Mass General Brigham
Health Plan

Ocaliva (obeticholic acid)
Effective 01/01/2024

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 is 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 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 for treatment of PBC in members 18 years of age or older when all of the following criteria are met:

A. Diagnosis of PBC is confirmed by at least two of the following three criteria:
   1. Biochemical evidence of cholestasis with elevation of alkaline phosphatase (ALP) level for at least 6 months duration
   2. Presence of antimitochondrial antibodies (AMA) (titer >1:40 by immunofluorescence or immunoenzymatic reactivity) or PBC-specific antinuclear antibodies (ANA) (e.g., anti-gp210, anti-sp100)
   3. Histologic evidence of PBC on liver biopsy (e.g., non-suppurative inflammation and destruction of interlobular and septal bile ducts)

B. Member has an elevated serum ALP level prior to initiation of therapy with the requested drug

C. Member meets at least one of the following requirements:

1. Inadequate response to at least 12 months of prior therapy with ursodeoxycholic acid (UDCA)/ursodiol and the member will continue concomitant therapy with UDCA/ursodiol, or
2. Intolerance to UDCA/ursodiol

D. Coverage will not be provided for members with decompensated cirrhosis (e.g., Child-Pugh Class B or C), members with a prior decompensation event, OR members with compensated cirrhosis with evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia).

Continuation of Therapy

Authorization may be granted for members who have achieved or maintained a clinical benefit from Ocaliva therapy demonstrated by any of the following: at least a 15% reduction in ALP level, ALP level less than 1.67-times ULN, or total bilirubin less than or equal to ULN.

Limitations

1. Initial approvals will be granted for 6 months.
2. Reauthorizations will be granted for 12 months.

References

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

Review History

12/13/2023: Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024