclusions may apply; contact 1-833-PKU-CARE (1-833-758-2273) to verify your prescribed auto-injectable epinephrine is covered under the program

As a member of the program, you are responsible for:

- Any out-of-pocket costs in situations where your insurance will not allow for the use of the PALYNZIQ Co-Pay Assistance Program for such costs

The program does not cover:

- Any out-of-pocket expenses for PALYNZIQ beyond the \$16,500 annual maximum benefit
- Products, aside from auto-injectable epinephrine, that are not offered by BioMarin
- Insurance premiums
- Transportation costs for clinic visits
- Co-pays related to clinic visits or lab tests

To be eligible, you must:

- Have a prescription for PALYNZIQ
- 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

BioMarin is committed to helping reduce the financial issues that can come between you and your treatment.

To determine eligibility and enroll: Call 1-833-PKU-CARE (1-833-758-2273)

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

*Valid only for those with commercial insurance. Offer not valid for prescriptions eligible to be reimbursed, in whole or in part, by Medicare, Medicaid or any other federal or state program (including any state prescription drug assistance programs) (eg, VA, DoD, TriCare), for cash-paying patients, where product is not covered by patient's commercial insurance, or where plan reimburses you for entire cost of your prescription drug. No claim for reimbursement of the out-of-pocket expense amount covered by the Program shall be submitted to any third party payer, whether public or private. Offer is not valid where prohibited by law. Valid only in the United States and Puerto Rico. This program is not health insurance. Offer may not be combined with any other rebate, coupon, or offer. Co-payment assistance under the Program is not transferable. BioMarin Pharmaceutical Inc. reserves the right to rescind, revoke or amend the program without notice. Patient certifies responsibility for complying with applicable limitations, if any, of any commercial insurance and reporting receipt of program rewards, if necessary, to any commercial insurer. This program is subject to termination or modification at any time.

†The PALYNZIQ Co-Pay Assistance Program will cover up to \$16,500 in assistance per calendar year for eligible patients. Some restrictions apply.

‡Valid only for those with commercial insurance. Auto-injectable epinephrine co-pay support is not available in California or Massachusetts. Some exclusions may apply; contact 1-833-758-2273 to verify your prescribed auto-injectable epinephrine is covered under the program.

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 adults 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 can happen any time during treatment with PALYNZIQ.

Severe allergic reactions are a serious but common side effect of PALYNZIQ.

- You will receive your first injection of PALYNZIQ in a healthcare setting where you will be closely watched for at least 1 hour after your injection for a severe allergic reaction
- Your healthcare provider will prescribe auto-injectable epinephrine for you, and will teach you (or your caregiver) and your observer, if needed, when and how to use it if you have a severe allergic reaction
- If you have a severe allergic reaction during treatment with PALYNZIQ, you will need to receive an injection of epinephrine immediately and get emergency medical help right away
- Your healthcare provider will decide if you (or your caregiver) are able to give the PALYNZIQ injections, recognize the signs and symptoms of a severe allergic reaction, give an injection of epinephrine, and call for emergency help, if needed
- Your healthcare provider may recommend that an adult observer (or your caregiver) be with you when you give your PALYNZIQ injection and for at least 1 hour after your injection to watch you for signs and symptoms of a severe allergic reaction and, if needed, give you an injection of epinephrine and call for emergency medical help

Stop injecting PALYNZIQ and get emergency medical care right away if you have any of the following symptoms:

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| • Fainting (passing out) | • Swelling of your face, lips, eyes, or tongue |
| • Dizziness or lightheadedness | • Throat tightness |
| • Sudden confusion | • Flushed skin |
| • Trouble breathing or wheezing | • Skin rash, itching, or raised bumps on skin |
| • Chest discomfort or chest tightness | • Nausea, vomiting, or diarrhea |
| • Fast heart rate | • Losing control of urine or stools |

Keep the auto-injectable epinephrine with you at all times during treatment with PALYNZIQ. Read the Patient Information that comes with the auto-injectable epinephrine that your healthcare provider prescribes for you for more information.

If you have a severe allergic reaction, do not continue to take PALYNZIQ until you talk with your healthcare provider. Your healthcare provider will tell you if you can continue treatment with PALYNZIQ.

People taking PALYNZIQ have also experienced **allergic reactions other than anaphylaxis**. Talk to your healthcare provider if you experience any allergic reactions when taking PALYNZIQ.

PALYNZIQ REMS: PALYNZIQ is available only through a restricted program called the PALYNZIQ REMS (Risk Evaluation and Mitigation Strategy). Talk to your healthcare provider about the PALYNZIQ REMS and how to enroll.

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 and herbal products.

Before injecting PALYNZIQ, talk to your healthcare provider right away if you cannot or will not use auto-injectable epinephrine to treat a severe allergic reaction. If you are pregnant or plan to become pregnant while taking PALYNZIQ, talk to your healthcare provider to discuss the risks and benefits of taking PALYNZIQ during pregnancy to you and your unborn baby. If you are breastfeeding or plan to breastfeed, talk to your healthcare provider about the best way to feed your baby if you take PALYNZIQ.

Before injecting PALYNZIQ, read the Medication Guide and Instructions for Use that come with your PALYNZIQ injection.

What should I tell my healthcare provider AFTER starting PALYNZIQ?

PALYNZIQ may cause serious side effects, including:

- Severe allergic reactions (anaphylaxis)
- Other allergic reactions to PALYNZIQ can happen during treatment with PALYNZIQ. Contact 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, stop your treatment with PALYNZIQ for a period of time, or prescribe medicine for you before your next PALYNZIQ injection to help reduce the side effects of an allergic reaction

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

These are not all of the possible side effects of PALYNZIQ. Speak with your healthcare provider right away about any side effects.

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 that you eat or drink. Your healthcare provider may change the amount of protein and Phe you should have in your diet during treatment with PALYNZIQ, depending on the levels 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 your next dose as scheduled and do not take 2 doses of PALYNZIQ to make up for the missed dose

Pregnancy Surveillance Program

- There is a pregnancy surveillance program for females who take PALYNZIQ during pregnancy, or who become pregnant while receiving PALYNZIQ or within 1 month after their last dose of PALYNZIQ. The purpose of this program is to collect information about the health of you and your baby while taking PALYNZIQ. Talk to your healthcare provider about how you can take part in this program or call BioMarin at 1-866-906-6100

You may report side effects to BioMarin at 1-866-906-6100.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see full [Prescribing Information](#) and [Medication Guide](#).