

Palynziq REMS Program Overview

Risk Evaluation and Mitigation Strategy

This overview describes the requirements of the PALYNZIQ® (pegvaliase-pqpz) REMS and the responsibilities of prescribers, pharmacies, and patients.

If you have any questions regarding the PALYNZIQ REMS, please visit PALYNZIQREMS.com or call 1-855-758-REMS (1-855-758-7367).

Please see Prescribing Information, including **BOXED WARNING**, for additional Important Safety Information

Palynziq[®]
(pegvaliase-pqpz) Injection

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What is the PALYNZIQ REMS?

- A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure the benefits of a drug continue to outweigh its risks.
- **Due to the risk of anaphylaxis, PALYNZIQ is available only through a restricted program called the PALYNZIQ REMS.**

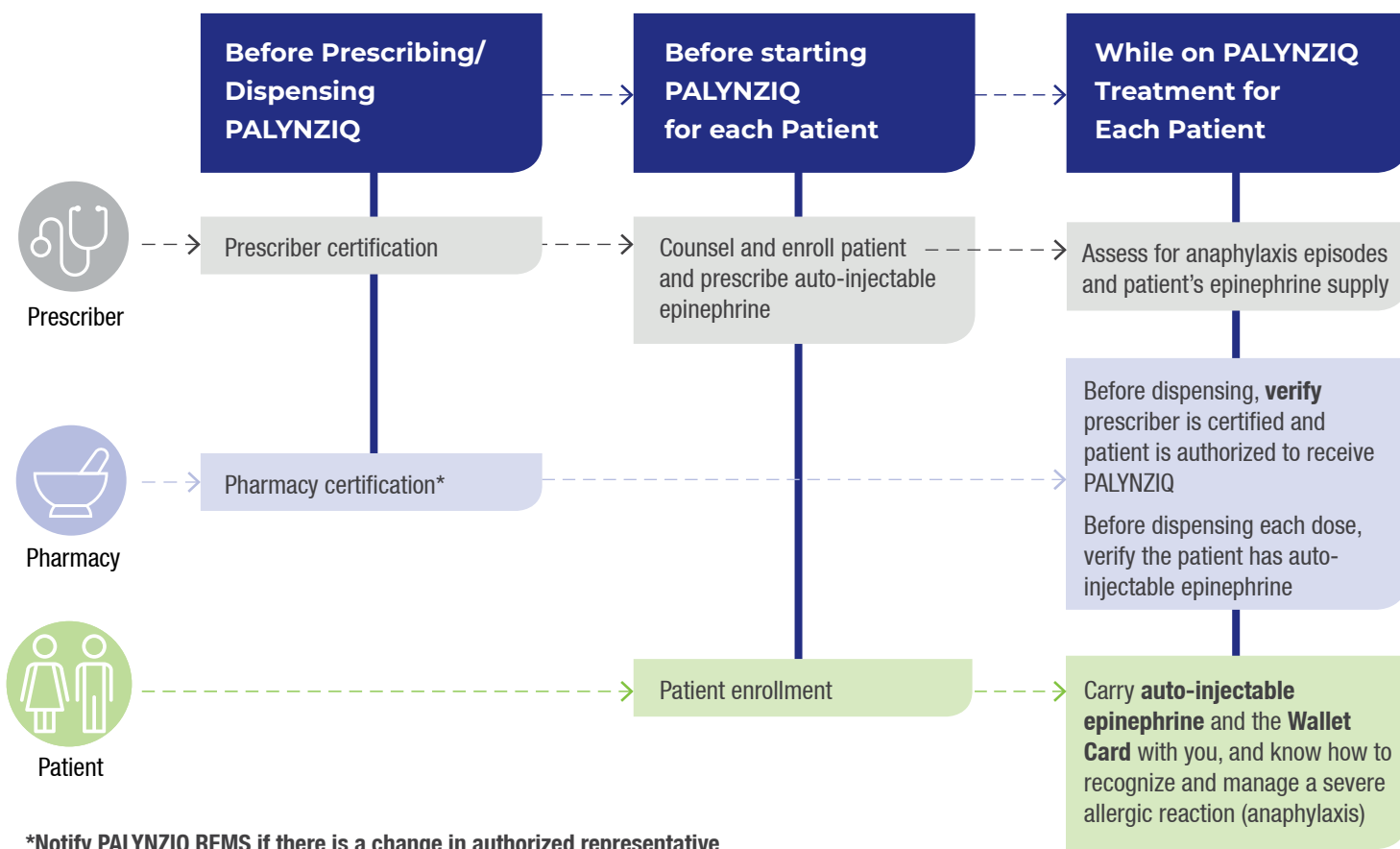
PALYNZIQ may cause anaphylaxis; patients may experience an anaphylaxis episode immediately or at any time after an injection of PALYNZIQ. Episodes of anaphylaxis are more common at the beginning of treatment, but they can also occur anytime during treatment.

