

CRITERIA FOR PRIOR AUTHORIZATION

Ocaliva® (obeticholic acid)

PROVIDER GROUP Professional

MANUAL GUIDELINES The following drug requires prior authorization:
Obeticholic acid (Ocaliva)

CRITERIA FOR INITIAL PRIOR AUTHORIZATION FOR OBETICHOLIC ACID: (must meet all of the following)

- Patient must have a diagnosis of primary biliary cholangitis (PBC)
- Patient must be 18 years of age or older
- Patient must have one of the following:
 - Must be used in combination with ursodeoxycholic acid (UDCA) in patients who have had inadequate biochemical response (ALP and/or total bilirubin reduction) to UDCA for at least 1 year
 - Can be used as monotherapy in patients unable to tolerate UDCA
- Dose must not exceed 10 mg per day
- Patient must not have complete biliary obstruction

CRITERIA FOR RENEWAL PRIOR AUTHORIZATION FOR OBETICHOLIC ACID: (must meet all of the following)

- Patient must have the following: ALP < 1.67 times the upper limit of normal (ULN), total bilirubin ≤ ULN, and an ALP decrease of at least 15%

LENGTH OF APPROVAL: 12 months

Notes:

- ALP ULN
 - Females: 118 U/L
 - Males: 124 U/L
- Bilirubin ULN
 - Females: 1.1 mg/dL
 - Males: 1.5 mg/dL

DRUG UTILIZATION REVIEW COMMITTEE CHAIR

PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

DATE

DATE