REALRx

PRIOR AUTHORIZATION REQUEST FORM

OCALIVA®

For authorization, please answer each question and fax this form PLUS chart notes back to Real Rx at 385-425-4052.

Failure to submit clinical documentation to support this request will result in a dismissal of the request.

If you have prior authorization questions, please call for assistance 385-425-5094.

Disclaimer: Prior authorization request forms are subject to change in accordance with Federal and State notice requirements.

Date:	Member Name:	ID#:
DOB:	Gender:	Physician:
Office Phone:	Office Fax:	Office Contact:
Height/Weight:		

Member must try formulary preferred drugs before a request for a non-preferred drug may be considered. If treatment with preferred products has not been successful, you must submit which preferred products have been tried, dates of treatment, and reason for failure. Reasons for failure must meet the Health Plan medical necessity criteria.

Product being requested: ☐ Ocaliva® (obeticholic acid)

Dosing/Frequency:_____

If the request is for reauthorization, proceed to reauthorization section.

Questions	Yes	No	Comments/Notes
1. Is this request for an **expedited** review? By checking the **"Yes"** box to request an expedited review (24 hours), you are certifying that applying the standard review time frame (72 hours) may place the member's life, health, or ability to regain maximum function in serious jeopardy.	☐	☐	
2. Does the member have a diagnosis of primary biliary cholangitis (PBC)?	☐	☐	**Please provide documentation**
3. Is the member 18 years of age or older?	☐	☐	
4. Is the request made by, or in consultation with, a hepatologist or gastroenterologist?	☐	☐	
5. Does the member have documentation of both of the following: • A positive AMA (antimitochondrial antibody) titer (> 1:40) on immunofluorescence OR M2 positive by enzyme-linked immunosorbent assay OR PBC-specific antinuclear antibodies, if AMA is negative? • History of elevated ALP (alkaline phosphatase) levels ≥ 1.5 times the upper limit of normal for ≥ 6 months OR liver biopsy showing histological evidence of PBC?	☐	☐	**Please provide documentation**
6. Do documented laboratory values show at least one of the following: • ALP levels ≥ 1.67 times the upper limit of normal	☐	☐	**Please provide documentation**

• Total bilirubin > the upper limit of normal, but < 2 times the upper limit of normal			
7. Has member had a trial and failure or intolerance/contraindication to ursodeoxycholic acid (ursodiol /UDCA) at a dose of 13 to 15mg/kg/day for at least 12 months? • Failure to UDCA defined as ALP ≥ 1.67x ULN • Intolerance to UDCA must be unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)	☐	☐	**Please provide documentation**
8. Will Ocaliva® be used in combination with UDCA unless contraindicated/intolerant?	☐	☐	
9. Does the member have a complete biliary obstruction?	☐	☐	**Please provide documentation**
10. Does the member have clinical complications of PBC or clinically significant hepatic decompensation including, but not limited to, the following? • Liver transplant, current placement on a liver transplant list, current Model for End Stage Liver disease (MELD) score ≥ 15, known esophageal varices, poorly controlled or diuretic resistant ascites, history of variceal bleeds or related interventions (e.g. beta blockers, bands, or shunt), hepatic encephalopathy, spontaneous bacterial peritonitis, hepatocellular carcinoma, bilirubin > 2 times the upper limit of normal, hepatorenal syndrome, serum creatinine > 2mg/dL, or advanced cirrhosis	☐	☐	**Please provide documentation**
REAUTHORIZATION			
1. Is the request for reauthorization of therapy?	☐	☐	
2. Is the biomedical response assessed after 1 year showing the following? • Bilirubin levels ≤ ULN • ALP < 1.67x the ULN • ALP decrease of ≥ 15% from baseline	☐	☐	**Please provide documentation**
3. Has member developed clinically significant liver-related adverse reactions?	☐	☐	
What medications and/or treatment modalities have been tried in the past for this condition? Please document name of treatment, reason for failure, treatment dates, etc.			
Additional information:			

Physician Signature:

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Policy PHARM- 068
Origination Date: 12/13/2019
Reviewed/Revised Date: 07/31/2023
Next Review Date: 07/31/2024
Current Effective Date: 08/01/2023