Obeticholic Acid (Ocaliva®)

Goal(s):

- Encourage use of ursodiol or ursodeoxycholic acid which has demonstrated decrease disease progression and increase time to transplantation.
- Restrict use to populations for which obeticholic acid has demonstrated efficacy.

Length of Authorization:

- Up to 12 months

Requires PA:

- Obeticholic acid

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code	
2. Is this request for continuation of therapy previously approved by the FFS program (patient has already been on obeticholic acid)?	**Yes:** Go to Renewal Criteria	**No:** Go to #3
3. Is the treatment for an adult with primary biliary cholangitis either: • without cirrhosis OR • with compensated cirrhosis who do not have evidence of portal hypertension (e.g. ascites, gastroesophageal varices, persistent thrombocytopenia)?	**Yes**: Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Does patient have a documented intolerance or contraindication to ursodiol?	**Yes:** Document symptoms of intolerance or contraindication and go to #6.	**No:** Go to #5
5. Has patient had a 12-month trial of ursodiol with inadequate response to therapy (Alkaline phosphatase [ALP] ≥1.67-times the ULN or total bilirubin greater than the ULN)?	**Yes**: Document baseline ALP and total bilirubin level and go to # 6 ALP:____ units/L Total Bilirubin __ mg/dL	**No**: Pass to RPh. Deny; medical appropriateness
6. Is obeticholic acid dosed according to the guidelines outlined in Table 1?	**Yes:** Approve for 12 months	**No**: Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
1. Is there evidence of improvement of primary biliary cholangitis, defined as: a. ALP <1.67-times the ULN; AND b. Decrease of ALP >15% from baseline: AND c. Normal total bilirubin level?	**Yes**: Document ALP and total bilirubin level go to # 2 ALP:_____ units/L Total Bilirubin __ mg/dL	**No**: Pass to RPh. Deny; medical appropriateness
2. Does dosing meet parameters outlined in Table 1?	**Yes**: Approve for up to 12 months	**No**: Pass to RPh. Deny; medical appropriateness

Table 1. Obeticholic Acid Dosing Regimen by Patient Population[1]

Staging/Classification	Non-Cirrhotic or Compensated Child-Pugh Class A	Patients with Intolerable Pruritus*	Decompensated cirrhosis (Child-Pugh Class B or C OR Patients with a Prior Decompensation Event (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia).
Initial dose for first 3 months	5 mg once daily	5 mg every other day for patients intolerant to 5 mg once daily 5 mg once daily for patients intolerant to 10 mg once daily Temporarily interrupt administration for 2 weeks. Restart at reduced dosage.	**Obeticholic acid therapy is contraindicated in these patients.**
Dose titration after first 3 months for patients who have not achieved adequate reduction in ALP and/or total bilirubin and who are tolerating obeticholic acid	10 mg once daily		
Maximum dose	10 mg once daily	5 mg once daily	

*Add an antihistamine or bile acid binding resin

1. OCALIVA (obeticholic acid) oral tablet Prescribing Information. New York, NY; Intercept Pharmaceuticals, Inc. May 2021.

P&T / DUR Review: *12/21 (DM); 01/17 (SS)*
Implementation: *1/1/22; 4/1/17*