BioMarin Patient and Physician Support (BPPS) Enrollment Forms

for

KUVAN

KUVAN®
(sapropterin dihydrochloride) Tablets

BPPS
BioMarin Patient & Physician Support

Instructions

for Completing Statement of Medical Necessity (SMN) and Prescription for KUVAN

If you need assistance with the attached form, please contact:

BioMarin Patient and Physician Support (BPPS)
E-mail: bpps@BMRN.com
P: 1-877-MY-KUVAN (1-877-695-8826), F: 1-888-863-3361 or 1-415-520-0548
BPPS hours of operation: M–F, 7AM–4 PM (PT)

1) Patient Information

Complete all sections: patient name, parent/guardian name (if applicable), mailing address, date of birth, sex, preferred method of contact, daytime/evening phone numbers, alternate phone number (if applicable), e-mail address, and language preference.

2) Insurance Information

Complete all sections for primary and secondary (if applicable) prescription benefits: check the type of plan the patient currently has, and indicate insurance name, phone number, subscriber, relationship to patient, group ID, member ID, and employer. Please also attach a copy of the front and back of the insurance card to this SMN.

3) Medical Information and Statement of Medical Necessity

Complete primary diagnosis and the section stating the medically necessary reason for prescribing KUVAN. Check the boxes that apply to your patient and add any additional comments as necessary. Also indicate whether any medication allergies exist.

4) Prescription

Please ensure that you complete all areas of the prescription legibly, accurately, and completely. Fill in the current weight section—please note that the weight should be reported in kilograms. Ensure that you have indicated the total dose in mg/kg body weight: select 10 mg/kg, 20 mg/kg, or fill in the "other" mg/kg dosing schedule. Indicate the number of days you are prescribing, the number of tablets and mg per day, and any refills that are available to the patient. Mark the patient directions and shipping instructions that you prefer. Please sign and date the form to make the prescription valid. **A prescription cannot be processed without a prescriber's full signature (no stamps or initials).**

5) Prescriber Declaration

Please review, sign, and date the declaration.

6) Prescriber Information

Complete all sections: prescriber's full name, office/site/clinic name, office contact (if different from prescriber), address, phone/fax numbers, e-mail, license number, DEA number, Medicaid number, tax ID, and NPI number.

7) Fax both pages of the completed SMN to BPPS at 1-888-863-3361 or 1-415-520-0548.

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Statement of Medical Necessity and Prescriptions

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Fax completed form with prescriber's signature to **1-888-863-3361** or **1-415-520-0548.**

PATIENT INFORMATION

Patient Name:	Date of Birth:	Sex: ☐ Male ☐ Female
Parent/Guardian Name (*if applicable):*		
Street Address:		Suite/Floor/Apt:
City:	State:	Zip:
Home Phone:	Work Phone:	Cellular/Other Phone:
E-mail Address:		Preferred Method of Contact: ☐ E-mail ☐ Phone *circle one*: **Home** | **work** | **other**
Language Preferred: ☐ English ☐ Spanish ☐ Other:		

INSURANCE INFORMATION – Please attach copies of the insurance card – front and back

☐ **Patient has no known coverage for prescription drugs**

PRIMARY PRESCRIPTION BENEFIT			
☐ HMO	☐ PPO	☐ Medicaid/CHIPs	☐ Other
Primary Insurance Name:			
Insurance Phone Number:			
Subscriber:			
Relationship to Patient:			
Member ID:	Group ID:		
Employer:			

SECONDARY PRESCRIPTION BENEFIT			
☐ HMO	☐ PPO	☐ Medicaid/CHIPs	☐ Other
Secondary Insurance Name:			
Insurance Phone Number:			
Subscriber:			
Relationship to Patient:			
Member ID:	Group ID:		
Employer:			

MEDICAL INFORMATION & STATEMENT OF MEDICAL NECESSITY

Primary Diagnosis (For ICD-9-CM other than 270.1, please contact BPPS)

ICD-9-CM	AMA Description
☐ 270.1	Phenylketonuria (PKU), includes hyperphenylalaninemia

Prolonged elevated blood phenylalanine (Phe) levels can result in severe neurologic damage, including severe mental retardation, microcephaly, delayed speech, seizures, and behavioral abnormalities.

