

# Statement of Medical Necessity and Prescriptions for KUVAN® (sapropterin dihydrochloride) Tablets or Powder for Oral Solution (Page 1 of 2)

KUVAN Therapy: **Tablet** ☐ **Powder** ☐

For assistance, please contact BioMarin RareConnections™.  
E-mail: [support@biomarin-rareconnections.com](mailto:support@biomarin-rareconnections.com) Phone: **1.877.MY.KUVAN** (1.877.695.8826)  
BioMarin RareConnections™ hours of operation: M–F, 6AM–5PM (PST)  
Fax completed form with prescriber's signature to **1.888.863.3361**

## PATIENT INFORMATION - Please fill out completely

Patient Name:		Date of Birth:	Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female
Parent/Guardian Name (if applicable):			
Street Address:		Suite/Floor/Apt:	
City:		State:	Zip Code:
Complete and Check Preferred Method of Contact	Email Address:		
Home Phone:	Work Phone:	Cell/Other Phone:	
Language Preferred: <input type="checkbox"/> English <input type="checkbox"/> Spanish <input type="checkbox"/> Other:			

## INSURANCE INFORMATION - Please attach copies of the insurance card, front and back

☐ **PATIENT HAS NO INSURANCE COVERAGE**

### PRIMARY INSURANCE

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

### SECONDARY INSURANCE

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

## MEDICAL INFORMATION & STATEMENT OF MEDICAL NECESSITY - Please fill out completely

### PRIMARY DIAGNOSIS

Short Description	ICD-9-CM	ICD-10-CM	Baseline Phe Levels (Before Trial):
<input type="checkbox"/> Classical Phenylketonuria (PKU)	270.1	E70.0	
<input type="checkbox"/> Other Hyperphenylalanemias (include additional specificity, if applicable)	270.1	E70.1	
<b>(For ICD-9-CM other than 270.1 or ICD-10-CM other than E70.0 and E70.1, please contact BPPS)</b>			

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:

Patient allergies? ☐ No Known ☐ Known

If Known allergies please list: \_\_\_\_\_

Please list the names of other medications the patient is currently taking: ☐ None

Please list Medications: \_\_\_\_\_

**KUVAN®**  
(sapropterin dihydrochloride)  
Tablets or Powder for Oral Solution

**BiOMARIN**  
**Rare**  
**Connections™**

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# Statement of Medical Necessity and Prescriptions for KUVAN® (sapropterin dihydrochloride) Tablets or Powder for Oral Solution (Page 2 of 2)

PATIENT NAME: \_\_\_\_\_

PATIENT DATE OF BIRTH: \_\_\_\_\_

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PROVIDERS, PLEASE COMPLETE **BOTH** PRESCRIPTIONS BELOW:

## STARTER AND KUVAN PATIENT ASSISTANCE PROGRAM PRESCRIPTION (K-PAP) For use by PAP Pharmacy only

### BIOMARIN WILL PROVIDE A TRIAL SUPPLY OF KUVAN FOR UP TO 30 DAYS.

Refills are for Kuvan Patient Assistance Program (K-PAP) only if necessary. A patient may be uninsured and still seek access to KUVAN (sapropterin dihydrochloride) Tablets/Powder.

Dose per kg Body Weight: <input type="checkbox"/> 10 mg/kg <input type="checkbox"/> 20 mg/kg <input type="checkbox"/> Other _____ mg/kg		Current Weight: _____ kg
Number of mg per Day:	Number of Days Supply/Rx: <input type="checkbox"/> 30 days <input type="checkbox"/> 90 days	Number of Refills: 12
<input type="checkbox"/> KUVAN, <b>Tablet 100 mg</b> / Number of <b>100 mg Tablets</b> per Day: _____ ( NDC Number: 68135-300-02 )		
<input type="checkbox"/> KUVAN, <b>Powder 100 mg</b> / Number of <b>100 mg Powder</b> Packets per Day: _____ ( NDC Number: 68135-301-11 )		
<input type="checkbox"/> KUVAN, <b>Powder 500 mg</b> / Number of <b>500 mg Powder</b> Packets per Day: _____ ( NDC Number: 68135-482-10 )		
Patient Directions (check all that apply): <input type="checkbox"/> Please contact your physician before starting use of this medication. <input type="checkbox"/> Take _____ 500mg (powder) and _____ 100mg (powder) once daily, as directed, with meal, for a total dose of _____ mg/day <input type="checkbox"/> Take _____ 100mg (tablet) once daily as directed, with meal, for a total dose of _____ mg/day <input type="checkbox"/> Other: _____		Shipping Instructions (check if applicable): <input type="checkbox"/> Dispensing pharmacy to notify prescriber when initial shipment is scheduled.
_____ <input type="checkbox"/> Signature/ Substitution permitted _____ Date		_____ <input type="checkbox"/> Signature/ Dispense as written _____ Date

(No Stamps or Initials) (If you are a New York Prescriber, Please use an original New York State Prescription Form)

