



PRIOR AUTHORIZATION REQUEST

BYLVAY

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 this request for initial or continuation of therapy? ☐ Initial (If checked, go to 6) ☐ Continuation (If checked, go to 2)		
2	Has the patient been receiving medication samples for the requested medication? [If yes, skip to question 6.]	Yes	No
3	Does the patient have a previously approved prior authorization (PA) on file with the current plan for the requested medication?	Yes	No

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[Note: If the patient does NOT have a previously approved PA on file for the requested medication, the renewal request will be considered under initial therapy.]
[If no, skip to question 6.]

- | | | | |
|----|---|-----|----|
| 4 | Has the patient been on established therapy for at least 3 months?
[If no, skip to question 6.] | Yes | No |
| 5 | 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.
[No further questions.] | Yes | No |
| 6 | What is the diagnosis or indication?
☐ Progressive Familial Intrahepatic Cholestasis (If checked, go to 7)

☐ Cholestatic pruritus with Alagille Syndrome (ALGS) (If checked, go to 20)

☐ Other (If checked, no further questions) | | |
| 7 | Is the patient 3 months of age or older?
[If no, no further questions.] | Yes | No |
| 8 | Does the patient have cirrhosis?
[If yes, no further questions.] | Yes | No |
| 9 | Does the patient have portal hypertension?
[If yes, no further questions.] | Yes | No |
| 10 | Does the patient have a history of a hepatic decompensation event?
[Note: Examples of a hepatic decompensation event include variceal hemorrhage, ascites, and hepatic encephalopathy.]
[If yes, no further questions.] | Yes | No |
| 11 | Does the patient have moderate-to-severe pruritus, according to the prescriber?
[If no, no further questions.] | Yes | No |
| 12 | Was the diagnosis of progressive familial intrahepatic cholestasis confirmed by genetic testing demonstrating a gene mutation affiliated with progressive familial intrahepatic cholestasis?
[Note: Gene mutations affiliated with progressive familial intrahepatic cholestasis include the <i>ATP8B1</i> gene, <i>ABCB11</i> gene, <i>ABCB4</i> gene, <i>TJP2</i> gene, <i>NR1H4</i> gene, and <i>MYO5B</i> gene.]
[If no, no further questions.] | Yes | No |
| 13 | Does the patient have an <i>ABCB11</i> variant resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3)?
[If yes, no further questions.] | Yes | No |
| 14 | Does the patient have a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory?
[If no, no further questions.] | Yes | No |

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15	Has documentation been submitted to confirm that the patient has an intolerance, contraindication to, or failed treatment for at least 3 months with ursodiol (ursodeoxycholic acid)? ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No
16	Has documentation been submitted to confirm that the patient has an intolerance, contraindication to, or failed treatment for at least 3 months with TWO different medications used for pruritus other than ursodiol? (Examples are cholestyramine, colestesvelam, diphenhydramine, rifampin). ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No
17	Will the requested medication be used concomitantly with Livmarli? [If yes, no further questions.]	Yes	No
18	Is the requested medication prescribed by or in consultation with a hepatologist, gastroenterologist, or a physician who specializes in progressive familial intrahepatic cholestasis? [If no, no further questions.]	Yes	No
19	Does the requested dose exceed Food and Drug Administration (FDA) approved label dosing for the requested indication? [Note: Dosing is up to 6 mg/day.] [No further questions.]	Yes	No
20	Is the patient 12 months of age or older? [If no, no further questions.]	Yes	No
21	Does the patient have a documented diagnosis of Alagille Syndrome (ALGS) with confirmed genetic testing demonstrating a JAG1 or NOTCH2 mutation? ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No
22	Does the patient have moderate-to-severe pruritus, according to the prescriber? [If no, no further questions.]	Yes	No
23	Does the patient have a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory? ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No
24	Does the patient have a baseline INR greater than or equal to 1.4? ACTION REQUIRED: Submit supporting documentation. [If yes, no further questions.]	Yes	No
25	Does the patient have a baseline alanine aminotransferase (ALT) greater than or equal to 10-times the upper limit of normal? ACTION REQUIRED: Submit supporting documentation. [If yes, no further questions.]	Yes	No
26	Does the patient have a baseline total bilirubin greater than or equal to 15-times the upper limit of normal? ACTION REQUIRED: Submit supporting documentation. [If yes, no further questions.]	Yes	No

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27	Does the patient have a history of a hepatic decompensation event? ACTION REQUIRED: Submit supporting documentation. [Note: Examples of a hepatic decompensation event include variceal hemorrhage, ascites, and hepatic encephalopathy.] [If yes, no further questions.]	Yes	No
28	Has documentation been submitted to confirm that the patient has an intolerance, contraindication to, or failed treatment for at least 3 months with ursodiol (ursodeoxycholic acid)? ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No
29	Has documentation been submitted to confirm that the patient has an intolerance, contraindication to, or failed treatment for at least 3 months with TWO different medications used for pruritus other than ursodiol? (Examples are cholestyramine, colesevelam, diphenhydramine, rifampin). ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No
30	Does the provider attest to obtain baseline levels of fat soluble vitamins and monitor during treatment? [If no, no further questions.]	Yes	No
31	Does the provider attest to obtain baseline liver function tests and monitor during treatment? [If no, no further questions.]	Yes	No
32	Will the requested medication be used concomitantly with Livmarli? [If yes, no further questions.]	Yes	No
33	Is the requested medication prescribed by or in consultation with a hepatologist or gastroenterologist? [If no, no further questions.]	Yes	No
34	Does the requested dose exceed Food and Drug Administration (FDA) approved label dosing for the requested indication? [Note: Dosing is 120 mcg/kg/day.]	Yes	No

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

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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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