

Criteria-Based Consultation Prescribing Program CRITERIA FOR DRUG COVERAGE

Obeticholic Acid (Ocaliva)

Notes:

- Quantity limits: Yes
- ^An adequate trial is defined as an alkaline phosphatase (ALP) \geq 1.67 times upper limit of normal after 6-12 months of treatment at UDCA doses of 13-15mg/kg/day.
- *Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation.

Initiation (new start) criteria: Non-formulary **obeticholic acid (Ocaliva)** will be covered on the prescription drug benefit for 6 months when the following criteria are met:

- Prescribed by a hepatologist.
- Adult (18 years and older) with a diagnosis of primary biliary cholangitis (PBC).
- Patient has failed an adequate trial[^] of ursodeoxycholic acid (UDCA) or has a contraindication or intolerance* to UDCA.
- Adherence to UDCA treatment is confirmed.
- Patient is taking an optimal regimen of cholesterol treatment (fenofibrate or statin) if most recent LDL-C greater than 190mg/dL.
- Absence of complete biliary obstruction.
- No history of severe pruritis.
- Patient is not listed for liver transplant.

Criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously: Non-formulary **obeticholic acid (Ocaliva)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- See below for continued use criteria for patients stable on the medication.

Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary **obeticholic acid (Ocaliva)** will be covered on the prescription drug benefit for 3 months when the following criteria are met:

- Adult (18 years and older) with a diagnosis of primary biliary cholangitis (PBC).

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Continued use criteria (after initiation): Non-formulary **obeticholic acid (Ocaliva)** will continue to be covered on the prescription drug benefit for 6 months when the following criteria are met:

- Adequate response to obeticholic acid defined as a reduction in ALP to less than 1.67 times upper limit of normal and an ALP decrease of at least 15% since the start of treatment on maximum tolerated dose.

Continued use criteria for patients stable on the medication: Non-formulary **obeticholic acid (Ocaliva)** continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by a hepatologist.
- Adequate response to obeticholic acid defined as a reduction in ALP to less than 1.67 times upper limit of normal and an ALP decrease of at least 15% since the start of treatment.
- Patient has completed liver function laboratory monitoring within the last 3 months (ALP, AST, ALT, total bilirubin).
- Patient has completed lipid lab monitoring within the last 6 months if lipid abnormalities present (HDL-C less than 40 mg/dL).
- Adherence to treatment is confirmed.