Anaphylaxis can be life-threatening and can occur quickly; inform your patients of the signs and symptoms, the appropriate use (when and how to use) auto-injectable epinephrine, and when to seek immediate medical care.

Anaphylaxis has been reported in patients who have used PALYNZIQ. The signs and symptoms of anaphylaxis may include:

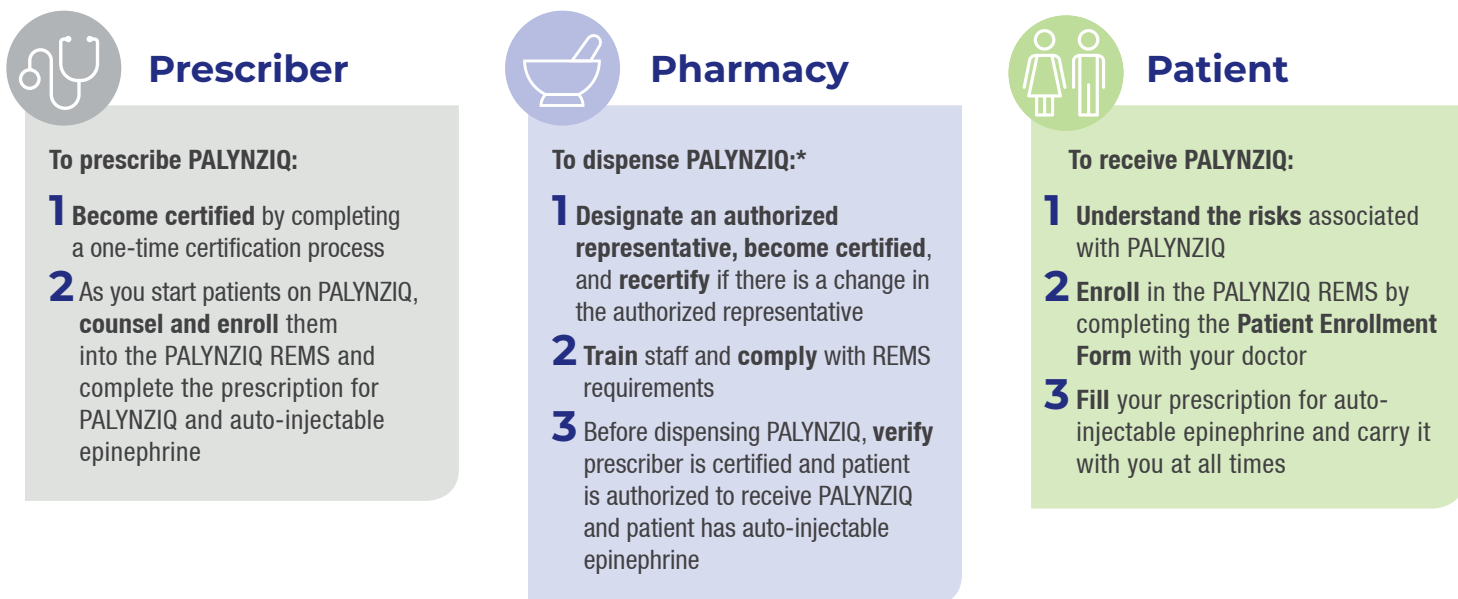
- Syncope, hypotension
- Hypoxia, dyspnea, wheezing
- Chest discomfort/chest tightness
- Tachycardia
- Angioedema (swelling of the face, lips, eyes, tongue)
- Throat tightness
- Skin flushing
- Rash, urticaria, pruritus
- Gastrointestinal symptoms (vomiting, nausea, diarrhea)

How Does the PALYNZIQ REMS Work?



What are the Requirements of the PALYNZIQ REMS?

In order to receive PALYNZIQ, prescribers, pharmacies, and patients must comply with the requirements of the PALYNZIQ REMS.



*PALYNZIQ is not available to all pharmacies. If you have any questions about the PALYNZIQ REMS or how to obtain PALYNZIQ, call 1-855-758-REMS (1-855-758-7367).



