CVS caremark™ {{PANUMCODE}}

Palynziq

Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-866-249-6155**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-866-814-5506.** For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

The recipient of this fax may make a request to opt-out of receiving telemarketing fax transmissions from CVS Caremark. There are numerous ways you may opt-out: The recipient may call the toll-free number at 877-265-2711, at any time, 24 hours a day/7 days a week. The recipient may also send an opt-out request via email to do_not_call@cvscaremark.com. An opt out request is only valid if it (1) identifies the number to which the request relates, and (2) if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within thirty days of receipt.

Patient's Name: {{MEMFIRST}} {{MEMLAST}}
Patient's ID {{MEMBERID}}
Physician's Name: {{PHYFIRST}} {{PHYLAST}}
Specialty: _____,
Physician Office Telephone: {{PHYSICIANPHONE}}
Request Initiated For: {{DRUGNAME}}

Date: {{TODAY}}
Patient's Date of Birth: {{MEMBERDOB}}

NPI#: _____
Physician Office Fax: {{PHYSICIANFAX}}

1. What is the diagnosis?
   ❑ Phenylketonuria (PKU)
   ❑ Other _____
2. What is the ICD-10 code? _____
3. Is this request for continuation of therapy with the requested product? ❑ Yes ❑ No *If No, skip to #5*
4. Is the patient currently receiving the requested product through samples or a manufacturer's patient assistance program? ❑ Yes ❑ No ❑ Unknown
5. The preferred product for your patient's health plan is Kuvan. Can the patient's treatment be switched to the referred product? ***If Yes, please call 1-866-814-5506 to have the updated form faxed to your office OR you may complete the PA electronically (ePA). You may sign up online via CoverMyMeds at: www.covermymeds.com/epa/caremark/ or call 1-866-452-5017.*** ❑ Yes ❑ No
6. Does the patient have a documented inadequate response or intolerable adverse event to treatment with the preferred product (Kuvan)? ***ACTION REQUIRED: If 'Yes', attach supporting chart note(s) and skip to #8.*** ❑ Yes ❑ No
7. Does the patient have a documented phenylalanine hydroxylase (PAH) deleterious genotype with two null-alleles? ***ACTION REQUIRED: If 'Yes', attach supporting chart note(s).*** ❑ Yes ❑ No *If No, complete this form in its entirety and State Step Therapy section.*
8. Was the diagnosis confirmed by a blood phenylalanine concentration greater than 600 micromol/L or genetic testing? ***ACTION REQUIRED: If 'Yes', attach supporting chart note(s).*** ❑ Yes ❑ No

Complete the following section based on new starts or continuation of therapy requests.

Section A: New Starts

9. Prior to initiation of the requested medication, what was the patient's baseline blood phenylalanine (Phe) concentration? _____ micromol/L ❑ No baseline blood Phe concentration

Send completed form to: Case Review Unit CVS Caremark Prior Authorization Fax: 1-866-249-6155

Section B: Continuation of Therapy

10. Has the patient achieved a clinical response as evidenced by blood phenylalanine concentration of less than or equal to 600 micromol/L? *If Yes, no further questions* ❑ Yes ❑ No

11. Has the patient been titrated to the maximum dose of 60 mg once daily?
If No, no further questions ❑ Yes ❑ No

12. Has the patient received continuous treatment with Palynziq for at least 16 weeks at the maximum dose of 60 mg once daily? ❑ Yes ❑ No

State Step Therapy

1. Is the requested drug being used for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)? ❑ Yes ❑ No

2. Does the prescribed quantity fall within the manufacturer's published dosing guidelines or within dosing guidelines found in the compendia of current literature (examples: package insert, AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)? ❑ Yes ❑ No

3. Does the patient reside in Maryland? ❑ Yes ❑ No *If No, skip to #7*

4. Is the alternate drug (Kuvan) FDA-approved for the medical condition being treated?
❑ Yes ❑ No *If No, no further questions.*

5. Has the prescriber provided proof, documented in the patient's chart notes, indicating that the requested drug was ordered for the patient in the past 180 days? ❑ Yes ❑ No *If No, skip to #7*

6. Has the prescriber provided proof, documented in the patient chart notes, that in their opinion the requested drug is effective for the patient's condition? ❑ Yes ❑ No *No further questions*

7. Are any of the following conditions met for the alternate drug (Kuvan)? *If Yes, indicate below and no further questions.*
❑ The alternate drug is contraindicated
❑ The alternate drug is likely to cause an adverse reaction, physical or mental harm
❑ The alternate drug is expected to be ineffective
❑ The alternate drug was previously tried or a drug in the same class or with the same action was previously tried and was stopped due to ineffectiveness or an adverse event
❑ The alternate drug is not in the patient's best interest
❑ The alternate drug was tried while covered by the current or the previous health benefit plan
❑ None of the above, *continue to #8*

8. Is the patient stable or currently receiving a positive therapeutic outcome with the requested drug and a change in the prescription drug is expected to be ineffective or cause harm to the patient? ❑ Yes ❑ No

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X_____

Prescriber or Authorized Signature **Date (mm/dd/yy)**

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