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

Fax completed form with prescriber's signature to **1.888.863.3361**
To learn more about BioMarin RareConnections™ call **1.833.PKU.CARE** (1.833.758.2273), **hours M–F, 8 AM–8 PM (ET)**

Palynziq® (pegvaliase-pqpz) Injection

All required fields are purple and bolded

PATIENT

First Name	Middle Initial	**Last Name**	Suffix
Date of Birth (mm/dd/yyyy)	**Gender** ☐ Male ☐ Female ☐ Other		
Address			Floor/Suite/ Unit
City		**State**	**ZIP Code**
Primary Phone	Mobile Phone ☐ (same as primary)	**Email**	
Preferred Method of Contact ☐ Primary Phone ☐ Mobile Phone ☐ Email		**Preferred Language:** ☐ English ☐ Spanish ☐ Other language (please specify)	
Authorized Representative Name (if applicable)			Relationship to Patient
Phone		Email	

PRESCRIBER

First Name		**Last Name**	
Specialty		**NPI Number**	
State License Number	**Medicaid Number**	**Tax ID**	
Name of Institution/Practice			
Address			Floor/Suite/Unit
City		**State**	**ZIP Code**
Phone	**Fax**	**Email**	
Preferred Method of Contact ☐ Phone ☐ Fax ☐ Email			
Primary Contact Name (if different from prescriber)			
Phone	Fax	Email	

INSURANCE

Provide copies of all medical and prescription cards — front and back

☐ Patient has no insurance

Primary Medical Insurance Name			**Insurance Phone**
Subscriber Name		**Relationship to Patient**	
Member ID	**Group**	**Plan Code**	
Prescription (PBM) Insurance Name			**Insurance Phone**
Subscriber Name			
Member ID	**RxBIN**	**RxPCN**	**RxGROUP**

Patient's Full Name	Date of birth (mm/dd/yyyy)

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

Patient allergies

☐ NKDA ☐ Yes (please list)

Concurrent medications

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 _____		

Auto-Injectable Epinephrine Prescription Confirmation*

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

If no, please check one:

☐ Auto-injectable epinephrine prescription given to patient or sent to retail pharmacy ☐ Specialty Pharmacy to fill prescription as follows:

Auto-injectable Epinephrine #2 pack ☐ 0.15 mg (15 kg–30 kg) ☐ 0.3 mg (≥ 30 kg) **Refills:** _____

Inject IM as needed for anaphylaxis reaction. Call for emergency medical support upon use. May repeat ×1 in 5 to 15 minutes if symptoms persist.

Ancillary Supplies—Specialty Pharmacy will provide the following items to patients on first dispense and as needed thereafter: **Sharps Container, Alcohol wipes and Band-Aids.**

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

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

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 Consent Form (PCF)
- 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 via this form or sent separately 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.

PATIENT CONSENT FORM

To learn more about BioMarin RareConnections™
call 1.866.906.6100, hours M–F, 8 AM–8 PM (ET)

References to "you," "your," "I," "me," "my," etc. in this form are to the patient, even if an authorized representative is signing this form on the patient's behalf.

FOR BIOMARIN TO ASSIST YOU WITH ITS MEDICINES AND RELATED CARE, YOU WILL NEED TO PROVIDE CONSENT TO BOTH YOUR HEALTHCARE PROVIDER AND BIOMARIN:

- Your healthcare provider needs your written consent to release your protected health information (PHI) to BioMarin
- BioMarin needs your written consent to share your information with service providers such as laboratories and pharmacies to assist you with accessing services that support your treatment
- BioMarin needs your consent to contact you with marketing and other communications about BioMarin's products, services, programs, and other topics of interest for marketing, educational, or other purposes; to assist you in getting help through additional services that support your treatment plan; and to allow you to provide feedback to BioMarin through market research
- As described below, your consent is voluntary and is not required for treatment, medications, or other care. Your consent is required for BioMarin to provide the product support services described here

SECTION A: CONSENT TO SHARE HEALTH INFORMATION FOR PATIENT SUPPORT SERVICES

By signing this Patient Consent Form (PCF), I hereby authorize my healthcare providers, health insurance carriers, laboratory providers, and pharmacy providers (collectively, Healthcare Entities) to use and disclose my individual health and identifying information, including but not limited to health insurance information, medical diagnosis and condition (including but not limited to laboratory test results such as diagnostic results as well as test results related to diagnosis or supportive testing), prescription information, and name, date of birth, sex, address, and telephone number to BioMarin and its agents and representatives, including but not limited to third parties authorized by BioMarin. I further authorize BioMarin to use my individual health and identifying information to administer the patient support program through BioMarin RareConnections™ and BioMarin's Clinical Coordinator Program and for the following additional purposes:

