PRIOR AUTHORIZATION PROGRAM REIMBURSEMENT REQUEST FORM
For rare diseases: Ocaliva (obeticholic acid)

Please fax form to: 1-866-840-1509

Please note that the patient **AND** physician must complete this form. **All fields are mandatory and must be completed. Incomplete forms may result in your application being declined.** Please retain a copy of this form for your records.

Instructions:

1. **PLEASE PRINT CLEARLY AND COMPLETE ALL SECTIONS.**
2. The patient/plan member must complete section A.
3. Your physician must complete section B. The cost, if any, of completing this form is at the expense of the patient/plan member.
4. Please return the form to your insurance company via Pharmacy Services at TELUS Health (a service provider of your insurance company) by fax to **1-866-840-1509**.
5. If you have any questions on the application of this program or the decision on reimbursement, or to inquire on the status of your Reimbursement Request Form, please contact your insurer.

A. Information to be Completed by Patient

Employee or Insured's Name	Drug Card Number __ __ - __ __ __ __ __ __ - __ __ __ __ __ __ __ __ __ __ - __ __	
Patient's Name	Patient's Date of Birth (DD/MMM/YYYY) __ __ / __ __ __ / __ __ __ __	Relationship to Employee/Insured ❑Employee ❑Spouse ❑Dependent

Please allow two business days for a response once all information is received and complete.
Notification of the results of this request will occur Monday to Friday between 9 am and 4 pm Eastern Time.

Please provide contact information and indicate **ONE** method of preferred contact for notification of the results:

❑ E-mail me at:	❑ Call me (and leave a message if I'm not there) at:	❑ Fax me at:
❑ Contact my pharmacy: Pharmacy Name		Pharmacy Phone Number

I certify that the information provided by me is true, correct and complete to the best of my knowledge. I authorize my insurance company, TELUS Health (a service provider of my insurance company), their authorized representatives, agents and service providers to use and exchange this information needed for underwriting, administration and paying claims with any person or organization who has relevant information pertaining to this claim including health professionals, institutions and investigative agencies in the event of an audit. I authorize my insurance company and/or TELUS Health (a service provider of my insurance company) to contact any licensed physician, institution, pharmacy or person who has any records or knowledge of me or my health with respect to this submitted claim.

SIGNATURE OF PATIENT/PARENT/LEGAL GUARDIAN _____

Date: (DD/MMM/YYYY): __ __ / __ __ __ / __ __ __ __

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B. Information to be Completed by Prescribing Physician

Drug Name	Strength	Dose
Ocaliva (obeticholic acid)		

Ocaliva (obeticholic acid) will be eligible for reimbursement only if the patient satisfies the conditions listed below and if the patient does not qualify for coverage under any other drug plan or government mandated program. If the patient is covered under another drug plan or government mandated program, the prior authorization program, as part of your drug benefits, may cover the portion not paid for by the primary plan. If "None of the above criteria" is indicated, the patient will not be eligible for reimbursement. **For Quebec plan members, please refer to the RAMQ exception drug criteria, if applicable.**

Eligibility Criteria

Please indicate if the patient satisfies the following initial criteria:

Initial Criteria (approval period of 1 year):

- ❑ For the treatment of patients with Primary Biliary Cholangitis (PBC) (31712002); **AND**
- ❑ The patient:
  - ❑ Is ≥ 16 years of age.; **AND**
  - ❑ Has a diagnosis of Primary Biliary Cholangitis (PBC), as evidenced by at least TWO of the following criteria at the time of diagnosis:
    - ❑ There is biochemical evidence of cholestasis with an alkaline phosphatase (ALP) elevation of at least 1.67 times the upper limit of normal (ULN), AND/OR total bilirubin greater than the upper limit of normal (ULN) but less than 2 times the ULN.
    - ❑ Presence of antimitochondrial antibody (AMA) with a titer of 1:40 or higher.
    - ❑ Histologic evidence (via liver biopsy) consistent with PBC.

    AND
  - ❑ Meets ONE of the following:
    - ❑ BOTH of the following:
      - ❑ The patient has tried treatment with ursodeoxycholic acid (UDCA) for at least 1 year and had an inadequate response[v], **AND**
      - ❑ The patient will continue treatment with ursodeoxycholic acid (UDCA) with Ocaliva

    OR
    - ❑ The patient has a documented intolerance, contraindication, or hypersensitivity to ursodeoxycholic acid (UDCA)[vi]

  AND
- ❑ Physician is a specialist or is experienced in the management of PBC

Renewal Criteria (approval period of 1 year):

- ❑ ONE of the following:
  - ❑ The patient is currently on AND will continue treatment with ursodeoxycholic acid (UDCA) with Ocaliva, **OR**
  - ❑ The patient has a documented intolerance, contraindication, or hypersensitivity to ursodeoxycholic acid (UDCA)

  AND
- ❑ The patient has had an alkaline phosphatase (ALP) decrease of at least 15% AND is less than 1.67-times the upper limit of normal (ULN)

OR

- ❑ None of the above applies

Relevant additional information _____

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Eligibility Criteria

Physician Information				
Physician's Name	License Number	Telephone Number	Fax Number	
Address		City	Province	Postal Code
Physician's Signature			Date: (DD/MMM/YYYY) __ __ / __ __ __ / __ __ __ __	