

Prior Authorization, Pharmacy and Health Case Management Information

The purpose of this information sheet is to provide you with details on how Great-West Life will be assessing and managing your claim through our prior authorization, designated pharmacy and if applicable, health case management programs. Our programs are designed to support your involvement in treatment and achieving a positive health outcome. For this reason it's important for you to know what to expect throughout this process so that you can remain focused on your health.

Prior Authorization

Certain prescription drugs call for a more detailed assessment and management process to help ensure that they represent reasonable treatment. Prior authorization requires that you request approval from Great-West Life for coverage of certain prescription drugs.

In order for your claim to be considered, additional information from you and your physician is needed to help us determine whether:

- there are other medications that may be tried first to treat your medical condition;
- there are lower cost medications available that are considered to be a reasonable treatment for your medical condition; and
- coverage is available for the prescribed drug under other programs.

If approved, the effective date of coverage will be the date coverage was approved by Great-West Life. Requests for coverage prior to the approval date will be considered on an exception basis only.

Pharmacy Information

Some Great-West Life group benefit plans may require you to purchase a drug requiring prior authorization from a pharmacy designated by Great-West Life. If this is the case for your group benefit plan, you may choose from the designated pharmacy(ies) available based on location. If your claim is approved, a health case manager will contact your physician to provide information and, where applicable, provide a form so that your physician can forward your prescription to the designated pharmacy you have selected. By completing this form, you authorize Great-West to, where applicable, communicate your choice of designated pharmacy to your physician.

Health Case Management

Where health case management applies under the terms of your group benefits plan, a health case manager may be assigned to your claim during the prior authorization process and you will be expected to participate in the program.

A health case manager can provide valuable support and assistance and work closely with you and your physician during your treatment plan. This may include:

- working with you and your physician to understand different drug treatment options;
- assisting you in understanding and accessing available support programs such as patient assistance programs and any benefits or programs that may be available to you under your current benefit plan; and
- ongoing communication and follow-up throughout an approved coverage period to help assess the prescribed drug treatment plan.

We look forward to continuing to work with you and your physician.

Form Completion Instructions:

- 1. Print this information sheet and the attached Request for Information form;**
- 2. Complete Part 1 and Part 2 of the Request for Information form;**
- 3. Have your physician complete Part 3 of the Request for Information form;**
- 4. Send the completed Request for Information form to us by mail or fax to the address or fax number noted below and at the end of the form.**

Mail to: The Great-West Life Assurance Company
Drug Services
PO Box 6000
Winnipeg MB R3C 3A5

Fax to: The Great-West Life Assurance Company
Fax 1-204-946-7664
Attention: Drug Services

Request for Information: Pheburane (sodium phenylbutyrate)

The purpose of this form is to obtain information required to assess your drug claim. To be eligible for coverage, the drug must represent reasonable treatment of the disease or injury upon which your claim is based. Approval for coverage of this drug may be reassessed at any time at Great-West Life's discretion.

IMPORTANT: Please answer all questions. Your claim assessment will be delayed if this form is incomplete or contains errors.

Any costs incurred for the completion of this form are the responsibility of the plan member/patient.

Please print

Part 1 Plan Member Information		
Plan Member:	Patient Name:	
Plan Name:	Plan Number:	Plan Member I.D. Number:
Patient Date of Birth (DD/MM/YYYY):	Address (number, street, city, province, postal code):	
Home Phone Number: _____ Work Phone Number: _____		
Cell Phone Number: _____		
Please indicate preferred contact phone number and if there are any times when telephone contact with you about your claim would be most convenient.		
Would you prefer to receive correspondence by email? <input type="checkbox"/> Yes <input type="checkbox"/> No (Note that some correspondence may still need to be sent by regular mail).		
If yes, provide email address: _____		
Part 2a Coordination of Benefits		
Are you currently on, or have you previously been on Pheburane? <input type="checkbox"/> Yes <input type="checkbox"/> No		
If Yes, a) indicate start date: (DD/MM/YYYY) _____		
b) coverage provided by: _____		
(if coverage is not provided by Great-West Life please provide Pharmacy print out showing purchase of Pheburane)		
Have you applied for coverage or received any financial assistance or other support related to this drug:		
Under any group benefit plan? <input type="checkbox"/> Yes <input type="checkbox"/> No	If Yes, name of covered family member: _____	
	Relationship: _____	
	Name of Insurance Company: _____	
	Plan number: _____ Plan Member I.D. number: _____	
	Provide details and attach documentation of acceptance or declination: _____	
Under a provincial program or from any other source? <input type="checkbox"/> Yes <input type="checkbox"/> No	If Yes, name of program or other source: _____	
	Provide details and attach documentation of acceptance or declination: _____	
	If No, please explain why application has not been made: _____	
Under a patient assistance program? <input type="checkbox"/> Yes <input type="checkbox"/> No	If Yes, name of program(s): _____	
	Patient assistance program I.D. number: _____	
	Patient assistance program contact person name and phone number: Contact name: _____ Phone number: _____	
Are you currently receiving disability benefits for the condition for which this drug has been prescribed? <input type="checkbox"/> Yes <input type="checkbox"/> No		

