SPECIAL AUTHORITY REQUEST OBETICHOLIC ACID

If you have received this fax in error, please write

MISDIRECTED across the front of the form and fax toll-free to 1-800-609-4884, then destroy the pages

received in error.

HLTH 5490 2022/11/10

For up-to-date criteria and forms, please check: www.gov.bc.ca/pharmacarespecialauthority

Ministry of

Health

Fax requests to 1-800-609-4884 (toll free) OR mail requests to: PharmaCare, Box 9652 Stn Prov Govt, Victoria, BC V8W 9P4 This facsimile is doctor-patient privileged and contains confidential information intended only for PharmaCare. Any other distribution, copying or disclosure is strictly prohibited.

If PharmaCare approves this Special Authority request, approval is granted solely for the purpose of covering prescription costs. PharmaCare approval does not indicate that the requested device is, or is not, suitable for any specific patient or condition.

Forms with information missing will be returned for completion. If no prescriber fax or mailing address is provided, PharmaCare will be unable to return a response.

SECTION 1 – PRESCRIBER'S INFORMATION

BRITISH

OLUMBIA

SECTION 2 – PATIENT INFORMATION

CRITICAL FOR A TIMELY RESPONSE	CRITICAL FOR Personal Health Number (PHN)
College ID (use ONLY College ID number) Phone Number (include area code)	Date of Birth (yyyy / mm / dd) Date of Application (yyyy / mm / dd)
	Patient (Given) Name(s)
Prescriber's Name and Mailing Address	Patient (Family) Name

SECTION 3 - INITIAL COVERAGE (duration of coverage: 1 year)

OBETICHOLIC ACID: 9901-0310

	Prescribed	by	а	gastroenterologist	
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For treatment of adult patient with confirmed diagnosis of primary biliary cholangitis (PBC) defined as:

- Positive antimitochondrial antibodies (AMA) OR
- Liver biopsy results consistent with PBC

AND

O Obeticholic acid will be used in combination with ursodeoxycholic acid (UDCA) in patient who has experienced an inadequate response to UDCA after a minimum of 12 months treatment

□ Indicate UDCA treatment start date (DD/MM/YYYY): _

Provide current clinical laboratory values as evidence of inadequate response:

	DATE (DD/MM/YYYY)	VALUE	ULN**
\Box ALP* \geq 1.67 x ULN**		(U/L)	(U/L)
AND/OR			
\Box Total Bilirubin > ULN** and < 2 x ULN**		(umol/L)	(umol/L)
AND/OR			

Compensated cirrhosis and supporting evidence of cirrhosis is attached (eg fibroscan, biopsy, ultrasound, and/or other clinical evidence of cirrhosis)

*ALP: Alkaline Phosphatase **ULN: Upper Limit of Normal

OR

O Obeticholic acid will be used as monotherapy in patient who has experienced documented and unmanageable intolerance to ursodeoxycholic acid (UDCA). Provide clinical details of intolerance:

OBETICHOLIC ACID

Patient (Given) Name(s)

Personal Health Number (PHN)

SECTION 4 - RENEWAL OF COVERAGE (duration of coverage: 1year)

OR

С

If the above criteria are not met, please provide supplemental information to demonstrate that patient has responded to, or will continue to benefit from, obsticholic acid. Please provide details, as applicable:

SECTION 5 - ADDITIONAL COMMENTS

Please note: Obeticholic acid is contraindicated in PBC patients with decompensated cirrhosis, or a prior decompensation event, or with compensated cirrhosis who have evidence of portal hypertension.

Personal information on this form is collected under the authority of, and in accordance with, the *British Columbia Pharmaceutical Services Act* 22(1) and *Freedom of Information and Protection of Privacy Act* 26 (a),(c),(e). The information is being collected for the purposes of (a) administering the PharmaCare program, (b) analyzing, planning and evaluating the Special Authority and other Ministry programs and (c) to manage and plan for the health system generally. If you have any questions about the collection of this information, call Health Insurance BC from Vancouver at 1-604-683-7151 or from elsewhere in BC toll free at 1-800-663-7100 and ask to consult a pharmacist concerning the Special Authority process.

I have discussed with the patient that the purpose of releasing their information to PharmaCare is to obtain Special Authority for prescription coverage and for the purposes set out here.

Prescriber's Signature (Mandatory)

PharmaCare may request additional documentation to support this Special Authority request.

Actual reimbursement is subject to the rules of a patient's PharmaCare plan, including any annual deductible requirement, and to any other applicable PharmaCare pricing policy.

PHARMACARE USE ONL	Ρ	HA	RN	IAC/	ARE	USE	ONLY	
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STATUS	EFFECTIVE DATE (YYYY / MM / DD)	DURATION OF APPROVAL