BlueCross BlueShield Federal Employee Program

IQIRVO
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.

Iqirvo (elafibranor)

****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 decompensated cirrhosis? ❑Yes ❑No
4. 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
5. 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**: Please answer the below questions:

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

ii. Will this medication be used in combination with UDCA (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. Does the patient have biliary obstruction? ❑Yes ❑No*

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

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

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

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

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

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

e. **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 for INITIATION 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 ursodeoxycholic 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** decompensated cirrhosis
- **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 CONTINUATION 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** decompensated cirrhosis
- **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