(Continued on next page)

Part 2b Patient Assistance Program Information

Have you enrolled in the patient assistance program for Pheburane? Yes No

If Yes, please provide the following information:

1. Has a phone call between the patient assistance program, the plan member and Great-West Life occurred regarding coverage available through your group benefit plan? Yes No

2. Patient assistance program patient ID Number: _____

3. Patient assistance program contact person name and phone number:

Contact Name: _____ Phone Number: _____

At Great-West Life, we recognize and respect the importance of privacy. Personal information that we collect is used for the purposes of assessing eligibility for this drug and for administering the group benefits plan. For a copy of our Privacy Guidelines, or if you have questions about our personal information policies and practices (including with respect to service providers), refer to www.greatwestlife.com or write to Great-West Life's Chief Compliance Officer.

I authorize Great-West Life, any healthcare provider, my plan administrator, any insurance or reinsurance company, administrators of government benefits or patient assistance programs or other benefits programs, other organizations, or service providers working with Great-West Life or any of the above, located inside or outside Canada, to exchange personal information when relevant and necessary for these purposes. I understand that personal information may be subject to disclosure to those authorized under applicable law within or outside Canada.

I acknowledge that the personal information is needed to assess eligibility for this drug and to administer the group benefits plan. I acknowledge that providing my consent will help Great-West Life to assess my claim and that refusing to consent may result in delay or denial of my claim. This consent may be revoked by me at any time by sending written instruction to that effect.

I certify that the information given is true, correct, and complete to the best of my knowledge.

Plan Member's signature: _____ Date: _____

Please have Part 3 completed by your prescribing physician.

Attach extra information if necessary.

Part 3 Physician Information (to be completed for all conditions for which Pheburane has been prescribed) Note to Physician: In order to assess a patient's claim for this drug, we require detailed information on the patient's prescription drug history as requested below.	
Name of prescribing physician (please print): _____	
Specialty: _____	
Address (number, street, city, province, postal code): _____	
Telephone Number (including area code): _____	Fax Number (including area code): _____
<p>1. Health Canada approved indication (include date of initial diagnosis) (MM/YYYY): _____</p> <p><input type="checkbox"/> Urea Cycle Disorder</p> <p>Please specify patient's enzyme deficiency:</p> <p><input type="checkbox"/> Carbamoyl Phosphate Synthetase (CPS) deficiency</p> <p><input type="checkbox"/> Ornithine Transcarbamylase (OTC) deficiency</p> <p><input type="checkbox"/> Argininosuccinate Synthetase (ASS) deficiency</p> <p><input type="checkbox"/> Other (Approved by Health Canada): _____ and complete questions 2 - 6 and Part 3 Other condition (Health Canada approved)</p> <p>Do not provide genetic test results</p> <p>Is this drug being prescribed in accordance with approved Health Canada indications¹?</p> <p><input type="checkbox"/> Yes, complete questions 2 - 6 and Part 3</p> <p><input type="checkbox"/> No, condition not approved by Health Canada: _____ and complete questions 2 - 4 and Off-Label use</p> <p>Do not provide genetic test results</p>	
¹Approved Health Canada Indications and Clinical Use for Pheburane:	
<ul style="list-style-type: none"> • Adjunctive therapy in the chronic management of urea cycle disorders, involving deficiencies of carbamoyl phosphate synthetase, ornithine transcarbamylase or argininosuccinate synthetase. • Treatment of <i>Neonatal-onset</i> presentation (complete enzyme deficiencies, presenting within the first 28 days of life). • Treatment of late-onset disease (partial enzyme deficiencies, presenting after the first month of life) who have a history of hyperammonemic encephalopathy. 	
<p>2. Prescribed dosage and regimen:</p> <p><input type="checkbox"/> If patient weighs < 20kg: Pheburane _____ mg/kg/day</p> <p><input type="checkbox"/> If patient weighs ≥ 20kg: Pheburane _____ g/m²/day</p> <p><input type="checkbox"/> Other (please specify): _____</p> <p>Provide rationale: _____</p> <p>Patient's current weight: _____ kg</p> <p>Patient's current body surface area: _____ m²</p>	
<p>3. What is the anticipated duration of treatment with this drug? _____</p>	
<p>4. Where will treatment be administered (e.g. in hospital, in physician's office, in clinic, at home)? _____</p> <p>a) Name of facility: _____</p> <p>b) If this drug will be administered in a hospital, will the patient be treated as an <input type="checkbox"/> in-patient or <input type="checkbox"/> out-patient?</p>	

