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)

Inclusion Criteria:

Patients must have a confirmed diagnosis of Phenylketonuria (PKU) and meet ALL of the following criteria.

Non-pregnant patients and patients actively planning pregnancy:

1. Compliance with low protein diet and formulas: Y ☐ N ☐
2. Blood Phe level > 360 µmol/l despite compliance with low protein diet over a 3-6 month timeframe:

Phe level #1: _____ Date (yyyy/mm/dd): _____/_____/_____
Phe level #2: _____ Date (yyyy/mm/dd): _____/_____/_____

3. Baseline protein intake assessed by dietitian: Y ☐ N ☐
4. Ability to comply with medication regimen: Y ☐ N ☐
5. Managed by metabolic/biochemical physician Y ☐ N ☐

Pregnant Patients:

1. Managed by metabolic/biochemical physician: Y ☐ N ☐
2. Baseline blood Phe level > 360 µmol/l despite compliance with all recommendations for dietary intervention & monitoring:

Phe level: _____ Date (yyyy/mm/dd): _____/_____/_____

Exclusion Criteria:

Patients will be excluded if they meet any of the following criteria.

Known hypersensitivity to sapropterin dihydrochloride or any of its excipients: Y ☐ N ☐

Any other contraindications: Y ☐ N ☐

Women who are nursing/breastfeeding: Y ☐ N ☐

Not on low protein diet OR not compliant with diet: Y ☐ N ☐

Test for Eligibility: 72 hour "Kuvan" Challenge (All Patients):

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

Phe level (baseline) prior to Kuvan Challenge or T_0 (µmol/l): _____ Date (yyyy/mm/dd): _____/_____/_____
Phe level at end of Kuvan Challenge (µmol/l): _____ Date (yyyy/mm/dd): _____/_____/_____
Drop in Phe level (%): _____
Dose of 20mg/kg/day given: Y ☐ N ☐

Version 1 – June 2013

Section 4 – Clinical Information

Baseline Assessments (pregnant patients excluded):

Baseline Phe tolerance level: _____ Date (yyyy/mm/dd): _____/_____/_____
Neurocognitive/behavioural assessment test (for ≥ 4 yrs of age): _____ Date (yyyy/mm/dd): _____/_____/_____
Developmental assessment test (for children < 4 yrs of age): _____ Date (yyyy/mm/dd): _____/_____/_____
Quality of life assessment type: _____ Date (yyyy/mm/dd): _____/_____/_____
Assessment results/findings (please attach reports OR provide details):
_____
_____

Clinical Assessment After a Six Month Trial (pregnant patients excluded):

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

Section 5 – Clinical Information – Annual Renewal Request (pregnant patients excluded)

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)
		/ /