BlueCross BlueShield Federal Employee Program.

OCALIVA
PRIOR APPROVAL REQUEST

Send completed form to:
Service Benefit Plan
Prior Approval
P.O. Box 52080 MC 139
Phoenix, AZ 85072-2080
Attn. Clinical Services
Fax: 1-877-378-4727

Additional information is required to process your claim for prescription drugs. Please complete the cardholder portion, and have the prescribing physician complete the physician portion and submit this completed form.

Patient Information (required)			**Provider Information (required)**		
Date:			Provider Name:		
Patient Name:			Specialty:	NPI:	
Date of Birth:	Sex: ❑Male ❑Female		Office Phone:	Office Fax:	
Street Address:			Office Street Address:		
City:	State:	Zip:	City:	State:	Zip:
Patient ID: **R**			Physician Signature:		
PHYSICIAN COMPLETES					

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Ocaliva (obeticholic acid)

****Check www.fepblue.org/formulary to confirm which medication is part of the patient's benefit**

NOTE: Form must be completed in its **entirety** for processing

Is this request for brand or generic? ❑Brand ❑Generic

1. Will the patient need more than 90 tablets every 90 days? ❑Yes***** ❑No
   If YES, please specify the requested quantity: _____ tablets every 90 days
2. Does the patient have a diagnosis of primary biliary cholangitis (PBC)? ❑Yes ❑No
3. Does the patient have cirrhosis? ❑Yes***** ❑No
   If YES, does the patient have compensated cirrhosis with evidence of portal hypertension? ❑Yes ❑No
4. Has the patient been on this medication continuously for the last **4 months** excluding samples? ***Please select answer below:***

❑**NO** – this is **INITIATION** of therapy, please answer the following questions:

a. Has the diagnosis been confirmed by elevated serum alkaline phosphatase level? ❑Yes***** ❑No

If YES, has the diagnosis been confirmed by at least **ONE** of the following tests: positive antimitochondrial antibody test, liver biopsy, or ultrasound scan of the liver? ❑Yes ❑No

b. Is the patient able to tolerate ursodeoxycholic acid (UDCA)? ***Please select answer below:***

❑**Yes**: Has the patient had an inadequate treatment response to a 1 year trial of ursodeoxycholic acid? ❑Yes ❑No

❑**No**: Is the patient intolerant to ursodeoxycholic acid despite attempts to minimize the adverse effects, such as a dose reduction, where appropriate? ❑Yes ❑No

c. Will Ocaliva be used in combination with UDCA (ursodeoxycholic acid)? ❑Yes ❑No

d. Does the patient have biliary obstruction? ❑Yes ❑No*****

If NO, will Ocaliva be discontinued if complete biliary obstruction occurs? ❑Yes ❑No

e. Does the prescriber agree to frequently monitor patient during treatment for elevations in liver biochemical tests, development of liver-related adverse reactions, and for changes in serum lipid levels? ❑Yes ❑No

❑**YES** – this is a PA renewal for **CONTINUATION** of therapy, please answer the following questions:

a. Will the patient be monitored during treatment for elevations in liver biochemical tests, development of liver-related adverse reactions, and for changes in serum lipid levels? ❑Yes ❑No

b. Does the prescriber agree to weigh the potential risks against the benefits of continuing treatment if the patient experiences clinically significant liver-related adverse reactions? ❑Yes ❑No

c. Is there evidence of complete biliary obstruction? ❑Yes ❑No

d. Has there been a decrease of at least 15% in serum alkaline phosphate (ALP)? ❑Yes ❑No

e. **MALE Patient**: Does the patient have a total bilirubin level less than or equal to 1.5 mg/dL? ❑Yes ❑No

f. **FEMALE Patient**: Does the patient have a total bilirubin level less than or equal to 1.1 mg/dL? ❑Yes ❑No

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To ensure a quick and accurate response to your approval request, please **submit medical records (e.g., chart notes, laboratory values)** and use of claims history pertaining to the diagnosis only. Please do not send in medical records of other diagnoses in order to streamline the process. Please use this page as a guideline of what documentation is required to process the prior authorization request.

***For more efficient processing, please provide the page number of the documented information in the medical record**

Documentation Required:

❑ Patient has **ONE** of the following: **PAGE _____ of _____**
- **NO** cirrhosis
- Compensated cirrhosis with no evidence of portal hypertension

Documentation Required for <u>INITIATION</u> of therapy:

❒ Submission of medical records documenting **ONE** of the following: **PAGE _____ of _____**
- **Inadequate response**: history of a minimum of a 1 year trial of ursodexycholic acid (UDCA)
- **Intolerance**: attempts to minimize the adverse effects with a history of a trial of ursodeoxycholic acid (UDCA)

❒ Submission of medical records documenting **ALL** of the following: **PAGE _____ of _____**
- Must be used in combination with UDCA in patients who are tolerant or used as monotherapy in patients who are unable to tolerate UDCA
- **NO** preliminary biliary obstruction prior to initiation of therapy and agreement to discontinue therapy if complete biliary obstruction develops
- Physician agrees to frequently monitor patient during treatment for elevations in liver biochemical tests, development of liver-related adverse reactions, and for changes in serum lipid levels
- Confirmation of diagnosis with elevated serum alkaline phosphatase level **AND ONE** of the following tests:
  - Positive antimitochondrial antibody test
  - Liver biopsy
  - Ultrasound scan of liver

Documentation Required for <u>CONTINUATION</u> of therapy:

❒ Submission of medical records documenting **ALL** of the following: **PAGE _____ of _____**
- Patient monitoring during treatment for elevations in liver biochemical tests, development of liver-related adverse reactions, and for changes in serum lipid levels
- Physician has weighed the potential risks against the benefits of continuing treatment in patients experiencing clinically significant liver-related adverse reactions
- **NO** evidence of complete biliary obstruction
- Confirmation of patient improvement with **ALL** of the following:
  - Serum alkaline phosphatase (ALP) decrease of at least 15%
  - Total bilirubin level of ≤ 1.1 mg/dL for females and ≤ 1.5 mg/dL for males

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Message:

Attached is a Prior Authorization request form.

For your convenience, there are 3 ways to complete a Prior Authorization request:

Electronically Online (ePA) Results in 2-3 **minutes** **FASTEST AND EASIEST**	Now you can get responses to drug Prior Authorization requests **securely** online. **Online** submissions may receive **instant** responses and do not require faxing or phone calls. Requests can be made 24 hours a day, 7 days a week. For more information on electronic prior authorization (ePA) and to register, go to **Caremark.com/ePA.**
Phone (4-5 **minutes** for response)	The FEP Clinical Call Center can be reached at **(877)-727-3784** between the hours of 7AM-9PM Eastern Time. A live representative will assist with the Prior Authorization, asking for the same information contained on the attached form. Please review the form and have your answers ready for faster service. The process over the phone takes on average between 4 and 5 minutes.
Fax (3-5 **days** for response)	Fax the attached form to **(877)-378-4727**. Requests sent via fax will be processed and responded to within 5 business days. The form must be filled out completely, if there is any missing information the Prior Authorization request cannot be processed. ***Please only fax the completed form once as duplicate submissions may delay processing times.***