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

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

For assistance, please contact BioMarin Patient and Physician Support (BPPS).
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**.

PATIENT INFORMATION - Please fill out completely

Patient Name:	Date of Birth:	Sex: ☐ Male ☐ 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: ☐ English ☐ Spanish ☐ 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
☐ Classical Phenylketonuria (PKU)	270.1	E70.0
☐ Other Hyperphenylalanemias (include additional specificity, if applicable)	270.1	E70.1

(For ICD-9-CM other than 270.1 or ICD-10-CM other than E70.0 and E70.1, please contact BPPS)

Baseline Phe Levels (Before Trial): _____

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

BPPS
BioMarin Patient & Physician Support

Statement of Medical Necessity and Prescriptions for KUVAN® (sapropterin dihydrochloride) Tablets for Oral Use 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

ALL PATIENTS RECEIVE A FREE 30-DAY STARTER SUPPLY OF KUVAN.

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: ☐ 10 mg/kg ☐ 20 mg/kg ☐ Other _____ mg/kg		Current Weight: kg
Number of mg per Day:	Number of Days Supply/Rx: ☐ 30 days ☐ 90 days	Number of Refills: 12
☐ KUVAN, ***Tablet 100 mg*** / Number of **100 mg Tablets** per Day:	(NDC Number: 68135-300-02)	
☐ KUVAN, ***Powder 100 mg*** / Number of **100 mg Powder** Packets per Day:	(NDC Number: 68135-301-11)	
☐ KUVAN, ***Powder 500 mg*** / Number of **500 mg Powder** Packets per Day:	(NDC Number: 68135-482-10)	

Patient Directions (check all that apply):
- ☐ Please contact your physician before starting use of this medication.
- ☐ Take _____ 500mg (powder) and _____ 100mg (powder) once daily, as directed, with meal, for a total dose of _____ mg/day
- ☐ Take _____100mg (tablet) once daily as directed, with meal, for a total dose of _____ mg/day
- ☐ Other: _____

Shipping Instructions (check if applicable):
- ☐ Dispensing pharmacy to notify prescriber when initial shipment is scheduled.

_____	_____	_____	_____
☐ Signature/ Substitution permitted	Date	☐ 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: ☐ 10 mg/kg ☐ 20 mg/kg ☐ Other _____ mg/kg		Current Weight: kg
Number of mg per Day:	Number of Days Supply/Rx: ☐ 30 days ☐ 90 days	Number of Refills: 12
☐ KUVAN, ***Tablet 100 mg*** / Number of **100 mg Tablets** per Day:	(NDC Number: 68135-300-02)	
☐ KUVAN, ***Powder 100 mg*** / Number of **100 mg Powder** Packets per Day:	(NDC Number: 68135-301-11)	
☐ KUVAN, ***Powder 500 mg*** / Number of **500 mg Powder** Packets per Day:	(NDC Number: 68135-482-10)	

Patient Directions (check all that apply):
- ☐ Please contact your physician before starting use of this medication.
- ☐ Take _____ 500mg (powder) and _____ 100mg (powder) once daily, as directed, with meal, for a total dose of _____ mg/day
- ☐ Take _____100mg (tablet) once daily as directed, with meal, for a total dose of _____ mg/day
- ☐ Other: _____

Shipping Instructions (check if applicable):
- ☐ Dispensing pharmacy to notify prescriber when initial shipment is scheduled.

_____	_____	_____	_____
☐ Signature/ Substitution permitted	Date	☐ 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:		

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 (REQUIRED): *(No Stamps or Initials)*	Date: