BIOMARIN Rare Connections™

Patient Enrollment Form for PALYNZIQ® (pegvaliase-pqpz) Injection

Fax completed form with prescriber's signature to **1.888.863.3361**
Phone: **1.833.PKU.CARE** (1.833.758.2273); hours: M–F, 6 AM–5 PM (PT)
Email: **support@biomarin-rareconnections.com**

Palynziq® (pegvaliase-pqpz) Injection

All required fields are purple and are noted with an asterisk (*).

PATIENT

Patient's Last Name*		**Patient's First Name***	
Date of Birth*	**Gender*** ☐ Male ☐ Female ☐ Other	Parent's/Guardian's Name (if applicable)	
Street Address*		Suite/Floor/Apt	
City*		**State***	**ZIP Code***

Preferred Method of Contact (please specify)*

☐ Cell Phone ☐ Home Phone ☐ Work Phone

☐ Email

Language Preferred: ☐ English ☐ Other language (please specify)

Alternate Contact Name	Relationship to Patient
Phone	Email

INSURANCE

Please complete the following* or attach copies of the insurance and prescription benefit cards, front and back. ☐ Insurance card copies attached ☐ Patient has no insurance

Primary Insurance Name*		Secondary Insurance Name	
Insurance Phone Number*		Insurance Phone Number	
Subscriber*		Subscriber	
Relationship to Patient*		Relationship to Patient	
Member ID*	Group ID	Member ID	Group ID
Employer*		Employer	

DIAGNOSIS/CLINICAL

Diagnosis ICD-10-CM*

☐ Classical Phenylketonuria (PKU) E70.0

☐ Other Hyperphenylalaninemias E70.1

☐ Other diagnosis *(please specify)* _____

Baseline Blood Phe Level

Date

Prolonged elevated blood phenylalanine (Phe) in adults can result in neurocognitive and neuropsychiatric impairment.
I am prescribing PALYNZIQ for this patient and find it medically necessary to reduce blood Phe levels for this patient.
Additional comments

Please list the names of other medications the patient is currently taking

☐ None

LOGISTICS

For Clinic Shipments Only **Check the box and provide information below for clinic shipments** (if applicable, for initial doses)

☐ Ship to clinic address below. The Specialty Pharmacy will contact the prescriber/clinic to coordinate shipment.

Clinic Point of Contact	Clinic Point-of-Contact Phone	Clinic Point-of-Contact Email

Shipping Address	State	ZIP Code

Special Delivery Instructions

Patient's Full Name*	Date of Birth*

PRESCRIBER

Prescriber's Last Name*	Prescriber's First Name*	Prescriber's Specialty: ☐ Genetics ☐ Internal Medicine ☐ Other (please specify)	
Office/Site/Clinic*		Office Contact	Office Contact's Phone Number
Phone Number*	Fax Number*	Email	
Street Address*			
City*		State License Number	
State*	ZIP Code*	Medicaid Number	
NPI Number*		Tax ID	

PRESCRIPTION

Please complete either right or left treatment sections for each row

Instructions: Please check box for each dose prescribed

Recommended Dosing for PALYNZIQ® (pegvaliase-pqpz) Injection Therapy				Customized Dosing for PALYNZIQ® (pegvaliase-pqpz) Injection Therapy			
Treatment	**PALYNZIQ Prescription**	**Quantity**	**Refills**	**Treatment**	**PALYNZIQ Prescription**	**Quantity**	**Refills**
Induction/ Titration	☐ Inject 2.5 mg (0.5 mL) SubQ • Once weekly for 4 weeks, then • Twice weekly for 1 week	6 2.5 mg (0.5 mL)	Not Applicable	Induction/ Titration	☐ Inject _____ mg SubQ Frequency _____		
Titration	☐ Inject 10 mg (0.5 mL) SubQ • Once weekly for 1 week, then • Twice weekly for 1 week, then • Four times a week for 1 week, then • Once daily for 1 week	14 10 mg (0.5 mL)	Not Applicable	Titration	☐ Inject _____ mg SubQ Frequency _____		
Maintenance	☐ Inject 20 mg (1 mL) SubQ • Daily for a minimum of 24 weeks	30 20 mg (1 mL)	5	Maintenance	☐ Inject _____ mg SubQ Frequency _____		
Maintenance	☐ Inject 40 mg (2 × 20 mg [(1 mL]) SubQ • Daily for a minimum of 16 weeks	60 20 mg (1 mL)	3	Maintenance	☐ Inject _____ mg SubQ Frequency _____		
Maximum	☐ Inject 60 mg (3 × 20 mg [1 mL]) SubQ • Daily for a maximum of 16 weeks	90 20 mg (1 mL)	3	Maximum	☐ Inject _____ mg SubQ Frequency _____		

Bridge Prescription†

☐ **Check the box for Sonexus Health Pharmacy to dispense a bridge fill for prescriptions if needed.**

†Bridge prescription is at no cost, for eligible patients within labeled indication only, and not contingent on purchase of any kind. Bridge prescription is intended to support continuation of prescribed therapy if there is a delay in insurance coverage determination. By checking the box for bridge prescription above, I, as the prescriber, with my signature below on this form, agree and attest that I will not submit a claim to or seek payment from the patient or any third-party payer (e.g., Medicaid, Medicare, private insurance, etc.) for payment/reimbursement for any free product(s) provided by BioMarin. I agree and understand that any free product provided by BioMarin may not be sold, traded, bartered, transferred, or returned for credit and will only be used for the patient named above on this form. BioMarin reserves the right to modify or terminate the program without notice at any time.

