

## Prior Authorization Request

KUVAN (sapropterin) and generics

### Instructions

**Please complete Part A and have your physician complete Part B.** Completion and submission is not a guarantee of approval. Any fees related to the completion of this form are the responsibility of the plan member. Drugs in the Prior Authorization Program may be eligible for reimbursement if the patient does not qualify for coverage under a primary plan or a government program. Drugs used for indications not approved by Health Canada may be denied. For Quebec plan members, RAMQ exception drug criteria may apply. The decision for approval versus denial is based on pre-defined clinical criteria, primarily based on Health Canada approved indication(s) and on supporting evidence-based clinical protocols. The plan member will be notified whether their request has been approved or denied. Please note that you have the right to appeal the decision made by Express Scripts Canada.

### Part A – Patient

#### Patient information

First Name:		Last Name:	
Insurance Carrier Name/Number:			
Group Number:		Client ID:	
Date of Birth (YYYY/MM/DD):		Relationship: <input type="checkbox"/> Employee <input type="checkbox"/> Spouse <input type="checkbox"/> Dependent	
Language: <input type="checkbox"/> English <input type="checkbox"/> French		Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female	
Address:			
City:	Province:	Postal Code:	
Email address:			
Telephone (home):	Telephone (cell):	Telephone (work):	

#### Coordination of benefits

<b>Patient Assistance Program</b>	Is the patient enrolled in any patient assistance program? <input type="checkbox"/> Yes <input type="checkbox"/> No Contact Name: _____ Fax: _____
<b>Provincial Coverage</b>	Has the patient applied for reimbursement under a provincial plan? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A What is the coverage decision of the drug? <input type="checkbox"/> Approved <input type="checkbox"/> Denied <b><i>*Attach decision letter*</i></b>
<b>Primary Coverage</b>	Has the patient applied for reimbursement under a primary plan? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A What is the coverage decision of the drug? <input type="checkbox"/> Approved <input type="checkbox"/> Denied <b><i>*Attach decision letter*</i></b>

### Authorization

On behalf of myself and my eligible dependents, I authorize my group benefit provider, and its agents, to exchange the personal information contained on this form. I give my consent on the understanding that the information will be used solely for purposes of administration and management of my group benefit plan. This consent shall continue so long as my dependents and I are covered by, or are claiming benefits under the present group contract, or any modification, renewal, or reinstatement thereof.

\_\_\_\_\_  
Plan Member Signature

\_\_\_\_\_  
Date



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### Part B – Prescriber

Please see instructions on page 1 and complete all sections below. Incomplete forms may result in automatic denial. Please do **not** provide genetic test information or results.

#### SECTION 1 – DRUG REQUESTED

KUVAN (sapropterin) and generics		<input type="checkbox"/> New request	<input type="checkbox"/> Renewal request*
Dose	Administration (ex: oral, IV, etc)	Frequency	Duration
Site of drug administration:			
<input type="checkbox"/> Home	<input type="checkbox"/> Physician's office/Infusion clinic	<input type="checkbox"/> Hospital (outpatient)	<input type="checkbox"/> Hospital (inpatient)

\* Please submit proof of prior coverage if available

#### SECTION 2 – ELIGIBILITY CRITERIA

##### 1. Please indicate if the patient satisfies the below criteria:

##### Phenylketonuria

###### INITIAL

- ☐ For the treatment of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin-(BH4)-responsiveness phenylketonuria (PKU), AND
- ☐ The patient's blood Phe levels have reduced by 30% or greater after a 30-day trial on the KUVAN Start Program managed by Innomar Strategies Inc., AND
- ☐ KUVAN will be used along with a phenylalanine (Phe)-restricted diet

###### RENEWAL

- ☐ The patient has demonstrated compliance with a phenylalanine (Phe)-restricted diet, AND
- ☐ The patient has demonstrated normal blood Phe levels (greater than 120 µmol/L and less than 360 µmol/L), OR
- ☐ The patient has demonstrated a blood Phe reduction of at least 30% compared to baseline if the Phe baseline level was less than 1200 µmol/L, OR
- ☐ The patient has demonstrated a blood Phe reduction of at least 50% compared to baseline if the Phe baseline level was greater than 1200 µmol/L

##### OR

- ☐ None of the above criteria applies.

Relevant additional information:

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### 2. Please list previously tried therapies

Drug	Dosage and administration	Duration of therapy		Reason for cessation	
		From	To	Inadequate response	Allergy/Intolerance
				<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>

### SECTION 3 – PRESCRIBER INFORMATION

Physician's Name:	
Address:	
Tel:	Fax:
License No.:	Specialty:
Physician Signature:	Date:

**Please fax or mail the completed form to Express Scripts Canada®**

**Fax:** Express Scripts Canada Clinical Services  
1 (855) 712-6329

**Mail:** Express Scripts Canada Clinical Services  
5770 Hurontario Street, 10<sup>th</sup> Floor  
Mississauga, ON L5R 3G5