

HEALTHY U CHIP

PRIOR AUTHORIZATION REQUEST FORM

OCALIVA®

For authorization, please answer each question and fax this form PLUS chart notes back to the Healthy U CHIP Prior Authorization Department 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. Does the member have a diagnosis of primary biliary cholangitis (PBC)?	<input type="checkbox"/>	<input type="checkbox"/>	Please provide documentation
2. Is the member 18 years of age or older?	<input type="checkbox"/>	<input type="checkbox"/>	
3. Is the request made by, or in consultation with, a hepatologist or gastroenterologist?	<input type="checkbox"/>	<input type="checkbox"/>	
4. Does the member have documentation of both of the following: <ul style="list-style-type: none"> 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? 	<input type="checkbox"/>	<input type="checkbox"/>	Please provide documentation
5. Do documented laboratory values show at least one of the following: <ul style="list-style-type: none"> ALP levels ≥ 1.67 times the upper limit of normal Total bilirubin > the upper limit of normal, but < 2 times the upper limit of normal 	<input type="checkbox"/>	<input type="checkbox"/>	Please provide documentation
6. Has member had a trial and failure or intolerance/contraindication to ursodeoxycholic acid (ursodiol	<input type="checkbox"/>	<input type="checkbox"/>	Please provide documentation

/UDCA) at a dose of 13 to 15mg/kg/day for at least 12 months? <ul style="list-style-type: none"> • Failure to UDCA defined as ALP \geq 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) 			
7. Will Ocaliva® be used in combination with UDCA unless contraindicated/intolerant?	<input type="checkbox"/>	<input type="checkbox"/>	
8. Does the member have a complete biliary obstruction?	<input type="checkbox"/>	<input type="checkbox"/>	Please provide documentation
9. Does the member have clinical complications of PBC or clinically significant hepatic decompensation including, but not limited to, the following? <ul style="list-style-type: none"> • Liver transplant, current placement on a liver transplant list, current Model for End Stage Liver disease (MELD) score \geq 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 	<input type="checkbox"/>	<input type="checkbox"/>	Please provide documentation
REAUTHORIZATION			
1. Is the request for reauthorization of therapy?	<input type="checkbox"/>	<input type="checkbox"/>	
2. Is the biomedical response assessed after 1 year showing the following? <ul style="list-style-type: none"> • Bilirubin levels \leq ULN • ALP < 1.67x the ULN • ALP decrease of \geq 15% from baseline 	<input type="checkbox"/>	<input type="checkbox"/>	Please provide documentation
3. Has member developed clinically significant liver-related adverse reactions?	<input type="checkbox"/>	<input type="checkbox"/>	
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-CHIP-068
 Origination Date: 07/01/2024
 Reviewed/Revised Date:
 Next Review Date:
 Current Effective Date: 07/01/2024

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