Clinical Policy Title:	obeticholic acid
Policy Number:	RxA.246
Drug(s) Applied:	Ocaliva®
Original Policy Date:	02/07/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Primary Biliary Cholangitis (must meet all):

1. Diagnosis of PBC;
2. Member meets one of the following (a or b):
   a. Member does not have cirrhosis;
   b. Member has compensated cirrhosis without evidence of portal hypertension;
3. Prescribed by or in consultation with a hepatologist or gastroenterologist;
4. Age ≥ 18 years;
5. Trail and failure (as evidenced by sustained elevation in liver function tests) of ≥ 12-month trial of UDCA (ursodiol) at a dose of ≥ 13 mg/kg/day, unless contraindicated or clinically significant adverse effects are experienced;
6. Prescribed in combination with UDCA, unless contraindicated or clinically significant adverse effects are experienced;
7. Dose does not exceed 10 mg per day.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Primary Biliary Cholangitis (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy as evidenced by one of the following (a or b):
   a. Initial reauthorization: reduction in alkaline phosphatase (ALP) level from pretreatment level;
   b. Subsequent reauthorization: continued reduction or maintenance of initial reduction in ALP level;
3. If request is for a dose increase, new dose does not exceed 10 mg per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

References

1. Obeticholic Acid for the Treatment of Nonalcoholic Steatohepatitis: Comparative Clinical Effectiveness and Value. Institute for Clinical and Economic Review (ICER). July 21, 2020. Available at: https://icer.org/wp-

content/uploads/2020/10/NECEPAC_OCA_NASH_Evidence_Report_FINAL.pdf. Accessed December 29, 2022.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Policy title was updated. 2. Approval duration for Medicaid was added. 3. Continued Therapy Approval criteria II.A.1 was rephrased. 4. References were updated.	06/16/2020	09/14/2020
Policy was reviewed: 1. Policy title table updated. 2. Clinical policy section standard verbiage was updated to include "The provision of prescriber samples…". 3. Continued therapy II.A.1 criteria was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 4. References were updated.	04/22/2021	06/10/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A.2: Updated to include new diagnostic criteria: a. Member does not have cirrhosis; b. Member has compensated cirrhosis without evidence of portal hypertension. 2. References reviewed and updated.	01/21/2022	04/18/2022
Policy was reviewed: 1. References were reviewed and updated.	12/29/2022	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023