Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

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) with 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**
IV. Individual will be utilizing Ocaliva (obeticholic acid) in combination with ursodiol (Urso 250, Urso Forte);

OR

V. 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:

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

I. Individual has achieved an adequate response of alkaline phosphatase or total bilirubin.

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.

Note: Ocaliva (obeticholic acid) has a black box warning for hepatic decompensation and failure in incorrectly dosed patients with decompensated cirrhosis or Child-Pugh Class B or C hepatic impairment. The recommended starting dose is 5 mg once weekly for patients with Child-Pugh Class B or C or a prior decompensation event.

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. 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: March 12, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; 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: March 12, 2019.