I am prescribing KUVAN for this patient, and find it medically necessary for the following reasons (check all that apply):

☐ I want to reduce Phe levels in this patient. ☐ Other:

Additional Comments:

Any known medication allergies? ☐ No ☐ Yes If Yes please list:

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Statement of Medical Necessity and Prescriptions

for KUVAN (Page 2 of 2)

PATIENT NAME: _____

Patient Date of Birth: _____

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E-mail: bpps@BMRN.com | Phone: **1-877-MY-KUVAN (1-877-695-8826)**
BPPS hours of operation: M–F, 6AM-5PM (PST)
Fax completed form with prescriber's signature to **1-888-863-3361** or **1-415-520-0548.**

Please Complete BOTH Prescriptions Below:

STARTER Prescription Only		
Product Name: *KUVAN, 100 mg Tablets*	NDC Number: 68135-0300-02	
Current Weight: kg	Dose per Kg Body Weight: ☐ 10 mg/kg ☐ 20 mg/kg ☐ Other mg/kg	Number of Days/Rx: 30 days
Number of Tablets per Day:	Number of Mg per Day:	Number of Refills: 0
Patient Directions (check all that apply): ☐ **Please contact your physician before starting use of this medication.** ☐ Take tablets once daily with food. ☐ Other:	**Shipping Instructions** (check if applicable): ☐ Dispensing pharmacy to notify prescriber when initial shipment is scheduled.	
Prescriber's Full Signature:		Date:
(No Stamps or Initials) (If you are a New York Prescriber, Please use an original New York State Prescription Form) ☐ Dispense as Written ☐ Substitution permitted		

Prescription (For Use by In-Network Specialty Pharmacy)		
Product Name: *KUVAN, 100 mg Tablets*	NDC Number: 68135-0300-02	
Current Weight: kg	Dose per Kg Body Weight: ☐ 10 mg/kg ☐ 20 mg/kg ☐ Other mg/kg	Number of Days/Rx: 30 day
Number of Tablets per Day:	Number of Mg per Day:	Number of Refills: 12
Patient Directions (check all that apply): ☐ **Please contact your physician before starting use of this medication.** ☐ Take tablets once daily with food. ☐ Other:	**Shipping Instructions** (check if applicable): ☐ Dispensing pharmacy to notify prescriber when initial shipment is scheduled.	
Prescriber's Full Signature:		Date:
(No Stamps or Initials) (If you are a New York Prescriber, Please use an original New York State Prescription Form) ☐ Dispense as Written ☐ Substitution permitted		

Prescriber Information		
Prescriber's Full Name:		
Office/Site/Clinic:	Office Contact:	
Phone:	Fax:	Email:
Address:		
Address:		
City	State:	Zip:
License Number:	DEA Number:	Medicaid Number:
Tax ID:	NPI Number:	

Prescriber Declaration

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 KUVAN based on my professional judgment of medical necessity. I authorize BioMarin or its affiliated companies or subcontractors to forward this prescription electronically, by facsimile, or by mail to a dispensing pharmacy chosen by the above-named patient. I also authorize the BPPS program to perform any steps necessary to obtain reimbursement for KUVAN, including but not limited to insurance verification and case assessment. I understand that BPPS may need additional information, and I agree to provide it as needed for the purposes of reimbursement.

Prescriber's Full Signature:	Date:

(No Stamps or Initial)

Instructions

for Patient Authorization to Share Health Information for Treatment With KUVAN

BioMarin Pharmaceutical Inc. created BioMarin Patient and Physician Support (BPPS) to help you with case management and to work with your insurance provider to try to help you get coverage, reimbursement, or payment for KUVAN. You will not be charged any money for any BPPS services. BPPS will make every effort to get reimbursement but cannot guarantee that it can find ways to pay for your medicine. You can learn more about these programs by contacting BPPS by phone at 1-877-MY-KUVAN (1-877-695-8826) or by e-mail at bpps@BMRN.com. The BPPS hours of operation are Monday through Friday from 7 AM to 4 PM (PT).

