PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Ocaliva (obeticholic acid)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Ocaliva, approved by the FDA in 2016, is a farnesoid X receptor (FXR) agonist indicated for the treatment of adults with primary biliary cholangitis (PBC) without cirrhosis, OR with compensated cirrhosis who do not have evidence of portal hypertension, either in combination with ursodeoxycholic acid (UDCA) with an inadequate response to UDCA or as monotherapy in patients unable to tolerate UDCA.
PBC is a progressive, autoimmune liver disease that leads to scarring and inflammation of the small bile ducts. It primarily affects women and is characterized by fatigue, pruritis, and jaundice. Antimitochondrial antibody (AMA) is found in 95% of PBC patients. FXR signaling protects hepatocytes against bile acid toxicity by impairing bile acid synthesis and stimulating choleresis.
Ursodiol (ursodeoxycholic acid [UDCA]) is the first-line treatment for PBC. It improves biochemical indices, delays histologic progression, and improves survival.
Accelerated approval of Ocaliva for PBC was based on a reduction in alkaline phosphatase (ALP). An improvement in survival or disease-related symptoms has not been established.

Ocaliva (obeticholic acid) will be considered for coverage when the following criteria are met:

Primary Biliary Cholangitis (PBC)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a hepatologist or gastroenterologist; AND
3. Member has a diagnosis of PBC confirmed by at least 2 of the following
   a) Biochemical evidence of cholestasis based on ALP elevation
   b) Presence of AMA or other PBC-specific antibodies, including sp100 or gp210
   c) Histologic evidence of nonsuppurative cholangitis and destruction of small or medium-sized bile ducts on biopsy; AND
4. Member had an inadequate response to UDCA after 1 year of treatment OR the member has documentation of intolerance to UDCA; AND
5. UDCA will be continued in combination with Ocaliva unless the patient has documented intolerance; AND
6. Member does NOT have any of the following:
   a) Decompensated cirrhosis (e.g., Child-Pugh B or C)
   b) Prior decompensation event
   c) Compensated cirrhosis with evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia)
   d) Complete biliary obstruction.
7. **Dosage allowed/Quantity limit:** 5 mg once daily for 3 months, then may increase to 10 mg once daily if an adequate reduction in ALP and/or total bilirubin has not been achieved.
   (QL: 30 tablets per 30 days)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must show improved (decreased) ALP and/or total bilirubin compared to baseline.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Ocaliva (obeticholic acid) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
06/14/2023	New policy for Ocaliva created.

References:

1. Ocaliva [prescribing information]. Intercept Pharmaceuticals, Inc.; 2022.
2. Horwich BH, Han H. Diagnosis and Treatment of Primary Biliary Cholangitis: A Patient-Friendly Summary of the 2018 AASLD Practice Guidance. *Clin Liver Dis (Hoboken*). 2021;18(5):255-259. Published 2021 Sep 13. doi:10.1002/cld.1158
3. Lindor KD, Bowlus CL, Boyer J, Levy C, Mayo M. Primary Biliary Cholangitis: 2018 Practice Guidance from the American Association for the Study of Liver Diseases. *Hepatology*. 2019;69(1):394-419. doi:10.1002/hep.30145
4. Lindor KD, Bowlus CL, Boyer J, Levy C, Mayo M. Primary biliary cholangitis: 2021 practice guidance update from the American Association for the Study of Liver Diseases. *Hepatology*. 2022;75(4):1012-1013. doi:10.1002/hep.32117
5. Nevens F, Andreone P, Mazzella G, et al. A Placebo-Controlled Trial of Obeticholic Acid in Primary Biliary Cholangitis. *N Engl J Med.* 2016;375(7):631-643. doi:10.1056/NEJMoa1509840
6. Hirschfield GM, Mason A, Luketic V, et al. Efficacy of obeticholic acid in patients with primary biliary cirrhosis and inadequate response to ursodeoxycholic acid. *Gastroenterology*. 2015;148(4):751-61.e8. doi:10.1053/j.gastro.2014.12.005
7. Krupa K, Hapshy V, Nguyen H, et al. Obeticholic Acid. [Updated 2023 Jan 17]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK567735/
8. Hirschfield GM, Dyson JK, Alexander GJM, et al. The British Society of Gastroenterology/UK-PBC primary biliary cholangitis treatment and management guidelines. *Gut*. 2018;67(9):1568-1594. doi:10.1136/gutjnl-2017-315259

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