Prescriber Requirements

Become Certified (One-time)

Before prescribing PALYNZIQ

1 Review the following educational materials on PALYNZIQ to understand the risks of anaphylaxis and the need for auto-injectable epinephrine, and the PALYNZIQ REMS:

- Prescribing Information
- Prescriber Guide
- REMS Program Overview

2 Complete and submit using the submission details at the end of this document:

- Prescriber Knowledge Assessment
- Prescriber Enrollment Form

3 Once completed, the PALYNZIQ REMS will notify you that you are certified to prescribe PALYNZIQ

Enroll Your Patients

Before starting each patient on PALYNZIQ

1 Counsel your patient about the risks associated with PALYNZIQ, including anaphylaxis and the need for auto-injectable epinephrine and share the resources below:

- Patient Guide: What You Need to Know
- Safety Video
- Wallet Card

2 Submit a completed Patient Enrollment Form to the PALYNZIQ REMS. Provide a completed copy of the form to the patient and retain a copy in the patient's records

3 Prescribe auto-injectable epinephrine and instruct the patient on when and how to use it

4 Assess the patient's need for an adult observer and premedications as described in the Prescriber Guide

At All Times

Once your patient is on PALYNZIQ

1 Report any anaphylaxis episodes to the PALYNZIQ REMS. You will be contacted for more information about these episodes

2 Assess the patient's supply of auto-injectable epinephrine and provide the patient with a prescription for auto-injectable epinephrine refills as necessary

3 Inform the PALYNZIQ REMS if a patient is no longer under your care or has discontinued PALYNZIQ

The completed forms should be submitted to the PALYNZIQ REMS online, using the PALYNZIQ REMS Portal at PALYNZIQREMS.com, via fax to 1-866-713-8421, or by mail to 200 Pinecrest Plaza, Morgantown WV 26505.



Pharmacy Requirements

Become Certified

Before dispensing PALYNZIQ for the first time:

1 Designate an authorized representative for the pharmacy. He or she will need to review the *REMS Program Overview* and will oversee implementation and ensure compliance with the PALYNZIQ REMS requirements

2 Have the authorized representative complete and submit the Pharmacy Enrollment Form by fax

- Once this step is completed, the PALYNZIQ REMS will contact you to complete certification
- Dispensing of PALYNZIQ is limited to a small number of contracted pharmacies that will be certified

3 Have the authorized representative ensure that all relevant staff involved in dispensing of PALYNZIQ are trained on the PALYNZIQ REMS requirements and that a record of training is maintained by the pharmacy

Ensure Compliance with REMS Requirements

When dispensing PALYNZIQ:

1 Before dispensing PALYNZIQ, **verify** that the prescriber is certified and the patient is authorized to receive PALYNZIQ by accessing the PALYNZIQ REMS Portal or by calling the PALYNZIQ REMS

2 Confirm and **document** that patient has auto-injectable epinephrine

3 Report any anaphylaxis episodes to the PALYNZIQ REMS. You may be contacted for more information about these episodes

4 Maintain appropriate documentation that all processes and procedures are in place and are being followed so that it can be provided upon request to BioMarin or a third party acting on behalf of BioMarin

5 Recertify in the PALYNZIQ REMS if a new authorized representative is designated by completing and submitting the Pharmacy Enrollment Form

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Patient Requirements

Enroll

Before starting PALYNZIQ:

