



# Prior Authorization Request

BYLVAY (odevixibat)

## 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

BYLVAY (odevixibat) <span style="float: right;"><input type="checkbox"/> New request    <input type="checkbox"/> Renewal request*</span>			
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:

#### Progressive Familial Intrahepatic Cholestasis

##### INITIAL

- For the treatment of pruritis associated with progressive familial intrahepatic cholestasis (PFIC), AND
- The patient is 6 months of age or older, AND
- The patient has a serum bile acid level of 100 µmol/L or greater, AND
- The patient has a mean scratch score of 2 or greater, AND
- The patient has had an inadequate response or has a documented intolerance or contraindication to at least 2 systemic agents for symptomatic treatment of pruritis (*Please list prior therapies in the chart below*)

##### RENEWAL

- The patient has demonstrated at least a 70% reduction in fasting serum bile acid levels or a level of 70 µmol/L or less, OR
- The patient has demonstrated clinical improvement from baseline defined by a scratch score of 1 or less or at least a 1-point improvement on the 5-point ordinal response scale

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  
6985 Financial Drive, Suite 300  
Mississauga, ON, L5N 0G3