

POLICY NAME	Ocaliva (obeticholic acid)	POLICY #	2551P
--------------------	----------------------------	-----------------	-------

Criteria

Coverage Criteria

- ☐ Ordered by a Gastroenterologist (stomach doctor)
- ☐ Member is age 18 or older
- ☐ 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
- ☐ Documented failure after 12 months, intolerance, or contraindication to ursodiol (ursodeoxycholic acid)
- ☐ Documentation of baseline liver function evaluation and intent to monitor liver function consistently

Exclusion Criteria – Any of the following prevents coverage

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