

Clinical Policy Title:	obeticholic acid
Policy Number:	RxA.246
Drug(s) Applied:	Ocaliva®
Original Policy Date:	02/07/2020
Last Review Date:	12/11/2025
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. Trial 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;
4. Prescribed in combination with UDCA, unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. Primary Biliary Cholangitis (must meet all):

1. Member is currently receiving medication in the past 120 days that has been authorized by RxAdvance or the member has met the initial approval criteria.

Approval Duration

All Lines of Business (except Medicare): 6 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 March 21, 2025.

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.	06/16/2020	09/14/2020

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<p>3. Continued Therapy Approval criteria II.A.1 was rephrased.</p> <p>4. References were updated.</p>		
<p>Policy was reviewed:</p> <p>1. Policy title table updated.</p> <p>2. Clinical policy section standard verbiage was updated to include “The provision of prescriber samples...”.</p> <p>3. Continued therapy II.A.1 criteria was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance...”.</p> <p>4. References were updated.</p>	04/22/2021	06/10/2021
<p>Policy was reviewed:</p> <p>1. Initial Approval Criteria, I.A.2: Updated to include new diagnostic criteria:</p> <p>a. Member does not have cirrhosis;</p> <p>b. Member has compensated cirrhosis without evidence of portal hypertension.</p> <p>2. References reviewed and updated.</p>	01/21/2022	04/18/2022
<p>Policy was reviewed:</p> <p>1. References were reviewed and updated.</p>	12/29/2022	04/13/2023
<p>Policy was reviewed.</p>	10/19/2023	10/19/2023
<p>Policy was reviewed:</p> <p>1. Removed prescriber criteria.</p> <p>2. Removed age criteria.</p> <p>3. Removed dosing criteria.</p> <p>4. Updated continuation of therapy language.</p> <p>5. Updated approval duration verbiage.</p> <p>6. Removed reauthorization requirement for positive response to therapy.</p> <p>7. References were reviewed and updated.</p>	3/21/2025	04/10/2025
<p>Policy reviewed</p>	12/11/2025	12/11/2025