BlueCross BlueShield Federal Employee Program

OCALIVA
(obeticholic acid)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Primary biliary cholangitis (PBC)

AND submission of medical records (e.g., chart notes, laboratory values) documenting **ONE** of the following:

a. Inadequate response
   i. History of a minimum of a 1 year trial of ursodeoxycholic acid (UDCA)
b. Intolerance
   i. An intolerance which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g., dose reduction) with a history of a trial of ursodeoxycholic acid (UDCA)

AND submission of medical records (e.g., chart notes, laboratory values) documenting **ALL** of the following:

a. Ocaliva must be used in combination with UDCA in patients who are tolerant or used as monotherapy in patients who are unable to tolerate UDCA
b. Confirmation of diagnosis with elevated serum alkaline phosphatase level **AND ONE** of the following tests:
   i. Positive antimitochondrial antibody test
   ii. Liver biopsy
   iii. Ultrasound scan of liver
c. Patient has **ONE** of the following:
   i. **NO** cirrhosis
   ii. Compensated cirrhosis with no evidence of portal hypertension
d. **NO** preliminary biliary obstruction prior to initiation of therapy and agreement to discontinue therapy if complete biliary obstruction develops

e. Physician agrees to frequently monitor patient during treatment for elevations in liver biochemical tests, development of liver-related adverse reactions, and for changes in serum lipid levels

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Prior - Approval Limits

Quantity 90 tablets per 90 days

Duration 6 months

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Primary biliary cholangitis (PBC)

AND submission of medical records (e.g., chart notes, laboratory values) documenting **ALL** of the following:

a. Confirmation of patient improvement with **ALL** of the following:
   i. Serum alkaline phosphatase (ALP) decrease of at least 15%
   ii. Total bilirubin level of ≤ 1.1 mg/dL for females and ≤ 1.5 mg/dL for males
b. The physician has weighed the potential risks against the benefits of continuing treatment in patients experiencing clinically significant liver-related adverse reactions
c. Patient has **ONE** of the following:
   i. **NO** cirrhosis
   ii. Compensated cirrhosis with no evidence of portal hypertension
d. **NO** evidence of complete biliary obstruction
e. Physician agrees to frequently monitor patient during treatment for elevations in liver biochemical tests, development of liver-related adverse reactions, and for changes in serum lipid levels

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Prior - Approval *Renewal* Limits

Quantity 90 tablets per 90 days

Duration 12 months