NOVA SCOTIA PROVINCIAL PHARMACARE PROGRAMS

Request for Insured Coverage of Sapropterin Dihydrochloride (Kuvan)

PATIENT INFORMATION

PATIENT SURNAME	PATIENT GIVEN NAME	HEALTH CARD NUMBER	DATE OF BIRTH

PATIENT ADDRESS

Ongoing funding of Kuvan will be considered for nonpregnant patients and patients actively planning pregnancy who have a diagnosis of Phenylketonuria (PKU) and who have demonstrated a response to the initial 6 month trial of sapropterin [reimbursed through the Supplier's Patient Support Program (PSP) 'BioMarin RareConnections']

For the management of patients with the diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) who meet **ALL** of the following criteria:

1. ☐ Nonpregnant patient (includes patients actively planning pregnancy)
2. ☐ Patient has met the inclusion criteria* and received an initial 6 month trial of sapropterin through the Supplier's PSP

   Kuvan Start Date: _____
3. ☐ Compliance with low protein diet, formulas, and Kuvan
4. ☐ During the 6 month trial period under the patient support program BioMarin RareConnections, patient has achieved a demonstrated response to the Kuvan responsiveness test or PKU clinical protocol, based on the following information:

   ☐ The clinic's definition for response; **AND**

   ☐ All relevant laboratory results used to determine that the patient was a responder to Kuvan
5. Patient meets **one** of the following:

   ☐ Normal sustained blood Phe levels [> 120 µmol/L and < 360 µmol/L] (At least 2 levels measured at least 1 month apart); **OR**

   ☐ Sustained blood Phe reduction of at least 30% (At least 2 levels measured at least 1 month apart) compared to baseline if the Phe baseline level is < 1200 µmol/L; **OR**

   ☐ Sustained blood Phe reduction of at least 50% (At least 2 levels measured at least 1 month apart) compared to baseline if the Phe baseline level is > 1200 µmol/L;
6. ☐ Demonstrated an increase in dietary protein tolerance based on targets set between the clinician and patient
7. ☐ Managed by a prescriber specialized in metabolic/biochemical diseases

* Please refer to the Formulary for full inclusion criteria for entry into the 6 month trial period

RENEWAL REQUEST

☐ Nonpregnant patient (includes patients actively planning pregnancy) **AND**

☐ Patient demonstrates ongoing response to treatment

PRESCRIBER NAME & ADDRESS:		
LICENCE #	PRESCRIBER SIGNATURE	DATE

If you need assistance, please contact the Pharmacare Office at (902) 496-7001 or 1-800-305-5026

Please Return Form To: Nova Scotia Pharmacare Programs
P.O. Box 500, Halifax, NS B3J 2S1, Fax: (902) 496-4440

NOVA SCOTIA