Ocaliva (obeticholic acid)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial approval duration: 6 months Continuing treatment approval duration: 1 year

Medications	Quantity Limit
Ocaliva (obeticholic acid)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for initiation of therapy with Ocaliva (obeticholic acid) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Individual has a diagnosis of primary biliary cholangitis (PBC) as confirmed by **two** of the following (AASLD 2018):
   A. Elevated alkaline phosphatase;
   B. Positive antimitochondrial antibodies (AMA) or other PBC-specific autoantibody titer;
   C. Liver biopsy with findings consistent with PBC;

AND

III. Individual has had a one year trial of ursodiol (Urso 250, Urso Forte); **AND**
IV. Documentation is provided that individual has had an inadequate response as demonstrated by one of the following:
   A. Alkaline phosphatase greater than or equal to 1.67 times the upper limit of normal; **OR**
   B. Total bilirubin greater than the upper limit of normal but less than two times the upper limit of normal; **AND**
V. Individual will be utilizing Ocaliva (obeticholic acid) in combination with ursodiol (Urso 250, Urso Forte);

OR

VI. Documentation is provided that individual has an intolerance to ursodiol (Urso 250, Urso Forte).

Continuing treatment with Ocaliva (obeticholic acid) may be approved when the individual has previously met the initiation criteria above and:

I. Documentation is provided that individual has achieved an adequate response of alkaline phosphatase or total bilirubin; **AND**
II. Individual has not experienced clinically significant hepatic adverse reactions while on therapy, including hepatic decompensation or compensated cirrhosis with portal hypertension.

Ocaliva (obeticholic acid) may not be approved for any of the following:

I. Individual has a diagnosis of nonalcoholic steatohepatitis (NASH), nonalcoholic fatty liver disease (NAFLD), primary sclerosing cholangitis (PSC), or biliary atresia; **OR**
II. Individual has complete biliary obstruction; **OR**
III. Individual has decompensated cirrhosis (Child-Pugh Class B or C), or a prior decompensation event; **OR**
IV. Individual has compensated cirrhosis with evidence of portal hypertension (for example, ascites, gastroesophageal varices, persistent thrombocytopenia).

Note:
Ocaliva has a black box warning for hepatic decompensation and failure, sometimes resulting in liver transplants and fatalities, in patients with compensated or decompensated cirrhosis. The black box warning also includes a contraindication for use in individuals with decompensated cirrhosis, a prior decompensation event, or with compensated cirrhosis who have evidence of portal hypertension. Permanent discontinuation of Ocaliva is recommended in those who develop hepatic decompensation, have compensated cirrhosis and develop portal hypertension, or experience clinically significant hepatic adverse reactions.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: June 11, 2021.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
5. Lindor KD, Bowlus CL, Boyer J, et. al. Primary biliary cholangitis: 2018 Practice guidance from the American Association for the Study of Liver Disease (AASLD). Hepatology. 2018. Available from: https://www.aasld.org/sites/default/files/guideline_documents/PracticeGuidelines-PBC-November2018.pdf. Accessed on: April 9, 2021.