In order to receive help from BPPS, you will need to sign the Authorization. By signing this form, you are allowing BPPS to use your Protected Health Information (PHI) related to elevated blood phenylalanine (Phe) levels to work on your case.

Also, your PHI may be used to contact you about opportunities to share your experience with taking KUVAN or to receive periodic information about phenylketonuria (PKU) treatment. Please check the appropriate box(es) on the Authorization based on your wishes, and initial and date this information.

You do not have to sign this form. However, if you choose not to sign this form, BPPS will not be able to provide support for you.

Authorization

What information about me will be disclosed or used?

This Authorization allows my healthcare providers, health plans, and health insurers to give my PHI, including medical records related to elevated blood Phe levels, and financial and insurance coverage information to BPPS. BPPS may share this information in writing or verbally with others as it works on my case. I have the right to see and request corrections to the PHI that is shared with BPPS.

Who is authorized to disclose my PHI?

Healthcare providers, health plans, health insurers, or others who may have my PHI related to my elevated blood Phe levels may share any information connected to getting treatment coverage and medical or other related services.

Who will get my PHI?

The PHI described in this form may be given to and used by BPPS and BioMarin, a biopharmaceutical manufacturer located at 105 Digital Drive, Novato, CA 94949, and its agents, contractors, or assignees. People who work for BioMarin or BPPS may use and see my information, but only for the purpose and terms on this form. All reasonable attempts will be made to keep this information private and confidential, but if it is accidentally shared with others, it may no longer be protected under state and federal privacy laws. BioMarin and BPPS strive to keep all PHI confidential.

How long will my permission last?

This Authorization will last for 10 years after the date that I sign this form. If I change my mind at any time and want to stop sharing my information, I can send BPPS a signed letter that states I do not want my personal information to be shared with BPPS. I understand that if I tell BPPS in writing to stop using my PHI, it will not change any actions BPPS took before I told it to stop. I also understand that if I stop sharing this information, BPPS will not be able to help with my prescriptions for KUVAN, and BPPS will not contact me except to let me know that it received my letter to stop this Authorization.

There is no penalty for choosing not to give my authorization.

I do not have to sign this form. If I choose not to sign this form, BPPS will not be able to provide support to me. If I choose not to share PHI with BPPS, I will not lose any rights or benefits that I may have had before I read this form or made my decision.

How will my PHI be used?

My PHI may be used by BPPS to:

a) help me get coverage, reimbursement, or payment for KUVAN;
b) track the use of KUVAN and provide this information to my healthcare providers upon request;
c) improve BPPS and other BioMarin programs; and
d) contact me about opportunities to share my experience with taking KUVAN.

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Patient Authorization
to Share Health Information for Treatment With KUVAN

I have read and understand the terms of this Authorization. I have asked all my questions about the use and disclosure of my Protected Health Information (PHI) and I am satisfied with the answers. I understand that BioMarin Patient and Physician Support (BPPS) does not in any way promise that it can find ways to pay for medically necessary products and services, and I know that I may have to pay for the costs of my care. By signing this form, I knowingly and voluntarily authorize the use and/or disclosure of my health information as described and agree that a copy or a facsimile of this form may be treated as a signed original.

I will be given a copy of the Authorization that I sign.

_____

Print Patient's Name

_____ _____

Signature of Patient (or Guardian) Date

_____ _____

Print Guardian's Name Relationship to Patient

_____ _____

Patient's/Guardian's Street Address Telephone Number

_____ _____

City, State, Zip Code E-mail Address

Best Time/Way to Contact Patient _____

Please check all that apply:

- ❑ I give my permission to be contacted about opportunities to share my experience with the medicine KUVAN.
- ❑ I give my permission to receive periodic information about PKU treatment.

Date _____ Initials _____

Please fax original to BPPS at 1-888-863-3361 or 1-415-520-0548.

Provide a copy of this form to the patient and place the original in patient's medical record.

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Matching Proven Science With Proven Needs