Mass General Brigham
Health Plan

Ocaliva (obeticholic acid)
Effective 04/01/2025

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Ocaliva (obeticholic acid) is a farnesoid X receptor (FXR) agonist indicated for the treatment of adult patients with primary biliary cholangitis (PBC):

- without cirrhosis or
- with compensated cirrhosis who do not have evidence of portal hypertension,

either in combination with ursodeoxycholic acid (UDCA) with an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA.

All other indications are considered experimental/investigational and not medically necessary.

Coverage Guidelines
Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted when all of the following criteria are met:

1. Member has a diagnosis of PBC is confirmed by at least two of the following:
    a. Biochemical evidence of cholestasis with elevation of alkaline phosphatase (ALP) level
    b. Presence of antimitochondrial antibodies (AMA) or PBC-specific antinuclear antibodies (ANA) (e.g., anti-gp210, anti-sp100)
    c. Histologic evidence of PBC on liver biopsy (e.g., non-suppurative inflammation and destruction of interlobular and septal bile ducts)
2. Member had an inadequate response for at least 12 months of treatment with UDCA (recommended dose is 13-15 mg/kg/day), or member had an intolerance or contraindication to UDCA
3. Member does not have decompensated cirrhosis
4. Requested medication is prescribed by or in consultation with a gastroenterologist or hepatologist
5. Ocaliva will not be used in combination with either of the following: elafibranor, seladelpar

Continuation of Therapy

Requests for reauthorization will be approved when all of the following criteria are met:

1. Member has demonstrated a positive response to therapy as indicated by at least one of the following:
    a. Alkaline phosphatase (ALP) less than 1.67 times the upper limit of normal (ULN)
    b. Total bilirubin less than or equal to the ULN
    c. ALP decrease greater than or equal to 15% from baseline
2. Member continues to not use Ocaliva in combination with either of the following: elafibranor, seladelpar

Limitations

Initial and reauthorization requests will be approved for 12 months.

References

1. European Association for the Study of the Liver. EASL Clinical Practice Guidelines: management of cholestatic liver diseases. *J Hepatol.* 2017;67:145-172.
2. Lindor KD, Gershwin E, Poupon R, et al. Primary biliary cirrhosis. *Hepatology.* 2009;50:291-308.
3. Ocaliva (obeticholic acid) [prescribing information]. New York, NY: Intercept Pharmaceuticals, Inc.; May 2022.

Review History

12/13/2023 - Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024
01/08/2025 – Reviewed and updated at January P&T. Updated language for diagnostic parameters as well as ursodiol trial. Added requirement that member does not have decompensated cirrhosis as well as that the prescriber is a specialist. Updated initial and reauthorization criteria to require that the member is not used Ocaliva in combination with Iqirvo or Livdelzi. Updated initial approval length to 12 months. Effective 04/01/2025.