



Drug Prior Authorization Form Pheburane (sodium phenylbutyrate)

The purpose of this form is to obtain information required to assess your drug claim.

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.

Canada Life recognizes and respects the importance of privacy. Personal information collected 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 Canada Life's personal information policies and practices (including with respect to service providers), refer to www.canadalife.com or write to Canada Life's Chief Compliance Officer.

I authorize Canada 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 Canada 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 consent will help Canada Life to assess my claim and that refusing to consent may result in delay or denial of my claim. Canada Life reserves the right to audit the information provided on this form at any time and this consent extends to any audit of my claim. This consent may be revoked by me at any time by sending written instruction to that effect.

I also consent to the use of my personal information for Canada Life and its affiliates' internal data management and analytics purposes.

If the patient is a person other than myself, I confirm that the patient has given their consent to provide their personal information and for Canada Life to use and disclose it as set out above.

I certify that the information given below is true, correct, and complete to the best of my knowledge. Failure to provide true, correct and complete information on this form could result in revocation of any approval decision, a requirement to repay paid claims or other appropriate action.

Plan Member's signature: _____

Date: _____

Form Completion Instructions:

1. Complete "Patient Information" sections.
2. Have the prescribing physician complete the "Physician Information" sections.
3. Send all pages of the completed form to us by mail, fax or email as noted below.

Note: As email is not a secure medium, any person with concerns about their prior authorization form/medical information being intercepted by an unauthorized party is encouraged to submit their form by other means.

Mail to: The Canada Life Assurance Company
Drug Claims Management
PO Box 6000
Winnipeg MB R3C 3A5

Fax to: The Canada Life Assurance Company
Fax 1-204-946-7664
Attention: Drug Claims Management

Email to: cldrug.services@canadalife.com
Attention: Drug Claims Management

For additional information regarding Prior Authorization and Health Case Management, please visit our Canada Life website at www.canadalife.com or contact Group Customer Contact Services at 1-800-957-9777. Deaf or hard of hearing and require access to a telecommunications relay service? Please contact us at 711 for TTY to Voice or 1-800-855-0511 for Voice to TTY.

(Continued on next page)

Patient Information Pheburane (sodium phenylbutyrate)

Plan Member Information – Complete all sections of this page (please print)

Plan Member:		Patient Name:	
Plan Name:	Plan Number:	Plan Member ID Number:	
Patient Date of Birth (DD/MM/YYYY):		Address (number, street, city, province, postal code):	

Please indicate preferred contact number and if there are any times when telephone contact with you about your claim would be most convenient.

May we contact you by email? (Note that some correspondence may still need to be sent by regular mail).

Yes No If yes, please provide email address: _____

Tell us if you have been on this drug before

Is the patient currently on, or previously been on this drug? Yes No

If Yes, a) indicate start date (DD/MM/YYYY): _____

b) coverage provided by: _____

(if coverage is not provided by Canada Life please provide pharmacy print-out showing purchase of this drug)

Tell us if you have coverage with any other benefits plan

Does the patient have drug coverage under any other group benefits plan? Yes No

If Yes, name of other Insurance Company: _____

If other plan is with Canada Life, tell us the plan and ID number: _____

Name of plan member: _____

Relationship to patient: _____

Provide details and attach documentation of acceptance or decline:

Tell us about any Provincial or other coverage you may have

Does the patient have coverage under a provincial program or from any other source? Yes No

If Yes, name of program or other source: _____

Provide details and attach documentation of acceptance or decline: _____

Is the patient currently receiving disability benefits for the condition for which this drug has been prescribed? Yes No

Tell us about any Patient Assistance Program you might be enrolled in

Has the patient enrolled in the patient assistance program for this drug? Yes No

If Yes, please provide the following information:

1. Patient assistance program patient ID Number: _____

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

Contact Name: _____ Phone Number: _____

Physician Information Pheburane (sodium phenylbutyrate)

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.

