

The purpose of this form is to obtain information required to assess your drug claim. For additional information regarding Prior Authorization and Health Case Management, please visit our Great-West Life website at [www.greatwestlife.com](http://www.greatwestlife.com).

**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.**

Great-West 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 Great-West Life's personal information policies and practices (including with respect to service providers), refer to [www.greatwestlife.com](http://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 consent will help Great-West Life to assess my claim and that refusing to consent may result in delay or denial of my claim. Great-West 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.

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 Great-West 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 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

**Email to:** [gwldrug.services@gwl.ca](mailto:gwldrug.services@gwl.ca)  
Attention: Drug Services

*(Continued on next page)*

**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 Ocaliva?  Yes  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 Ocaliva)

**Tell us if you have coverage with any other benefits plan**

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

If Yes, name of other Insurance Company: \_\_\_\_\_

If other plan is with Great-West Life, tell us the plan and ID number: \_\_\_\_\_

Name of plan member: \_\_\_\_\_

Relationship to patient: \_\_\_\_\_

**Provide details and attach documentation of acceptance or declination:**

\_\_\_\_\_  
\_\_\_\_\_

**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 declination: \_\_\_\_\_

Is the patient currently receiving disability benefits for the condition for which Ocaliva 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 Ocaliva?  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: \_\_\_\_\_

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**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:

- 5mg orally once daily
- 10mg orally once daily
- Other (please specify): \_\_\_\_\_  
Provide rationale: \_\_\_\_\_

Patient's weight \_\_\_\_\_ kg (for weight-based dosing)

Date determined (MM/YYYY): \_\_\_\_\_

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

- Primary Biliary Cholangitis  
Complete questions 1 - 6 and Physician's Information
- Other (approved by Health Canada): \_\_\_\_\_  
Complete questions 1 - 6 and Other condition (Health Canada approved)
- Other (prescribed use is not approved by Health Canada): \_\_\_\_\_  
Complete questions 1 - 6 and Off-label use

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 Ocaliva has been prescribed instead of an alternate drug in the same therapeutic class.

\_\_\_\_\_  
\_\_\_\_\_

**Physician's Information (continued) (please print)**

**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)	Details of Outcome
Ursodeoxycholic acid (UDCA)				<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: _____ _____
				<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: _____ _____

**Primary biliary cholangitis (PBC)**

Diagnosis has been confirmed by:

Biochemical evidence of cholestasis based on persistent Alkaline phosphatase (ALP) elevation equal or greater than 1.5 times upper limit of normal (ULN).  Yes  No

Presence of antimitochondrial antibodies (AMA) at a titre of 1:40 or higher.  Yes  No

Liver biopsy consistent with PBC.  Yes  No

Ocaliva is being prescribed in combination with ursodeoxycholic acid (UDCA).  Yes  No

Patient has had an inadequate biochemical response to (UDCA).  Yes  No

ALP is currently > 1.67 x upper limit of normal.  Yes  No

Patient is intolerant to (UDCA) and Ocaliva is being prescribed as monotherapy.  Yes  No

**Required results and reports for all initial applications**

Results and reports supportive of a diagnosis of primary biliary cholangitis (PBC)

Current ALP drawn within the previous 6 months

Current Bilirubin drawn within the previous 6 months

ALP Lab report ALP > 1.67 x upper limit of normal indicating an inadequate response to treatment with (UDCA)

**Renewal Request – Genetic test results are not required**

Start date of treatment (MM/YYYY): \_\_\_\_\_

**Lab reports must be submitted**

Current ALP U/L result \_\_\_\_\_ Date determined (DD/MM/YYYY): \_\_\_\_\_

Current total bilirubin \_\_\_\_\_ Date determined (DD/MM/YYYY): \_\_\_\_\_

**Other condition (Health Canada approved)**

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

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**Off-label use**

**Questions 1-6 must be completed.**

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 Ocaliva has been prescribed off-label instead of an alternate drug with an approved indication for this condition.

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

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

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**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 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 Great-West 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 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**

**Email to: [gwldrug.services@gwl.ca](mailto:gwldrug.services@gwl.ca)  
Attention: Drug Services**