

PRIMARY BILIARY CHOLANGITIS PRIOR AUTHORIZATION REQUEST PRESCRIBER FAX FORM

Only the prescriber may complete this form. This form is for prospective, concurrent, and retrospective reviews.

The following documentation is **REQUIRED**. Incomplete forms will be returned for additional information. For formulary information please visit www.myprime.com. Start saving time today by filling out this form electronically. Visit covermy meds.com to begin using this free service.

What is the priority level of this request?

- Standard review
- Expedited/Urgent review – prescriber certifies that waiting for a standard review could seriously harm the patient’s life, health or ability to regain maximum function

Today’s Date: _____

PATIENT AND INSURANCE INFORMATION

Date of Service (if differs from Today’s Date): _____

Patient Name (First):	Last:	M:	DOB (mm/dd/yyyy):
Patient Address:	City, State, Zip:	Patient Telephone:	
Member ID Number:	Group Number:		

PRESCRIBER/CLINIC INFORMATION

Prescriber Name:	Prescriber NPI#:	Specialty:	Contact Name:
Clinic Name:	Clinic Address:		
City, State, Zip:	Phone #:	Secure Fax #:	

PLEASE ATTACH ANY ADDITIONAL INFORMATION THAT SHOULD BE CONSIDERED WITH THIS REQUEST

Patient’s Diagnosis:

- Primary biliary cholangitis (PBC)
- Other (ICD code plus description): _____

Medication Requested:	Strength:
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Dosing Schedule:	Quantity per Month:
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For all requests:

1. Is the patient currently treated with the requested agent? Yes No
If yes, is the patient currently stable on the requested agent? **Please note, chart notes are required**..... Yes No
2. Does the patient have decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy)? Yes No
3. Is the prescriber a specialist in the area of the patient’s diagnosis (e.g., gastroenterologist, hepatologist), or has the prescriber consulted with a specialist in the area of the patient’s diagnosis? Yes No
4. Does the patient have any FDA labeled contraindications to the requested agent? Yes No
If yes, please specify FDA labeled contraindication: _____
5. Is the patient’s age within FDA labeling for the requested indication for the requested agent? Yes No
If no, please provide support for using the requested agent for the patient’s age for the requested indication: _____
6. Please list all reasons for selecting the requested agent, strength, dosing schedule, and quantity over alternatives (e.g., contraindications, allergies, history of adverse drug reactions to alternatives, lower dose has been tried, information supporting dose over FDA max). **Please note, documentation may be required:** _____

For Primary biliary cholangitis (PBC) requests:

7. Has the patient’s diagnosis been confirmed by at least TWO of the following: 1) biochemical evidence of cholestasis with an alkaline phosphatase (ALP) elevation, 2) positive presence of antimitochondrial antibody (AMA), 3) if AMA is negative, positive presence of other PBC-specific autoantibodies (e.g., sp100, gp210), AND/OR 4) histologic evidence of nonsuppurative destruction cholangitis and destruction of interlobular bile ducts? Yes No

Please continue to the next page.

Patient Name (First):	Last:	M:	DOB (mm/dd/yyyy):
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8. Has the patient's baseline alkaline phosphatase (ALP) level and total bilirubin level (prior to therapy with the requested agent) been measured?..... Yes No
9. Has the patient tried and had an inadequate response after at least 1 year of therapy with ursodeoxycholic acid (UDCA) (inadequate response after 1 year of treatment with UDCA is defined as ALP greater than the upper limit of normal [ULN], and/or total bilirubin greater than ULN but less than 2x ULN)? Yes No
 If yes, will the patient continue therapy with ursodeoxycholic acid (UDCA) in combination with the requested agent? Yes No
10. Does the patient have an intolerance or hypersensitivity to therapy with ursodeoxycholic acid (UDCA)?..... Yes No
 If yes, please explain intolerance/hypersensitivity: _____

 If no, does the patient have an FDA labeled contraindication to ursodeoxycholic acid (UDCA)? Yes No
 If yes, please specify FDA labeled contraindication: _____

For Ocaliva (obeticholic acid) requests:

*** Please submit chart notes to support the answers to the following questions:**

11. Has the patient tried and had an inadequate response to ONE preferred agent? The preferred agents are Iqirvo (elafibranor) and Livdelzi (seladelpar). Yes No
12. Was ONE preferred agent listed above discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? Yes No
13. Does the patient have an intolerance or hypersensitivity to ONE preferred agent listed above?..... Yes No
14. Does the patient have an FDA labeled contraindication to ALL preferred agents listed above?..... Yes No
15. Are ONE of the following expected of ONE preferred agent listed above: 1) to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug, 2) cause a significant barrier to the patient's adherence of care, 3) worsen a comorbid condition, 4) decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities, OR 5) cause an adverse reaction or cause physical or mental harm?..... Yes No
16. Is ONE preferred agent listed above not in the best interest of the patient based on medical necessity?..... Yes No
17. Has the patient tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE preferred agent, AND that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? Yes No

For renewal requests:

18. Has the patient had clinical benefit with the requested agent? Yes No

For Primary biliary cholangitis (PBC) requests:

19. Will the requested agent be used in combination with ursodeoxycholic acid (UDCA)?..... Yes No
 If no, does the patient have an intolerance, hypersensitivity, or an FDA labeled contraindication to therapy with ursodeoxycholic acid (UDCA)? Yes No
 If yes, please explain intolerance/hypersensitivity/contraindication: _____

20. Has the patient had clinical benefit with the requested agent as indicated by an alkaline phosphatase (ALP) decrease of greater than or equal to 15% from baseline (prior to therapy with the requested agent) AND ALP is less than the upper limit of normal (ULN)? Yes No
21. Has the patient had clinical benefit with the requested agent as indicated by a total bilirubin less than or equal to the upper limit of normal (ULN)?..... Yes No

Please fax or mail this form to:
 Prime Therapeutics LLC
 Clinical Review Department
 2900 Ames Crossing Road Suite 200
 Eagan, MN 55121

TOLL FREE

Phone: **Fax: 877.243.6930**
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BCBSNM: 800.544.1378
BCBSOK: 800.991.5643
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