Patient Allergies ☐ **NKDA**

Auto-Injectable Epinephrine Prescription Confirmation*

Patient has possession of auto-injectable epinephrine? ☐ Yes ☐ No

If no, auto-injectable epinephrine prescription will be filled as follows (check one):

☐ At local retail pharmacy (prescription given to patient) ☐ At Specialty Pharmacy (attached to this prescription)

Ancillary Supplies—Specialty Pharmacy will confirm patient need for all selected ancillary supplies prior to each shipment

☐ Sharps Container ☐ Alcohol Wipes ☐ Gauze ☐ Band-Aids ☐ Gloves (latex free)

Premedication Prescriptions: If applicable, please make a selection below.

Will patient require additional premedication prescriptions? ☐ Yes ☐ No

Premedication prescriptions will be filled as follows (check one):

☐ At local retail pharmacy (prescription given to patient) ☐ At Specialty Pharmacy (attached to this prescription)

Special Delivery Instructions

PRESCRIBER DECLARATION

Prescriber Declaration: I understand and agree that, as the prescriber, I will comply with my state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Non-compliance with state-specific requirements could result in outreach to me, as the prescriber. I verify that the patient and prescriber information contained in this enrollment form is complete and accurate to the best of my knowledge and that I have prescribed PALYNZIQ based on my professional judgment of medical necessity. I authorize BioMarin Pharmaceutical Inc., its affiliates, agents, and contractors (collectively, "BioMarin") to act on my behalf for the limited purposes of transmitting this prescription to the appropriate pharmacy designated by the above-named patient utilizing their benefit plan. I also authorize the BioMarin RareConnections™ program to perform any steps necessary to secure reimbursement for PALYNZIQ, including but not limited to insurance verification and case assessment. I understand that BioMarin or BioMarin RareConnections may need additional information, and I agree to provide it as needed for the purposes of securing reimbursement.

Prescriber's Signature. Please make a selection*

Prescriber's Signature/Dispense as Written (no stamps or initials) Date	Prescriber's Signature/Substitution Permitted (no stamps or initials) Date

Palynziq®
(pegvaliase-pqpz) Injection

GETTING YOUR PATIENT STARTED WITH PALYNZIQ

PALYNZIQ® (pegvaliase-pqpz) Injection is only available via Specialty Pharmacy by using the PALYNZIQ BioMarin RareConnections™ Patient Enrollment Form

Complete the PALYNZIQ BioMarin RareConnections Patient Enrollment Form in its entirety and fax both pages to 1.888.863.3361

Every effort is made to limit the number of calls to your office. Please ensure that:

- All fields are complete
- Patient has signed a BioMarin RareConnections Patient Authorization Form (PAF)
- Prescription information is complete
- For all dose adjustments after the initial PALYNZIQ Patient Enrollment Form has been completed, a new prescription or verbal prescription is needed
- Attach all additional prescriptions to this document if Specialty Pharmacy is to fill

Upon receipt of the completed PALYNZIQ BioMarin RareConnections Patient Enrollment Form, BioMarin RareConnections will help to confirm coverage with your patient's health plan

BioMarin RareConnections may contact your office via phone, fax, or email to:

- Obtain any required information that was left off the PALYNZIQ BioMarin RareConnections Patient Enrollment Form
- Obtain additional information required by insurance companies

Please advise your patient that a Specialty Pharmacy will be calling to help coordinate delivery of the PALYNZIQ prescription

- The Specialty Pharmacy will contact your patient/clinic to obtain a verbal confirmation of the delivery address prior to mailing the medication
- The Specialty Pharmacy will confirm patient need for all selected ancillary supplies prior to each shipment
- The Specialty Pharmacy will verify REMS* clinic certification and patient enrollment prior to each shipment
- Premedication will require a separate prescription if the Specialty Pharmacy is to fill prescription
- Auto-Injectable Epinephrine prescription will be needed if Specialty Pharmacy is to fill prescription

RECOMMENDED DOSING REGIMEN

TREATMENT	PALYNZIQ DOSAGE	DURATION†
Induction	2.5 mg once weekly	4 weeks
Titration	2.5 mg twice weekly	1 week
	10 mg once weekly	1 week
	10 mg twice weekly	1 week
	10 mg four times per week	1 week
	10 mg once daily	1 week
Maintenance‡	20 mg once daily	24 weeks
	40 mg once daily	16 weeks
Maximum§	60 mg once daily	16 weeks

*REMS: Risk Evaluation and Mitigation Strategy.
†Additional time may be required prior to each dosage escalation based on patient tolerability.
‡Individualize treatment to the lowest effective and tolerated dosage. Consider increasing to 40 mg once daily in patients who have not achieved a response with 20 mg once daily continuous treatment for at least 24 weeks. Consider increasing to a maximum of 60 mg once daily in patients who have not achieved a response with 40 mg once daily continuous treatment for at least 16 weeks *(see Clinical Studies [14] section of Prescribing Information)*.
§Discontinue PALYNZIQ in patients who have not achieved an adequate response after 16 weeks of continuous treatment at the maximum dosage of 60 mg once daily.