

OBETICHOLIC ACID SPECIAL AUTHORIZATION REQUEST FORM

Patients may or may not meet eligibility requirements as established by Alberta Government sponsored drug programs.

Please complete all required sections to allow your request to be processed.

PATIENT INFORMATION				COVERAGE TYPE	
PATIENT LAST NAME	FIRST NAME INITIAL		INITIAL	☐ Alberta Blue Cross ☐ Alberta Human Services	
BIRTH DATE (YYYY-MM-DD)	ALBERTA PERSONAL HEALTH NUMBER		MBER	☐ Other	
STREET ADDRESS	CITY PROV POSTAL CO		POSTAL CODE	ID/CLIENT/COVERAGE NUMBER	
PRESCRIBER INFORMATION					
PRESCRIBER LAST NAME FIRST NAME INITIAL			PRESCRIBER PROFESSIONAL ASSOCIATION REGISTRATION		
			☐ CPSA ☐ ACO REGISTRATION NUMBER☐ CARNA ☐ ADA+C		
STREET ADDRESS			ACP Other PHONE FAX		
CITY, PROVINCE				FAX	
POSTAL CODE			FAX NUMBER MUST BE PROVIDED WITH EACH REQUEST SUBMITTED		
Please provide the following information for NEW requests (check ALL that apply)					
Diagnosis ☐ Primary biliary cholangitis (PBC) → confirmed by ☐ Positive antimitochondrial antibodies (AMA) ☐ Liver biopsy results consistent with PBC					
Other (specify)					
Previous therapy					
Ursodeoxycholic acid (UDCA) has been used? Yes No (explain)					
a) UDCA has been used for a minimum of 12 months? Yes No					
b) Indicate response					
☐ Documented and unmanageable intolerance					
Other (specify)					
Concomitant use of UDCA					
For patients who had an inadequate respo			holic acid be u	sed in combination with UDCA?	
a) Alkaline phosphatase (ALP) Units/L b) Bilirubin mmol/L					
a) Alkaline phosphatase (ALP) Units/L					
Date			Date		
Reference range			Reference range		
Please provide the following information	on for RENEWAL r	equests			
Current measures					
Alkaline phosphatase (ALP) Units/L Date			Reference range		
Concomitant use of UDCA? Yes					
Additional information relating to request					
PRESCRIBER'S SIGNATURE	DATE		I this request to		
		10009 10	8 Street NW, Edm	al Drug Services nonton, Alberta T5J 3C5 onton • 1-877-828-4106 toll free all other areas	
ONCE YOUR REQUEST HAS SU	CCESSFULLY TRANSI				

The information on this form is being collected and pursuant to sections 20, 21 and 22 of the Health Information Act, and sections 33 and 34 of the Freedom of Information and Protection of Privacy Act, for the purposes of determining or verifying eligibility to participate in a program or receive a benefit, product or health service. If you have any questions regarding the collection or use of this information, please contact an Alberta Blue Cross privacy matters representative toll-free at 1-855-498-7302 or write to Privacy Matters, Alberta Blue Cross, 10009 108 Street, Edmonton AB T5J 3C5.







OBETICHOLIC ACID SPECIAL AUTHORIZATION CRITERIA

Criteria for coverage

Patients may or may not meet eligibility requirements as established by Alberta government sponsored drug programs.

OBETICHOLIC ACID (e.g. Ocaliva) special authorization criteria

For the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA, where the following criteria are met:

- I. A confirmed diagnosis of PBC, defined as:
- Positive antimitochondrial antibodies (AMA); or
- Liver biopsy results consistent with PBC.

AND

II.a. The patient has received ursodeoxycholic acid (UDCA) for a minimum of 12 months and has experienced an inadequate response to UDCA and can benefit from the addition of obeticholic acid. An inadequate response is defined as:

- alkaline phosphatase (ALP) >= 1.67 x upper limit of normal (ULN) and/or
- bilirubin > ULN and < 2 x ULN.

OR

II.b. The patient has experienced documented and unmanageable intolerance to UDCA and can benefit from switching therapy to obeticholic acid.

AND

III. Initiated by a gastroenterologist or hepatologist (or an internal medicine specialist with an interest in gastroenterology / hepatology on a case-by-case basis, in geographic areas where access to these specialities is not available).

Initial coverage may be approved for a period of 12 months.

Ongoing coverage may be considered only if the patient continues to benefit from treatment with obeticholic acid as evidenced by:

- A reduction in the ALP level to less than 1.67 x ULN; or
- A 15 per cent reduction in the ALP level compared with values before beginning treatment with obeticholic acid.

Continued coverage may be approved for up to 12 months.



