BRITISH COLUMBIA | Ministry of Health

SPECIAL AUTHORITY REQUEST
SAPROPTERIN

HLTH 5815 2022/08/29

○ **INITIAL - Complete sections 1 - 4**   ○ **RENEWAL - Complete sections 1 - 3, and 5**

For up-to-date criteria and forms, please check: www.gov.bc.ca/pharmacarespecialauthority

Fax requests to 1-800-609-4884 (toll free) OR mail requests to: PharmaCare, Box 9652 Stn Prov Govt, Victoria, BC V8W 9P4
This facsimile is doctor-patient privileged and contains confidential information intended only for PharmaCare. Any other distribution, copying or disclosure is strictly prohibited.

If PharmaCare approves this Special Authority request, approval is granted solely for the purpose of covering prescription costs. PharmaCare approval does not indicate that the requested medication is, or is not, suitable for any specific patient or condition.

If you have received this fax in error, please write MISDIRECTED across the front of the form and fax toll-free to 1-800-609-4884, then destroy the pages received in error.

Forms with information missing will be returned for completion. If no prescriber fax or mailing address is provided, PharmaCare will be unable to return a response.

SECTION 1 – SPECIALIST INFORMATION

Name and Mailing Address	
College ID (use ONLY College ID number)	Phone Number (include area code)
CRITICAL FOR A TIMELY RESPONSE →	Specialist's Fax Number

SECTION 2 – PATIENT INFORMATION

Patient (Family) Name	
Patient (Given) Name(s)	
Date of Birth (YYYY / MM / DD)	Date of Application (YYYY / MM / DD)
CRITICAL FOR PROCESSING →	Personal Health Number (PHN)

SECTION 3 – MEDICATION REQUESTED AND PATIENT WEIGHT

SAPROPTERIN
100 mg tablets, 100 mg or 500 mg sachet with powder for oral solution

9901-0367

Current Weight: ________________ **(kg)**
A maximum of 20 mg/kg per day will be approved for eligible patients.

Must be requested by a specialist in metabolic/biochemical diseases

SECTION 4 – CRITERIA FOR INITIAL COVERAGE: 6 MONTHS OR 1 YEAR AS BELOW

PharmaCare coverage is considered for the treatment of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin-responsive (BH4-responsive) phenylketonuria (PKU) in patients that meet the following criteria

Approval subject to patient having met ALL of the criteria below (mark boxes and complete blanks as applicable):

A. ☐ Confirmed diagnosis of phenylketonuria (PKU) AND managed by a physician specialized in metabolic/biochemical diseases

B. ☐ Adherence to low-protein diet and formulas AND baseline protein intake assessment by a dietitian

C. Please check applicable button and complete the following table:

○ Patient has baseline blood phenylalanine (Phe) levels > 360 µmol/L despite adherence to a low protein diet (requires at least 2 baseline levels during the preceeding 3 to 6 month time frame); coverage will be for 6 months **OR**

○ Patient is pregnant and has baseline blood phenylalanine (Phe) levels > 360 µmol/L despite adherence with all recommendations for dietary intervention and monitoring. Please note: only one level >360 µmol/L is required and coverage will be for 1 year.

BASELINE BLOOD LEVELS	LEVEL (µmol/L)	DATE (YYYY/ MM / DD)
Baseline level 1 (if pregnant only need 1 level)		
Baseline level 2		

D. ☐ Ability to adhere with medication regimen

Please complete additional information on page 2 >>

Patient (Family) Name	Patient (Given) Name(s)	Personal Health Number (PHN)

SECTION 5 – CRITERIA FOR RENEWAL: 1 YEAR

Approval subject to patient having met ALL of the criteria below (mark boxes and complete blanks as applicable):

A. ☐ Adherence to low protein diet and formulas and sapropterin AND followed by a dietitian and metabolic/biochemical diseases specialist

B. Patient's phenylalanine levels meet the treatment targets, demonstrated by at least 2 levels measured at least 1 month apart . Please check applicable button and fill in table:

◯ Normal sustained blood Phe levels < 360 µmol/L, **OR**

◯ Sustained blood Phe reduction of at least 30% compared to baseline if the Phe baseline level is < 1200 µmol/L, **OR**

◯ Sustained blood Phe reduction of at least 50% compared to baseline if the Phe baseline level is > 1200 µmol/L

	Phe Blood Levels	LEVEL (µmol/L)	DATE (YYYY/ MM / DD)
a.	Baseline level		
b.	Renewal level 1		
c.	Renewal level 2 (at least 1 month apart from Renewal level 1)		

C. ☐ Demonstrated increase of dietary protein tolerance based on targets set between the clinician and patient

SECTION 6 – ADDITIONAL COMMENTS

Report all adverse events to the post-market surveillance program, Canadian Vigilance, toll-free 1-866-234-2345 (health professionals only).

Personal information on this form is collected under the authority of, and in accordance with, the *British Columbia Pharmaceutical Services Act* 22(1) and *Freedom of Information and Protection of Privacy Act* 26 (a),(c),(e). The information is being collected for the purposes of (a) administering the PharmaCare program, (b) analyzing, planning and evaluating the Special Authority and other Ministry programs and (c) to manage and plan for the health system generally. If you have any questions about the collection of this information, call Health Insurance BC from Vancouver at 1-604-683-7151 or from elsewhere in BC toll free at 1-800-663-7100 and ask to consult a pharmacist concerning the Special Authority process.

I have discussed with the patient that the purpose of releasing their information to PharmaCare is to obtain Special Authority for prescription coverage and for the purposes set out here.

Metabolic/Biochemical Specialist Signature (Mandatory)

PharmaCare may request additional documentation to support this Special Authority request. Actual reimbursement is subject to the rules of a patient's PharmaCare plan, including any annual deductible requirement, and to any other applicable PharmaCare pricing policy.

PHARMACARE USE ONLY

STATUS	EFFECTIVE DATE (YYYY / MM / DD)	DURATION OF APPROVAL