

LIVMARLI (maralixibat)

Pre - PA Allowance

None

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

- 1. Cholestatic pruritus associated with Alagille syndrome (ALGS)
 - a. 3 months of age or older
 - b. Diagnosis has been confirmed by **ONE** of the following:
 - i. Genetic testing (e.g., JAGGED1 mutation)
 - Patient has bile duct paucity AND at least 3 major clinical features of ALGS (e.g., cholestasis, cardiac defect, skeletal abnormality, ophthalmic abnormality, or characteristic facial features)
- 2. Cholestatic pruritus associated with progressive familial intrahepatic cholestasis (PFIC)
 - a. 12 months of age or older
 - b. **NO** PFIC type 2 with ABCB11 variants causing non-functional or complete absence of bile salt export pump protein

AND ALL of the following:

- 1. **NO** clinically significant portal hypertension or decompensated cirrhosis
- 2. Inadequate treatment response, intolerance, or contraindication to **ONE** of the following:
 - a. Cholestyramine
 - b. Rifampin
 - c. Ursodeoxycholic acid (UDCA)
- Patient has had baseline liver function tests (LFTs) and serum fat-soluble vitamin (FSV) levels performed
- 4. Prescriber agrees to monitor liver function tests (LFTs) and serum fat-soluble vitamin (FSV) levels during treatment

Prior - Approval Limits

Quantity

Diagnosis	Quantity
Alagille Syndrome (ALGS)	30 mg per day per day OR
Progressive Familial Intrahepatic Cholestasis	40 mg per day



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(PFIC)	

Duration 12 months

Prior - Approval Renewal Requirements

Diagnoses

Patient must have **ONE** of the following:

- 1. Cholestatic pruritus associated with Alagille syndrome (ALGS)
 - a. 3 months of age or older
- 2. Cholestatic pruritus associated with progressive familial intrahepatic cholestasis (PFIC)
 - a. 12 months years of age or older

AND ALL of the following:

- 1. Improvement in pruritus symptoms, or observed improvement in scratching
- 2. **NO** clinically significant portal hypertension or decompensated cirrhosis
- 3. Prescriber agrees to monitor LFTs and serum FSV levels during treatment

Prior - Approval Renewal Limits

Same as above