



Patient Enrollment Form for PALYNZIQ® (pegvaliase-pqqz) 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**



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

| | | | | | |
|----------------|---|--|---|-------------------------|--|
| PATIENT | Patient's Last Name* | | Patient's First Name* | | |
| | Date of Birth* | | Gender* <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Other | | |
| | Street Address* | | Parent's/Guardian's Name (if applicable) | | |
| | City* | | State* | ZIP Code* | |
| | Preferred Method of Contact (please specify)* | | | | |
| | <input type="checkbox"/> Cell Phone <input type="checkbox"/> Home Phone <input type="checkbox"/> Work Phone | | | | |
| | <input type="checkbox"/> Email | | | | |
| | Language Preferred: <input type="checkbox"/> English <input type="checkbox"/> Other language (please specify) | | | | |
| | Alternate Contact Name | | | Relationship to Patient | |
| | Phone | | Email | | |

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|------------------|---|----------|--------------------------|----------|
| INSURANCE | Please complete the following* or attach copies of the insurance and prescription benefit cards, front and back. <input type="checkbox"/> Insurance card copies attached <input type="checkbox"/> 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 | |

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|---------------------------|--|--|--------------------------|--|
| DIAGNOSIS/CLINICAL | Diagnosis ICD-10-CM* | | Baseline Blood Phe Level | |
| | <input type="checkbox"/> Classical Phenylketonuria (PKU) E70.0 <input type="checkbox"/> Other Hyperphenylalaninemias E70.1 <input type="checkbox"/> Other diagnosis (<i>please specify</i>) _____ | | 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 | | | |

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|-------------------------------|--|--|-------------------------------|-------------------------------|----------|
| LOGISTICS | For Clinic Shipments Only Check the box and provide information below for clinic shipments (if applicable, for initial doses) | | | | |
| | <input type="checkbox"/> 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 | | | | | |

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|-----------------------------|-----------------------|
| Patient's Full Name* | Date of Birth* |
|-----------------------------|-----------------------|

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|-------------------|--------------------------------|---------------------------------|---|-------------------------------|
| PRESCRIBER | Prescriber's Last Name* | Prescriber's First Name* | Prescriber's Specialty: <input type="checkbox"/> Genetics <input type="checkbox"/> Internal Medicine <input type="checkbox"/> 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 | |

| | | | | | | | | |
|--|--|---|----------------------|----------------|--|--|-----------------|----------------|
| Please complete either right or left treatment sections for each row | | | | | | | | |
| Instructions: Please check box for each dose prescribed | | | | | | | | |
| PRESCRIPTION | Recommended Dosing for PALYNZIQ® (pegvaliase-pqqz) Injection Therapy | | | | Customized Dosing for PALYNZIQ® (pegvaliase-pqqz) Injection Therapy | | | |
| | Treatment | PALYNZIQ Prescription | Quantity | Refills | Treatment | PALYNZIQ Prescription | Quantity | Refills |
| | Induction/Titration | <input type="checkbox"/> 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 | <input type="checkbox"/> Inject _____ mg SubQ Frequency _____ | | |
| | Titration | <input type="checkbox"/> 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 | <input type="checkbox"/> Inject _____ mg SubQ Frequency _____ | | |
| | Maintenance | <input type="checkbox"/> Inject 20 mg (1 mL) SubQ • Daily for a minimum of 24 weeks | 30 20 mg (1 mL) | 5 | Maintenance | <input type="checkbox"/> Inject _____ mg SubQ Frequency _____ | | |
| | Maintenance | <input type="checkbox"/> Inject 40 mg (2 x 20 mg [1 mL]) SubQ • Daily for a minimum of 16 weeks | 60 20 mg (1 mL) | 3 | Maintenance | <input type="checkbox"/> Inject _____ mg SubQ Frequency _____ | | |
| Maximum | <input type="checkbox"/> Inject 60 mg (3 x 20 mg [1 mL]) SubQ • Daily for a maximum of 16 weeks | 90 20 mg (1 mL) | 3 | Maximum | <input type="checkbox"/> Inject _____ mg SubQ Frequency _____ | | | |
| Bridge Prescription† | | | | | | | | |
| <input type="checkbox"/> 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 | | | | | | <input type="checkbox"/> NKDA | | |
| Auto-Injectable Epinephrine Prescription Confirmation* | | | | | | | | |
| Patient has possession of auto-injectable epinephrine? <input type="checkbox"/> Yes <input type="checkbox"/> No | | | | | | | | |
| If no, auto-injectable epinephrine prescription will be filled as follows (check one): | | | | | | | | |
| <input type="checkbox"/> At local retail pharmacy (prescription given to patient) <input type="checkbox"/> At Specialty Pharmacy (attached to this prescription) | | | | | | | | |
| Ancillary Supplies—Specialty Pharmacy will confirm patient need for all selected ancillary supplies prior to each shipment | | | | | | | | |
| <input type="checkbox"/> Sharps Container <input type="checkbox"/> Alcohol Wipes <input type="checkbox"/> Gauze <input type="checkbox"/> Band-Aids <input type="checkbox"/> Gloves (latex free) | | | | | | | | |
| Premedication Prescriptions: If applicable, please make a selection below. | | | | | | | | |
| Will patient require additional premedication prescriptions? <input type="checkbox"/> Yes <input type="checkbox"/> No | | | | | | | | |
| Premedication prescriptions will be filled as follows (check one): | | | | | | | | |
| <input type="checkbox"/> At local retail pharmacy (prescription given to patient) <input type="checkbox"/> At Specialty Pharmacy (attached to this prescription) | | | | | | | | |
| Special Delivery Instructions | | | | | | | | |

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|---|---|--|
| 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 | |

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.