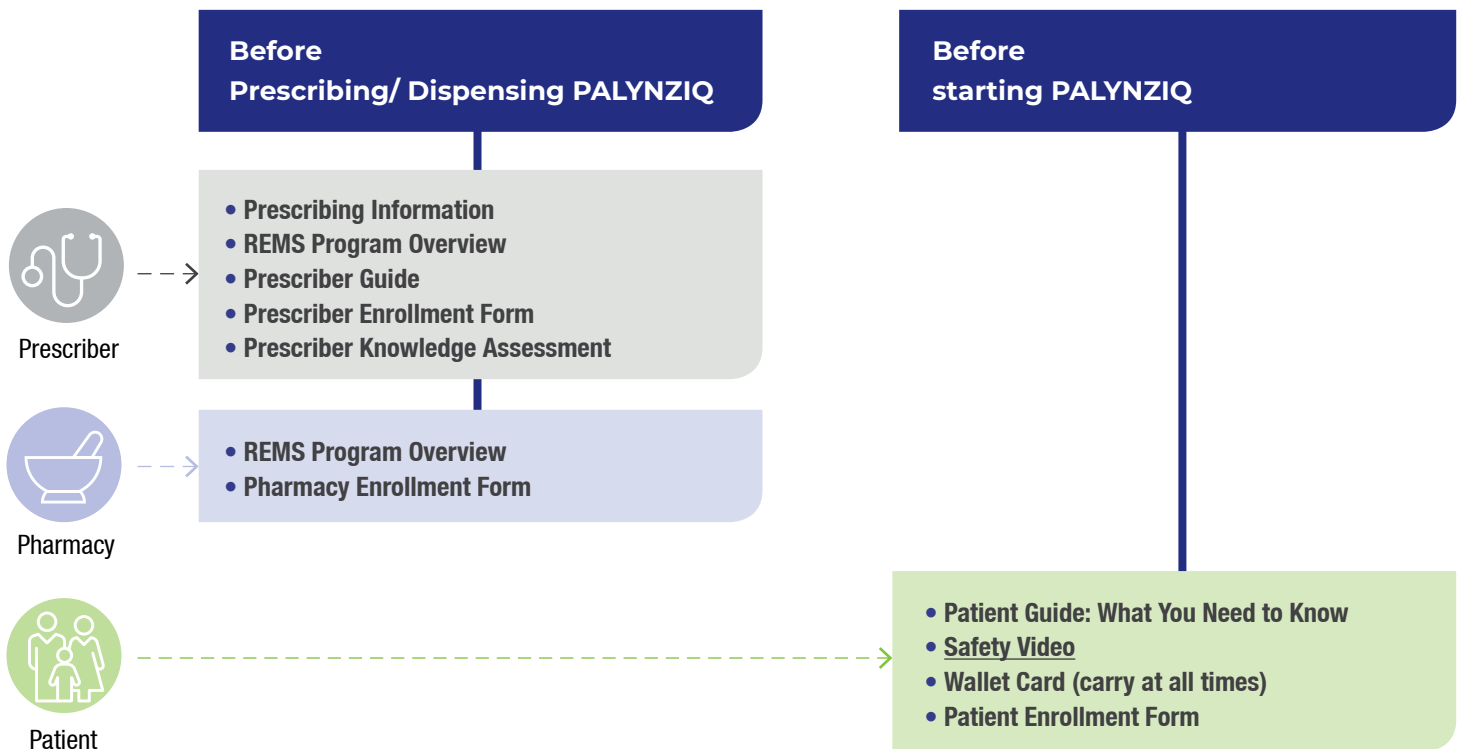
- 1 Discuss** with your doctor and understand:
 - The risks associated with PALYNZIQ, including anaphylaxis
 - The need for (including how and when to use) an auto-injectable epinephrine
- 2 Receive** and **read** the:
 - **Patient Guide: What You Need to Know**
 - **Wallet Card** (fill in your name and your doctor's information)
- 3 Watch** the **Safety Video**
- 4 Complete** the **Patient Enrollment Form** with your doctor
- 5 Receive** and **fill** a prescription for auto-injectable epinephrine

During treatment

After starting PALYNZIQ:

- 1 Carry** auto-injectable **epinephrine** with you at all times
- 2 Inform your healthcare providers** if you have any signs or symptoms of a severe allergic reaction (anaphylaxis) after receiving PALYNZIQ and if you need more auto-injectable epinephrine
- 3 Show** the **Wallet Card** to your doctor or emergency responder when you have any medical treatment for any condition, even if it's not for your phenylketonuria (PKU). Inform all doctors you are being treated with PALYNZIQ
- 4 Notify** the PALYNZIQ REMS if you **change your PALYNZIQ doctors** if your **contact information changes**, or if you **discontinue treatment with PALYNZIQ**

PALYNZIQ REMS Resources



PALYNZIQ is indicated to reduce blood phenylalanine concentrations in adult patients with phenylketonuria (PKU) who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management.

Please see the Medication Guide and Prescribing Information, including **BOXED WARNING**, for more information.

PALYNZIQ REMS Portal Overview

PALYNZIQREMS.com

- PALYNZIQ REMS Portal is a web-based tool designed to:
 - Provide real-time access to PALYNZIQ REMS patient, prescriber, and pharmacy information
 - Maintain compliance with the PALYNZIQ REMS
- PALYNZIQ REMS Portal allows prescribers to instantly certify themselves, enroll patients, and manage their patients online
- PALYNZIQ REMS Portal is accessed with secure username and password provided upon registration

Additional questions:

Please visit PALYNZIQREMS.com or call the PALYNZIQ REMS at 1-855-758-REMS (1-855-758-7367) for more information about the PALYNZIQ REMS.

Please see the Medication Guide and Prescribing Information, including **BOXED WARNING**, for more information.

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Phone: 1-855-758-REMS (1-855-758-7367) Fax: 1-866-713-8421

Mail: PALYNZIQ REMS, 200 Pinecrest Plaza, Morgantown WV 26505