**Request for Information:
Pheburane (sodium phenylbutyrate)**

Part 3 continued

5. Please provide medical rationale why Pheburane has been prescribed instead of an alternate drug in the same therapeutic class. **Do not provide genetic test results.**

6. Drug(s) past and present	Dosing Regimen	Start Date (DD/MM/YYYY)	End Date (DD/MM/YYYY)	Patient response to treatment (if discontinued, provide details of intolerance, contraindication, or failure at maximum dose)

Initial Request – Do not provide genetic test results

Required documentation: Please ensure the following test results are included in the application.

- Enzyme analysis OR plasma amino acid / urine orotic acid analysis
- Baseline plasma ammonia level at diagnosis (prior to starting any nitrogen-binding agents)
- Baseline glutamate level at diagnosis (prior to starting any nitrogen-binding agents)
- Baseline fasting or random blood glucose level at diagnosis (prior to starting any nitrogen-binding agents)
- Current plasma ammonia level (within 3 months of request date)

Patient's baseline calculated anion gap at diagnosis (prior to starting any nitrogen-binding agents): _____ mEq/L

Date of result (DD/MM/YY): _____

1. Pheburane is being prescribed for:

- UCD in patients with *neonatal-onset* presentation (complete enzyme deficiencies, presenting within the first 28 days of life)

OR

- UCD in patients with *late-onset* disease (partial enzyme deficiencies, presenting after the first month of life) who have a history of hyperammonemic encephalopathy

2. Will Pheburane be used for the treatment of acute hyperammonemia? Yes No

3. Will Pheburane be used concomitantly with dietary protein restriction and/or dietary supplements (e.g. essential amino acids, arginine, citrulline, protein-free calorie supplements)? Yes No

4. Number of acute hyperammonemic episodes patient has experienced in the past 6 months:

Specify dates of episodes (DD/MM/YYYY): _____

**Request for Information:
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Renewals – Do not provide genetic test results

Required documentation: Please ensure the following test results are included in the application.

- Current plasma ammonia level (within 3 months of request date)
- Current glutamate level (within 3 months of request date)

Pheburane start date (DD/MM/YYYY): _____

Number of acute hyperammonemia episodes patient has experienced in the past 6 months: _____

Specify dates of episodes (DD/MM/YYYY): _____

Other condition (Health Canada approved) – Do not provide genetic test results

Please provide any relevant information related to the disease and attach supporting documentation .

Off-label use – Do not provide genetic test results

Is there evidence supporting the off-label use of this drug? Yes No

Provide clinical literature/studies to support the request for off-label use, such as:

- At least two Phase II or two Phase III clinical trials showing consistent results of efficacy; and
- Published recommendations in evidence-based guidelines supporting its use.

Provide medical rationale why Pheburane has been prescribed off-label instead of an alternate drug with an approved indication for this condition.

Provide any pertinent medical history or information to support this off-label request.

If this is a renewal request, provide documentation showing treatment efficacy since previous request.

Drug(s) past and present	Dosing Regimen	Start Date (DD/MM/YYYY)	End Date (DD/MM/YYYY)	Patient response to treatment (if discontinued, provide details of intolerance, contraindication, or failure at maximum dose)

**Request for Information:
Pheburane (sodium phenylbutyrate)**

Note for Physician: To be eligible for reimbursement, Great-West Life may require your patient to purchase a drug requiring prior authorization from a pharmacy designated by Great-West Life. If applicable, a health case manager will contact you with further information.

I certify that the information provided on this Part 3 is true, correct and complete.

Physician's signature: _____ Date: _____

License No.: _____

It is important to provide the requested information in detail to help avoid delay in assessing claims for the above drug. The completed Request for Information form can be returned to Great-West Life by mail or fax.

Mail to: The Great-West Life Assurance Company
Drug Services
PO Box 6000
Winnipeg MB R3C 3A5

Fax to: The Great-West Life Assurance Company
Fax 1-204-946-7664
Attention: Drug Services