Ocaliva (obeticholic acid)
Policy Number: C16447-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
07/01/2019	07/2019	07/2020
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL**
	RXPA	Q2 2019

PRODUCTS AFFECTED:
Ocalvia (obeticholic acid)

DRUG CLASS:
Farnesoid X Receptor (FXR) Agonists

ROUTE OF ADMINISTRATION:
Oral

PLACE OF SERVICE:
Specialty Pharmacy

AVAILABLE DOSAGE FORMS: Ocaliva (obeticholic acid) 5 mg tablet,10 mg tablet

FDA-APPROVED USES: indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA.

COMPENDIAL APPROVED OFF-LABELED USES: None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS: primary biliary cholangitis (PBC)

REQUIRED MEDICAL INFORMATION:

A. PRIMARY BILIARY CHOLANGITIS:
   1. Patient has a diagnosis of PBC as defined by TWO of the following criteria: Biochemical evidence of cholestasis based on ALP elevation, Presence of AMA, or other PBC-specific autoantibodies (including sp100 or gp210, if AMA is negative), or Histologic evidence of nonsuppurative destructive cholangitis and destruction of interlobular bile ducts.
      AND
   2. The prescriber has documented the patient's baseline (prior to treatment) alkaline phosphatase (ALP) level
      AND
   3. Patient has been receiving ursodiol therapy (e.g., ursodiol generics, Urso 250® ,Urso Forte®, Actigall®) for ≥ 1 year at doses of 13-15mg/kg/day and has had an inadequate response (alkaline phosphate level > 1.67 times the upper limit of

normal); OR According to the prescribing physician the patient is unable to tolerate ursodiol therapy.
AND
4. Patient does not have complete biliary obstruction
AND
5. Patient does NOT have moderate to severe liver impairment (Child-Pugh-Turcotte B and C)

DURATION OF APPROVAL: Initial authorization: 6 months, Continuation of therapy: 12 months

QUANTITY: recommended starting dosage is 5 mg orally once daily in adult patients who have not achieved an adequate biochemical response to an appropriate dosage of UDCA for at least 1 year or are intolerant to UDCA.

If an adequate reduction in ALP and/or total bilirubin has not been achieved after 3 months of 5 mg once daily, and the patient is tolerating Ocaliva, increase the dosage to 10 mg once daily.

PRESCRIBER REQUIREMENTS: Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician

AGE RESTRICTIONS: 18 years of age or older

GENDER:
Male and female

CONTINUATION OF THERAPY:
A. PRIMARY BILIARY CHOLANGITIS:
1. The patient has had an alkaline phosphatase (ALP) decrease of at least 15% AND is less than 1.67-times the upper limit of normal (ULN)
AND
2. The patient is not reporting any toxicities from the medication

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION: All other uses of Ocalvia (obeticholic acid) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications include:

OTHER SPECIAL CONSIDERATIONS: None

BACKGROUND:
Ocaliva is indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA. Ocaliva was approved for this indication under accelerated approval based on reduction in alkaline phosphatase (ALP). An improvement in survival or PBC-related symptoms has not been established. The prescribing information notes that continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Description/Mechanism of Action: Ocaliva is structurally similar to an endogenous bile acid, with the addition of an ethyl group in the 6-alpha position (6α-ethyl-CDCA), which makes it a 100-fold more potent agonist at the 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. Activation of FXR reduces the intracellular

concentrations of bile acids in hepatocytes by suppressing de novo synthesis from cholesterol and by increased transport of bile acids out of the hepatocytes. In general, these mechanisms limit the amount of circulating bile acid, while promoting choleresis, and therefore reduce hepatic exposure to bile acids

APPENDIX: None

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