## PRESCRIPTION (For Use by In-Network Specialty Pharmacy)

Dose per kg Body Weight: <input type="checkbox"/> 10 mg/kg <input type="checkbox"/> 20 mg/kg <input type="checkbox"/> Other _____ mg/kg		Current Weight: _____ kg
Number of mg per Day:	Number of Days Supply/Rx: <input type="checkbox"/> 30 days <input type="checkbox"/> 90 days	Number of Refills: 12
<input type="checkbox"/> KUVAN, <b>Tablet 100 mg</b> / Number of <b>100 mg Tablets</b> per Day: _____ ( NDC Number: 68135-300-02 )		
<input type="checkbox"/> KUVAN, <b>Powder 100 mg</b> / Number of <b>100 mg Powder</b> Packets per Day: _____ ( NDC Number: 68135-301-11 )		
<input type="checkbox"/> KUVAN, <b>Powder 500 mg</b> / Number of <b>500 mg Powder</b> Packets per Day: _____ ( NDC Number: 68135-482-10 )		
Patient Directions (check all that apply): <input type="checkbox"/> Please contact your physician before starting use of this medication. <input type="checkbox"/> Take _____ 500mg (powder) and _____ 100mg (powder) once daily, as directed, with meal, for a total dose of _____ mg/day <input type="checkbox"/> Take _____ 100mg (tablet) once daily as directed, with meal, for a total dose of _____ mg/day <input type="checkbox"/> Other: _____		Shipping Instructions (check if applicable): <input type="checkbox"/> Dispensing pharmacy to notify prescriber when initial shipment is scheduled.
_____ <input type="checkbox"/> Signature/ Substitution permitted _____ Date		_____ <input type="checkbox"/> Signature/ Dispense as written _____ Date

(No Stamps or Initials) (If you are a New York Prescriber, Please use an original New York State Prescription Form)

## PRESCRIBER INFORMATION - Please fill out completely

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:	
<b>Prescriber Declaration</b> 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 (REQUIRED): (No Stamps or Initials)		Date:



(sapropterin dihydrochloride)  
Tablets or Powder for Oral Solution

### Indication

KUVAN® (sapropterin dihydrochloride) Tablets for Oral Use and Powder for Oral Solution are approved to reduce blood Phe levels in people with a certain type of Phenylketonuria (PKU). KUVAN is to be used with a Phe-restricted diet.

### Important Safety Information

It is not possible to know if KUVAN will work for you without a trial of the medicine. Your doctor will check your blood Phe levels when you start taking KUVAN to see if the medicine is working.

Starting KUVAN does not eliminate the need for ongoing dietary management. Any change to your diet may impact your blood Phe level. Follow your doctor's instructions carefully. Your doctor and dietitian will continue to monitor your diet and blood Phe levels throughout your treatment with KUVAN **to make sure your blood Phe levels are not too high or too low**. If you have a fever, or if you are sick, your Phe level may go up. Tell your doctor and dietitian as soon as possible so they can make any necessary changes to your treatment.

Children younger than 7 years old treated with KUVAN doses of 20 mg/kg per day are at an increased risk for low levels of blood Phe compared with children 7 years and older. Frequent blood monitoring is recommended in this population to ensure that blood Phe levels do not fall too low.

Tell your doctor if you have ever had liver or kidney problems, have poor nutrition or have a loss of appetite, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed.

KUVAN is a prescription medicine and should not be taken by people who are allergic to any of its ingredients. KUVAN and other medicines may interact with each other. Tell your doctor about **all the medicines you take**, including prescription and over-the-counter medicines, vitamins, herbal and dietary supplements.

If you forget to take your dose of KUVAN, take it as soon as you remember that day. Do not take 2 doses in a day. If you take too much KUVAN, call your doctor for advice.

The most common side effects reported when using KUVAN are headache, runny nose and nasal congestion, sore throat, diarrhea, vomiting, and cough. Additional adverse reactions reported in connection with worldwide marketing include sore throat, heartburn or pain in the esophagus, inflammation of the lining of the stomach, indigestion, stomach pain, and nausea. These are not all the possible side effects seen with KUVAN. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1.800.FDA.1088.

KUVAN can cause serious side effects, including:

- **Severe allergic reactions.** Stop taking KUVAN and **get medical help right away** if you develop any of these symptoms of a severe allergic reaction:

- |                                 |                               |
|---------------------------------|-------------------------------|
| ◦ Wheezing or trouble breathing | ◦ Nausea                      |
| ◦ Flushing                      | ◦ Lightheadedness or fainting |
| ◦ Coughing                      | ◦ Rash                        |

- **Inflammation of the lining of the stomach (gastritis).** Gastritis can happen with KUVAN and may be severe.

**Call your doctor right away if you have any:**

- |  |                                |
|--|--------------------------------|
| ◦ Severe upper stomach-area discomfort or pain | ◦ Blood in your vomit or stool |
| ◦ Black, tarry stools                          | ◦ Nausea and vomiting          |

- **Too much or constant activity (hyperactivity) can happen with KUVAN.** Tell your doctor if you have any signs of hyperactivity, including fidgeting, moving around or talking too much.

For more information, call BioMarin RareConnections™ at 1.866.906.6100.

Please read the full Patient Information at <http://www.kuvan.com/patients/kuvan-patient-information.html>