Clinical Policy: Obeticholic acid (Ocaliva)

Reference Number: PA.CP.PHAR.287
Effective Date: 01/2018
Last Review Date: 10/16 Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness ® clinical policy for obeticholic acid (Ocaliva™).

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness® that Ocaliva is **medically necessary** when one of the following criteria are met:

I. Initial Approval Criteria

A. Primary biliary cholangitis (must meet all)**:**

1. Diagnosis of primary biliary cholangitis (PBC) evidenced by the presence of at least 2 of the following:
   a. Elevated alkaline phosphatase level;
   b. Antimitochondrial antibodies (AMA);
   c. Histologic evidence of PBC (nonsuppurative destructive cholangitis and destruction of interlobular bile ducts);
2. Failure of ursodeoxycholic acid (UDCA) at the dose of ≥ 13mg/kg/day for at least 6 months, evidenced by sustained elevation in liver function tests, unless member has contraindication or intolerance to UDCA;
3. Ocaliva will be used in combination with UDCA, unless contraindicated or intolerant;
4. Prescribed dose of Ocaliva does not exceed 10 mg once daily;
5. Member does not have complete biliary obstruction.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PHAR.57 - Global Biopharm Policy

II. Continued Approval

A. Primary biliary cholangitis (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or Continuity of Care policy applies;
2. Member is responding positively to therapy as evidenced by (a or b):
   a. Initial reauthorization: reduction in alkaline phosphatase level from pretreatment level;
   b. Subsequent reauthorization: continued reduction or maintenance of initial reduction in alkaline phosphatase level;
3. Prescribed dose of Ocaliva does not exceed 10 mg once daily;
4. Member does not have complete biliary obstruction.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or
2. Refer to PA.CP.PHAR.57 - Global Biopharm Policy**.**

Background

Description/Mechanism of Action:

Obeticholic acid is an agonist for farnesoid X receptor (FXR), a nuclear receptor expressed in the liver and intestine. FXR is a key regulator of bile acid, inflammatory, fibrotic, and metabolic pathways. FXR activation decreases the intracellular hepatocyte concentrations of bile acids by suppressing de novo synthesis from cholesterol as well as by increased transport of bile acids out of the hepatocytes. These mechanisms limit the overall size of the circulating bile acid pool while promoting choleresis, thus reducing hepatic exposure to bile acids.

Formulations:

Ocaliva is available in 5 mg and 10 mg tablets for oral administration.

FDA Approved Indication(s):

Ocaliva is a FXR agonist indicated for the treatment of

- PBC in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA.

Appendices

Appendix A: Abbreviation Key

FXR: farnesoid X receptor
PBC: primary biliary cholangitis
UDCA: ursodeoxycholic acid

Reviews, Revisions, and Approvals	Date	Approval Date

References

1. Ocaliva Prescribing Information. New York, NY: Intercept Pharmaceuticals, Inc.; May 2016. Available at https://ocaliva.com/. Accessed July 15, 2016.
2. Poupon R. Overview of the treatment of primary biliary cholangitis (primary biliary cirrhosis). In: UpToDate, Waltham, MA: Walters Kluwer Health; 2016. Available at www.UpToDate.com. Accessed July 2016.
3. Lindor, KD, Gershwin ME, Poupon R et al. AASLD Practice Guidelines: Primary biliary cirrhosis. Hepatology. 2009; 50(1): 291-308.