



Montana Healthcare Programs
Drug Prior Authorization Coverage Criteria

Ocalvia™ (obeticholic acid)

Review Criteria

Member must meet all the following criteria:

- Subject to Preferred Drug List requirements
- Member must have diagnosis of either primary biliary cholangitis (PBC) or nonalcoholic fatty liver disease (a.k.a., NAFLD or NAFL or NASH)
 - Diagnosis of primary biliary cholangitis:
 - Member must have an inadequate biochemical response to treatment with an appropriate dosage of ursodiol for at least one year
 - May be approved in combination with ursodiol or as monotherapy, if member cannot tolerate ursodiol alone
 - Diagnosis of nonalcoholic fatty liver disease:
 - May approve over ursodiol (provides a better benefit, per studies)