

Policy Name:	Ocaliva (obeticholic acid)	Policy#:	2551P
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Purpose of the Policy

The purpose of this policy is to define coverage criteria for Ocaliva (obeticholic acid).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Ocaliva (obeticholic acid) under the specialty pharmacy benefit if the following criteria are met.

Criteria

1. Coverage Criteria

- 1.1 Ordered by a Gastroenterologist (stomach doctor)
- 1.2 Member is age 18 or older
- 1.3 Diagnosis of primary biliary cholangitis (PBC) based on 2 of the following:
 - Alkaline phosphatase (ALP) greater than or equal to 1.5 x ULN
 - Presence of antimitochondrial antibodies (AMA) at a titre of 1:40 or higher
 - Histologic evidence of nonsuppurative destructive cholangitis and destruction of interlobular bile ducts
- 1.4 Documented failure after 12 months, intolerance, or contraindication to ursodiol (ursodeoxycholic acid)
- 1.5 Documentation of baseline liver function evaluation and intent to monitor liver function consistently

2. Exclusions

- 2.1 If member has complete biliary obstruction in either liver or gall bladder
- 2.2 Evidence of decompensated cirrhosis, a prior decompensation event, or with compensated cirrhosis who have evidence of portal hypertension

3. Managed Dose Limit

- 3.1 A managed dose limit will be in place of #30 tablets per 30 days

4. Approval Period

- 4.1 Initial: 12 months
- 4.2 Reauthorization: 12 months with documented benefit from therapy

CPT Codes

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HCPCS Codes

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References

1. Ocaliva (obeticholic acid) [prescribing information]. Morristown, NJ: Intercept Pharmaceuticals Inc; May 2022.
2. Lindor KD, Bowlus CL, Boyer J, et al. Primary biliary cholangitis: 2021 practice guidance update from the American Association for the Study of Liver Diseases. Hepatology 2022; 75:1012.

3. Rudic JS, Poropat G, Krstic MN, et al. Ursodeoxycholic acid for primary biliary cirrhosis. Cochrane Database Syst Rev 2012; 12:CD000551.
4. FDA Drug Safety Communication. Serious liver injury being observed in patients without cirrhosis taking Ocaliva (obeticholic acid) to treat primary biliary cholangitis. Food and Drug Administration website. Available at <https://www.fda.gov/media/184316/download?attachment>. Accessed 3 March 2025.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.