

Saskatchewan Ministry of Health

Drug Plan and Extended Benefits Branch

Request for Kuvan®

Please submit the completed form and/or any additional relevant information by: fax to 306-798-1089, email to dp.sys.support@health.gov.sk.ca, mail to the Drug Plan and Extended Benefits Branch, 2nd floor, 3475 Albert Street, Regina, SK S4S 6X6, or phone at 306-787-3317 (in Regina) or toll-free at 1-800-667-7581.

This form is intended to facilitate the submission of requests for funding consideration. Additional documentation to support the request may be required. **Please ensure that all appropriate information for each section is provided to avoid delays.**

Section 1 – Prescriber Information			Section 2 – Patient Information		
First Name	Initial	Last Name	First Name	Initial	Last Name
Mailing Address Street No. Street Name			Saskatchewan Health Services Number		
City		Postal Code	Gender Male Female		
Treatment Centre			Body Weight (kg)		
Telephone No.	Fax No.		Date of Birth (yyyy/mm/dd) / /		
Email Address			New Request (Complete Section 4)		Renewal (Complete Section 5)

Section 3 – Drug Dosage and Regimen	
Drug Product: Kuvan® (sapropterin dihydrochloride)	DIN: 02350580
Dosage Form: 100mg tablets	Dose per Kg Body Weight: _____ mg/kg/day
Expected Treatment Start Date (yyyy/mm/dd): / /	

Section 4 – Clinical Information – Prior to Manufacturer Sponsored Trial (Maximum of 185 days of Kuvan Provided)	
<p>Inclusion Criteria: Patients must have a confirmed diagnosis of Phenylketonuria (PKU) and meet ALL of the following criteria.</p> <p>Non-pregnant patients and patients actively planning pregnancy:</p> <p>1. Compliance with low protein diet and formulas: Y N</p> <p>2. Blood Phe level > 360 µmol/l despite compliance with low protein diet over a 3-6 month timeframe:</p> <p>Phe level #1: _____ Date (yyyy/mm/dd): ____/____/____</p> <p>Phe level #2: _____ Date (yyyy/mm/dd): ____/____/____</p> <p>3. Baseline protein intake assessed by dietitian: Y N</p> <p>4. Ability to comply with medication regimen: Y N</p> <p>5. Managed by metabolic/biochemical physician Y N</p> <p>Pregnant Patients:</p> <p>1. Managed by metabolic/biochemical physician: Y N</p> <p>2. Baseline blood Phe level > 360 µmol/l despite compliance with all recommendations for dietary intervention & monitoring:</p> <p>Phe level: _____ Date (yyyy/mm/dd): ____/____/____</p>	<p>Exclusion Criteria: Patients will be excluded if they meet any of the following criteria.</p> <p>Known hypersensitivity to sapropterin dihydrochloride or any of its excipients: Y N</p> <p>Any other contraindications: Y N</p> <p>Women who are nursing/breastfeeding: Y N</p> <p>Not on low protein diet OR not compliant with diet: Y N</p>
<p>Test for Eligibility: 72 hour “Kuvan” Challenge (All Patients):</p> <p>Check appropriate box: Clinic Protocol Blood Phe levels measured at the following time points (hrs): T-48, T-24, T0, T4, T12, T24, T48 and T72</p> <p>Phe level (baseline) prior to Kuvan Challenge or T₀ (µmol/l): _____ Date (yyyy/mm/dd): ____/____/____</p> <p>Phe level at end of Kuvan Challenge (µmol/l): _____ Date (yyyy/mm/dd): ____/____/____</p> <p>Drop in Phe level (%): _____</p> <p>Dose of 20mg/kg/day given: Y N</p>	

Section 4 – Clinical Information

Baseline Assessments (pregnant patients excluded):

Date (yyyy/mm/dd): / /

Date (yyyy/mm/dd): / /

Date (yyyy/mm/dd): / /

Date (yyyy/mm/dd): / /

Assessment results/findings (please attach reports OR provide details):

- | | | | | |
|----|---|-----------------------------------|---|---|
| 1. | Compliance with low protein diet/formula/Kuvan: | | Y | N |
| 2. | Phe levels (provide 2 levels measured at least 1 month apart demonstrating sustained benefit from Kuvan): | | | |
| | Phe level (μmol/l): _____ | Date (yyyy/mm/dd): ____/____/____ | | |
| | Phe level (μmol/l): _____ | Date (yyyy/mm/dd): ____/____/____ | | |
| 3. | Increase in dietary protein tolerance based on target set between clinician and patient: | | Y | N |
| | Phe tolerance level at 1-2 months post baseline: _____ | Date (yyyy/mm/dd): ____/____/____ | | |
| | Phe tolerance level at 4-6 months post baseline: _____ | Date (yyyy/mm/dd): ____/____/____ | | |
| 4. | Did patient have a clinically meaningful age appropriate improvement in: | | | |
| a) | Neurocognitive/behavioural assessment test for ≥ 4 yrs of age (see attached report): | | Y | N |
| | Type of test: _____ | Date (yyyy/mm/dd): ____/____/____ | | |
| | OR | | | |
| b) | Developmental assessment test for children < 4 years of age (see attached report): | | Y | N |
| | Type of test: _____ | Date (yyyy/mm/dd): ____/____/____ | | |
| | OR | | | |
| c) | Quality of life assessment test (see attached report): | | Y | N |
| | Type of test: _____ | Date (yyyy/mm/dd): ____/____/____ | | |
| 5. | Managed by a metabolic/biochemical disease specialist: | | Y | N |

Initial 6 Month Assessment (pregnant patients only):

Phe level (μmol/l): _____ Date (yyyy/mm/dd): ____/____/____

Phe level ($\mu\text{mol/l}$): _____ Date (yyyy/mm/dd): ____/____/____

(NOTE: renewals will not be considered beyond end of pregnancy)

- | | | | | |
|----|---|-----------------------------------|---|---|
| 1. | Compliance with diet/formula/Kuvan: | | Y | N |
| 2. | Phe levels (provide 2 levels measured at least 1 month apart demonstrating sustained benefit from Kuvan): | | | |
| | Phe level (µmol/l): _____ | Date (yyyy/mm/dd): ____/____/____ | | |
| | Phe level (µmol/l): _____ | Date (yyyy/mm/dd): ____/____/____ | | |
| 3. | Maintenance in dietary protein tolerance based on target set between clinician and patient: | | Y | N |
| | Phe tolerance: _____ | Date (yyyy/mm/dd): ____/____/____ | | |
| 4. | Did patient maintain a clinically meaningful age appropriate improvement in: | | | |
| a) | Neurocognitive/behavioural assessment test (see attached report): | | Y | N |
| | Type of test: _____ | Date (yyyy/mm/dd): ____/____/____ | | |
| | OR | | | |
| b) | Developmental assessment test for children < 4 years of age (see attached report): | | Y | N |
| | Type of test: _____ | Date (yyyy/mm/dd): ____/____/____ | | |
| | OR | | | |
| c) | Quality of life assessment test (see attached report): | | Y | N |
| | Type of test: _____ | Date (yyyy/mm/dd): ____/____/____ | | |
| 5. | Managed by a metabolic/biochemical disease specialist: | | Y | N |

Prescriber's Signature (Mandatory)	Prescriber Number	Date (YYYY/MM/DD)
		/ /