Attach extra information if necessary. **GENETIC TEST RESULTS ARE NOT REQUIRED**

Physician's Information (please print)

Name of prescribing physician: _____

Specialty: _____

Address (number, street, city, province, postal code): _____

Telephone Number (including area code): _____	Fax Number (including area code): _____
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1. Prescribed dosage and regimen:

- If patient weighs < 20kg: Pheburane _____ mg/kg/day
- If patient weighs ≥ 20kg: Pheburane _____ g/m²/day
- Other (please specify): _____
Provide rationale: _____
- Patient's weight: _____ kg (for weight-based dosing)
Date determined (MM/YYYY): _____
- Patient's current body surface area: _____ m²
Date determined (MM/YYYY): _____

2. Health Canada Indication (include date of initial diagnosis) (MM/YYYY): _____

- Urea Cycle Disorder
- Please specify patient's enzyme deficiency:
 - Carbamoyl Phosphate Synthetase (CPS) deficiency
 - Ornithine Transcarbamylase (OTC) deficiency
 - Argininosuccinate Synthetase (ASS) deficiency
- Other (approved by Health Canada): _____

Complete questions 1 – 6 and Other Condition (Health Canada approved)

Is this drug being prescribed in accordance with approved Health Canada indications¹?

- Yes, complete questions 1 – 6 and Physician's Information
- No, prescribed use is not approved by Health Canada: _____

Complete questions 1 – 6 and Off-label use

¹Approved Health Canada Indications and Clinical Use for Pheburane:

- Adjunctive therapy in the chronic management of urea cycle disorders, involving deficiencies of carbamylphosphate synthetase, ornithine transcarbamylase or argininosuccinate synthetase.
- Treatment of Neonatal-onset presentation (complete enzyme deficiencies, presenting within the first 28 days of life).
- Treatment of lateonset disease (partial enzyme deficiencies, presenting after the first month of life) who have a history of hyperammonemic encephalopathy.

Physician Information Pheburane (sodium phenylbutyrate)

Physician's Information (please print)

3. What is the anticipated duration of treatment with this drug? _____

4. Where will treatment be administered? Home Physician's Office Private clinic Hospital in-patient Hospital out-patient

5. Please provide medical rationale why this drug has been prescribed instead of an alternate drug in the same therapeutic class:

6. Drug and Treatment History – must be completed for every request.

Drug(s) and Treatment(s) past and present	Dosing Regimen	Start Date (DD/MM/YYYY)	End Date (DD/MM/YYYY)	Clinical Results/Outcome
				<input type="checkbox"/> Failure <input type="checkbox"/> Intolerance <input type="checkbox"/> Other Clinical details: _____ _____
				<input type="checkbox"/> Failure <input type="checkbox"/> Intolerance <input type="checkbox"/> Other Clinical details: _____ _____
				<input type="checkbox"/> Failure <input type="checkbox"/> Intolerance <input type="checkbox"/> Other Clinical details: _____ _____

Initial Request - Genetic test results are not required

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/YYYY): _____

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

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

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

Number of acute hyperammonemic episodes patient has experience in the past 6 months: _____

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

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Renewal Request - Genetic test results are not required

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 hyperammonemic episodes patient has experienced in the past 6 months: _____

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

Other condition (Health Canada approved) - Genetic test results are not required

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

Off-label use – Genetic test results are not required

Questions 1 – 6 must be completed.

Date of initial diagnosis (DD/MM/YYYY): _____

Is there clinical 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 this drug has been prescribed off-label instead of an alternative 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 efficacy since previous request.



Physician Information
Pheburane (sodium phenylbutyrate)

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

I certify that the information provided is true, correct, and complete.

Physician's Signature: _____ Date: _____

License Number: _____

It is important to provide the requested information in detail to help avoid delay in assessing claims for the above drug. This form may be subject to audit. The completed form can be returned to Canada Life by mail, fax, or email.

Note: As email is not a secure medium, any person with concerns about their prior authorization form/medical information being intercepted by an unauthorized party is encouraged to submit their form by other means.

Mail to: The Canada Life Assurance Company
Drug Claims Management
PO Box 6000
Winnipeg MB R3C 3A5

Fax to: The Canada Life Assurance Company
Fax 1-204-946-7664
Attention: Drug Claims Management

Email to: cldrug.services@canadalife.com
Attention: Drug Claims Management