



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

**Criteria for coverage****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)  $\geq 1.67$  x upper limit of normal (ULN) and/or
- bilirubin  $> \text{ULN}$  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.