Prior Authorization Request Form for

Obeticholic acid (Ocaliva)

JOHNS HOPKINS MEDICINE
JOHNS HOPKINS HEALTHCARE
7231 Parkway Drive, Suite 100, Hanover, MD 21076

FAX Completed Form and Applicable Progress Notes to: (410) 424-4037

USFHP Pharmacy Prior Authorization Form

To be completed by Requesting provider	
Drug Name:	Strength:
Dosage/Frequency (SIG):	Duration of Therapy:

Questions? Contact the Pharmacy Dept at: (888) 819-1043, option 4

Clinical Documentation must accompany form in order for a determination to be made.

Step 1 **Please complete patient and physician information** (please print):

Patient Name: _____ Physician Name: _____

Address: _____ Address: _____

_____ _____

Sponsor ID # _____ Phone #: _____

Date of Birth: Secure Fax #:

Step 2 **Please complete the clinical assessment:**

1. Is the patient greater than or equal to 18 years of age?	☐ Yes Proceed to question **2**	☐ No **STOP** **Coverage not approved**
2. Does the patient have a diagnosis of primary biliary cholangitis (PBC)?	☐ Yes Proceed to question **3**	☐ No **STOP** **Coverage not approved**
3. Is Ocaliva prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician?	☐ Yes Proceed to question **4**	☐ No **STOP** **Coverage not approved**
4. Has the patient received this medication under the TRICARE benefit in the last 6 months? *Please choose "No" if the patient did not previously have a TRICARE approved PA for Ocaliva*	☐ Yes (subject to verification) Proceed to question **8**	☐ No Proceed to question **5**
5. Has the diagnosis of primary biliary cholangitis (PBC) been confirmed by at least TWO of the following: alkaline phosphatase (ALP) elevated above the upper limit of normal (ULN) as defined by normal laboratory reference values; positive anti-mitochondrial antibodies (AMAs); histologic evidence of PBC from a liver biopsy?	☐ Yes Proceed to question **6**	☐ No **STOP** **Coverage not approved**
6. Has the patient been receiving ursodiol therapy (for example, ursodiol generics, Urso 250, Urso Forte, Actigall) for one year or greater and has had an inadequate response?	☐ Yes **Sign and date below**	☐ No Proceed to question **7**
7. Is the patient unable to tolerate ursodiol therapy?	☐ Yes **Sign and date below**	☐ No **STOP** **Coverage not approved**

8. Has the patient responded to Ocaliva as determined by the prescribing physician (for example, improved biochemical markers of PBC [alkaline phosphatase (ALP), bilirubin, gamma-glutamyl transpeptidase (GGT), aspartate aminotransferase (AST), alanine aminotransferase (ALT) levels)?	☐ Yes **Sign and date below**	☐ No **STOP** **Coverage not approved**

Step 3 **I certify the above is true to the best of my knowledge.** Please sign and date:

_____ _____
Prescriber Signature Date

[31 July 2019]

For Internal Use Only	
☐ Approved:	Duration of Approval: _____month(s)
☐ Denied:	Authorized By:
☐ Incomplete/Other:	PA#:
Date Faxed to MD:	Date Decision Rendered: