

## obeticholic acid (OCALIVA)

### Diagnosis Considered for Coverage:

- Primary biliary cholangitis (also known as primary biliary cirrhosis)

### Coverage Criteria:

For diagnosis listed above:

- Patient is at least 18 years old, and
- Prescribed or in consultation with a hepatologist or GI specialist, and
- Not being used for non-alcoholic steatohepatitis (NASH) or non-alcoholic fatty liver disease (NAFLD), and
- Patient does not have complete biliary obstruction, advanced cirrhosis (e.g., evidence of liver decompensation or portal hypertension), and
- Current alkaline phosphatase (ALP) is > 167% above upper limit of normal (ULN), and
- Dose does not exceed 10 mg per day, and
- One of the following:

**For use with ursodiol:** inadequate response despite a compliant consecutive 12-month use of ursodiol therapy

**For monotherapy:** intolerable side effect or contraindication to ursodiol.

### Reauthorization

- Not being used for non-alcoholic steatohepatitis (NASH) or non-alcoholic fatty liver disease (NAFLD), **and**
- Patient does not have advanced cirrhosis (e.g., evidence of liver decompensation or portal hypertension) or complete biliary obstruction, **and**
- Current alkaline phosphatase (ALP) is  $\geq$  15% reduced from baseline, **and**
- Dose does not exceed 10 mg per day.

### Coverage Duration: one year

Effective Date: 8/30/2023