Pharmacy Drug Policy Checklist

POLICY NAME	Ocaliva (obeticholic acid)	POLICY #	

Criteria

Exclusion Criteria – Any of the following prevents coverage

- ☐ **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

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