- to contact my healthcare provider and collect, enter, and maintain my health information in a database;
- to contact my insurers as needed to verify my insurance coverage, review reimbursement requirements, verify other financial assistance for which I might be eligible, assist with the processing of claims, or otherwise assist in obtaining coverage or financial assistance for my treatment, including but not limited to in relation to post-administration monitoring;
- to determine eligibility for program offerings, including but not limited to financial assistance services; and
- to contact me to follow up on any BioMarin RareConnections enrollment requirements, receive education, discuss and provide information and education on my treatment and any follow-up requirements, discuss the effectiveness of support services, and provide support services, education, and adherence reminders such as to take my BioMarin medication. BioMarin Clinical Coordinators do not work under the direction of your healthcare provider or give medical advice. BioMarin Clinical Coordinators are trained to direct patients to their healthcare provider for treatment-related advice

Once my health information has been disclosed to BioMarin, I understand that federal privacy laws no longer protect the information. However, BioMarin agrees to protect my health information by using and disclosing it only for purposes authorized in this PCF or as required by law or regulations. California residents, to learn more about the information BioMarin may collect about you, how we use that information, and your rights under the California Consumer Privacy Act (CCPA), please review our CCPA Privacy Policy, available at biomarin.com/data-privacy-center.
I understand that pharmacy providers, or others working on their behalf, may receive remuneration from BioMarin in exchange for the health information and/or for any therapy support services provided.

This PCF expires in ten (10) years, or such shorter amount of time required by applicable state law, after the date I sign it as indicated by the date next to my signature, unless otherwise canceled earlier as set forth below. I understand I have a right to receive a copy of this PCF.

I understand that I may refuse to sign this PCF. I further understand that my treatment (including with a BioMarin product), payment for treatment, insurance enrollment, or eligibility for insurance benefits are not conditioned upon my agreement to sign this PCF, but if I do not sign it, or if I later cancel it, I will not be able to receive BioMarin's therapy support services.

I understand that I may cancel this PCF at any time by mailing a letter to BioMarin at BioMarin RareConnections at 680 Century Point, Lake Mary, FL 32746 or emailing support@biomarin-rareconnections.com. Canceling this PCF will end my consent for my Healthcare Entities to further disclose my health information to BioMarin after they are notified of my cancellation but will not affect previous disclosures by them pursuant to this PCF. Canceling this PCF will not affect my ability to receive treatment, payment for treatment, or my eligibility for health insurance.

SECTION B: CONSENT FOR MARKETING/OTHER COMMUNICATIONS

By signing this Patient Consent Form (PCF), I hereby authorize my Healthcare Entities to use and disclose my individual health and identifying information to BioMarin for marketing purposes or to otherwise provide me with information about BioMarin products, services, research, clinical trials, and programs or other topics of interest, and to conduct market research or otherwise ask me about my experience with or thoughts about such topics. I understand and agree that BioMarin and companies working with BioMarin may use my individual health and identifying information to contact me by mail, email, fax, telephone call, or text message for these purposes. I understand and agree that any information that I provide may be used by BioMarin to help develop new products, services, and programs. I further understand that BioMarin will not sell or transfer my personal data to any unrelated third party for marketing purposes without my express permission.

SECTION C: BIOMARIN CO-PAY ASSISTANCE PROGRAM ELIGIBILITY

The BioMarin Co-Pay Assistance Program pays for eligible out-of-pocket costs, where applicable, associated with a qualifying BioMarin therapy up to a maximum amount per calendar year. The program is valid ONLY for qualifying patients residing in the 50 U.S. states or in Puerto Rico, where not prohibited by law, with commercial insurance who have a valid prescription for an FDA-approved indication for the qualifying BioMarin therapy. By participating in the program, patients acknowledge that they understand and agree to comply with the complete program terms and conditions available at BioMarin-RareConnections.com or on request by contacting BioMarin RareConnections at 1.866.906.6100.

1 To authorize your consent, please complete all fields below.

Patient's First Name _____ Middle Initial _____ Patient's Last Name _____ Suffix _____ Date of Birth _____ Gender ☐ Male ☐ Female ☐ Other

Patient's/Authorized Representative's Name (if applicable) _____ Relationship to Patient _____

Patient's/Authorized Representative's Address _____ Floor/Suite/Unit _____ City _____ State _____ ZIP Code _____

Preferred Method of Contact (please specify) ☐ Primary Phone _____

☐ Mobile Phone (leave blank if mobile is primary phone) _____ ☐ Email _____

Preferred Language ☐ English ☐ Spanish ☐ Other Language (please specify) _____

2 Please read and sign below.

I have read and understand Section A in this PCF, the Consent to Share Health Information for Patient Support Services, and agree to the terms stated therein. A consent signature is required in order to receive BioMarin services.

Patient's/Authorized Representative's Signature _____ Date _____

Print Authorized Representative's Name (if applicable) _____ Relationship to Patient _____

3 Please read and sign below.

I have read and understand Sections B and C in this PCF, the Consent for Marketing/Other Communications and the Co-Pay Assistance Program Eligibility, and agree to the terms stated therein.

Patient's/Authorized Representative's Signature _____ Date _____

Print Authorized Representative's Name (if applicable) _____ Relationship to Patient _____

Print and fax your completed form (both pages) to 1.888.863.3361.

Note for healthcare providers: once your patient has completed this form, provide a copy to them and place the original in the patient's medical record.

BIOMARIN

BIOMARIN Rare Connections™