AETNA BETTER HEALTH® Coverage Policy/Guideline				
Name:	Ocaliva		Page:	1 of 2
Effective Date:	1/12/2025		Last Review Date:	11/22/2024
Applies to:	☒Illinois ☒Florida Kids	☒New Jersey ☒Pennsylvania Kids	☒Maryland ☐Virginia	☒KY PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Ocaliva under the patient's prescription drug benefit.

Description:

FDA-Approved Indication

Ocaliva is indicated for the treatment of adult patients 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.

This indication is approved under accelerated approval based on a reduction in alkaline phosphatase (ALP). An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

All other indications are considered experimental/investigational and not medically necessaryAll other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Ocaliva

Policy/Guideline:

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. For initial requests: Pretreatment serum alkaline phosphatase (ALP) level
B. For continuation of therapy: Current serum alkaline phosphatase (ALP) and/or current total bilirubin level

Exclusions

Coverage will not be provided for members with either of the following exclusions:

A. Member has decompensated cirrhosis (e.g., Child-Pugh Class B or C) or a prior decompensation event.
B. Member has compensated cirrhosis with evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia).

Prescriber Specialties

This medication must be prescribed by or in consultation with a hepatologist or gastroenterologist

Criteria for Initial Approval:

Primary biliary cholangitis (PBC) (previously known as primary biliary cirrhosis)

Authorization of 12 months may be granted for treatment of PBC in adult members when ALL the following criteria are met:

A. Diagnosis of PBC is confirmed by at least TWO of the following criteria:
   1. Biochemical evidence of cholestasis with elevation of alkaline phosphatase (ALP) level for at least 6 months duration.
   2. Presence of antimitochondrial antibodies (AMA) (titer >1:40 by immunofluorescence or immunoenzymatic reactivity) or PBC-specific antinuclear antibodies (ANA) (e.g., anti-gp210, anti-sp100).
   3. Histologic evidence of PBC on liver biopsy (e.g., non-suppurative inflammation and destruction of interlobular and septal bile ducts).
B. Member has an elevated serum ALP level prior to initiation of therapy with the requested drug.
C. Member meets EITHER of the following criteria:
   1. Member has had an inadequate response to at least 12 months of prior therapy with ursodeoxycholic acid (UDCA)/ursodiol and the member will continue concomitant therapy with UDCA/ursodiol.
   2. Member has an intolerance to UDCA/ursodiol.

Criteria for Continuation of Therapy

Authorization of 12 months may be granted for members who have achieved or maintained a clinical benefit from Ocaliva therapy as evidenced by ANY of the following:

A. At least a 15% reduction in serum ALP level
B. Serum ALP level less than 1.67 times upper limit of normal (ULN)
C. Total bilirubin less than or equal to ULN

Approval Duration and Quantity Restrictions:

Approval: 12 months

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

References:

1. Ocaliva [package insert]. Morristown, NJ: Intercept Pharmaceuticals, Inc.; May 2022.
2. Lindor KD, Bowlus CL, Boyer J, et al. Primary biliary cholangitis: 2018 Practice guidance from the American Association for the study of liver diseases. *Hepatology*. 2019;69(1):394-419.
3. European Association for the Study of the Liver. EASL clinical practice guidelines: The diagnosis and management of patients with primary biliary cholangitis. *J Hepatol*. 2017;67(1):145-172.