PRIOR AUTHORIZATION REQUEST

PRIMARY BILIARY CHOLANGITIS (PBC) – IQIRVO AND LIVZDELZI

Patient Information:

Name:	
Member ID:	
Address:	
City, State, Zip:	
Date of Birth:	

Prescriber Information:

Name:	
NPI:	
Phone Number:	
Fax Number	
Address:	
City, State, Zip:	

Requested Medication

Rx Name:	
Rx Strength	
Rx Quantity:	
Rx Frequency:	
Rx Route of Administration:	
Diagnosis and ICD Code:	

Your patient's prescription benefit requires that we review certain requests for coverage with the prescriber. You have prescribed a medication for your patient that requires Prior Authorization before benefit coverage or coverage of additional quantities can be provided. Please complete the following questions then fax this form to the toll-free number listed below. Upon receipt of the completed form, prescription benefit coverage will be determined based on the plan's rules.

SECTION A: Please note that supporting clinical documentation is required for **ALL** PA requests. Pharmacy prior authorization reviews can be subject to trial with additional medications that are not listed within the criteria. The policies are subject to change based on COMAR requirements, MDH transmittals and updates to treatment guidelines.

1	Is the request for an INITIAL or a CONTINUATION of therapy? [] Initial (If checked, go to 7) [] Continuation (If checked, go to 2)		
2	Is the patient currently receiving the requested medication? [If no, skip to question 7.]	Yes	No

If you have any questions, call: 1-888-258-8250

Version 05.2026

PRIOR AUTHORIZATION REQUEST

3	Has the patient been receiving medication samples of the requested medication? [If yes, skip to question 7.]	Yes	No
4	Does the patient have a previously approved prior authorization (PA) on file with the current plan? [Note: If the patient does NOT have a previously approved PA on file for the requested medication with the current plan, the renewal request will be considered under initial therapy.] [If no, skip to question 7.]	Yes	No
5	Has the patient been on established therapy for AT LEAST 3 months? [If no, skip to question 7.]	Yes	No
6	Has documentation been submitted to confirm that the patient has had a clinically significant response to therapy, as determined by the prescriber? ACTION REQUIRED: Submit supporting documentation. [Note: Examples of a response to requested medication are improved biochemical markers of primary biliary cholangitis (PBC) (for example, alkaline phosphatase (ALP), bilirubin, gamma-glutamyl transpeptidase (GGT), aspartate aminotransferase (AST), or alanine aminotransferase (ALT) levels).] [No further questions.]	Yes	No
7	What is the indication? [] Primary Biliary Cholangitis (PBC) (If checked, go to 8) [] Other (If checked, no further questions)		
8	Is the patient 18 years of age or older? [If no, no further questions.]	Yes	No
9	Has documentation been submitted to confirm the patient has primary biliary cholangitis (PBC) as evidenced by: A) Alkaline phosphatase (ALP) is elevated above the upper limit of normal as defined by normal laboratory reference values, B) Positive anti-mitochondrial antibodies or other primary biliary cholangitis-specific autoantibodies, including sp100 or gp210, if antimitochondrial antibodies are negative, OR C) The patient's histologic evidence of PBC from a liver biopsy (for example, non-suppurative inflammation and destruction of interlobular and septal bile ducts)? ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No
10	Does the provider attest the patient does NOT have a have a history of hepatic decompensation (for example, ascites, gastroesophageal varices, variceal bleeding, hepatic encephalopathy, and coagulopathy) AND currently does not have active decompensation? [If no, no further questions.]	Yes	No
11	Does the patient have complete biliary obstruction?	Yes	No

PRIOR AUTHORIZATION REQUEST

	[If yes, no further questions.]		
12	Has documentation been submitted to confirm that the patient has had a treatment failure with AT LEAST 1 year of Ursodiol unless intolerant or contraindicated? ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No
13	Is the requested medication being prescribed by or in consultation with a gastroenterologist and/or hepatologist? [If no, no further questions.]	Yes	No
14	What medication is being requested? [] Iqirvo (If checked, go to 15) [] Livdelzi (If checked go to 18)		
15	Has documentation been submitted with laboratory values obtained within the last 90 days for the following: A) Alkaline phosphatase (ALP) greater than or equal to 1.67 times upper limit of normal (ULN), AND B) Total bilirubin less than or equal to 2 times ULN? ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No
16	Will the requested medication be used in combination with Livdelzi (seladelpar)? [If yes, no further questions.]	Yes	No
17	Does the prescribed dosing exceed Food and Drug Administration (FDA) approved indication? [Dosing: 80 mg once daily.] [No further questions.]	Yes	No
18	Has documentation been submitted with laboratory values obtained within the last 90 days for the following: A) Alkaline phosphatase (ALP) greater than or equal to 1.67 times upper limit of normal (ULN), B) Aspartate aminotransferase (AST) less than or equal to 3 times ULN, C) Alanine Aminotransferase (ALT) less than or equal to 3 times ULN, D) Total bilirubin less than or equal to 2 times ULN, E) Estimated Glomerular Filtration Rate (eGFR) greater than 45 mL/min/1.73m2, F) International Normalized Ratio (INR) less than 1.1 times ULN, and G) Platelet count greater than or equal to 100,000 cells per microliter? ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No
19	Will the requested medication be used in combination with Iqirvo (elafibranor)? [If yes, no further questions.]	Yes	No
20	Will the requested medication be given with concomitant Organic Anion Transporter 3 (OAT3) inhibitors (for example, probenecid) or strong Cytochrome P450 family 2 subfamily C member 9 (CYP2C9) inhibitors (for example, clotrimazole, fluconazole, or gemfibrozil)?	Yes	No

PRIOR AUTHORIZATION REQUEST

	[If yes, no further questions.]		
21	Does the prescribed dosing exceed Food and Drug Administration (FDA) approved indication? [Dosing: 10 mg once daily.]	Yes	No

Please document the diagnoses, symptoms, and/or any other information important to this review:

SECTION B: Physician Signature

PHYSICIAN SIGNATURE DATE

FAX COMPLETED FORM TO: 1-833-896-0656

Disclaimer: An authorization is not a guarantee of payment. Member must be eligible at the time services are rendered. Services must be a covered Health Plan Benefit and medically necessary with prior authorization as per Plan policy and procedures.

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