Livmarli (Maralixibat)

EXCEPTION DRUG STATUS (EDS) REQUEST FORM

Fax: (204) 942-2030 or 1-877-208-3588

Prescriber Name:	**Fax Number:**
Prescriber Address:	**Phone Number:**
	Prescriber License Number (NOT Billing Number):

Patient First Name:	**PHIN:**	**MHSC:**
Patient Last Name:	**Patient's Date of Birth:**	
◯ **Initial Request**	◯ **Renewal Request**	
Strength, Dosage Form and Regimen:	**Expected Duration of Therapy**	

Exception Drug Status (EDS) approval is only granted upon demonstration that the patient meets the coverage criteria of the EDS listing. Please provide the following details about how this patient meets the specific criteria for coverage. Manitoba Health may request additional documentation to support this EDS request.

For INITIAL Requests:			
Diagnosis/Indication:	◯ Cholestatic pruritus with Alagille Syndrome (ALGS)		
	◯ Other:		
Please select YES or NO to the following:			
Patient is 12 months of age or older.		◯ YES	◯ NO
Patient has moderate to severe itch defined as an average daily score of 2 or more on the Itch Reported Outcome (ItchRO) OR Clinician Scratch Scale (CSS) for 2 consecutive weeks. **Baseline average daily ItchRO score: _____ Start Date: _____ End Date: _____** **OR** **Baseline average daily CSS score: _____ Start Date: _____ End Date: _____**		◯ YES	◯ NO
Patient has evidence of cholestasis, with at least **ONE** of the following:			
• Total serum bile acids (sBA) > 3 x upper limit of normal (ULN) for age		◯ YES	◯ NO
• Conjugated bilirubin > 1 mg/dL		◯ YES	◯ NO
• Fat soluble vitamin deficiency otherwise unexplainable		◯ YES	◯ NO
• Gamma glutamyltransferase (GGT) > 3 x ULN for age		◯ YES	◯ NO
• Intractable pruritis explainable only by liver disease		◯ YES	◯ NO
Patient is currently being treated with, or has received an adequate trial with, a systemic treatment for pruritus prior to initiating maralixibat (e.g., ursodeoxycholic acid (UDCA), rifampin, sertraline, naltrexone, cholestyramine) **for at least one month**.		◯ YES	◯ NO

Treatment History (provide information for systemic treatment(s) for pruritis):

Name of Drug	***Dosing Regimen***	***Start Date***	***End Date (if applicable)***	***Outcome of Treatment***
				☐ Ineffective: ☐ Intolerance (specify): ☐ Contraindication (specify): ☐ Other (specify):

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				☐ Ineffective: ☐ Intolerance (specify): ☐ Contraindication (specify): ☐ Other (specify):
				☐ Ineffective: ☐ Intolerance (specify): ☐ Contraindication (specify): ☐ Other (specify):

Patient is under the care of a hepatologist or gastroenterologist with experience in the diagnosis and management of ALGS.	◯ YES	◯ NO
Does the patient have **ANY** of the following?		
• Biliary diversion	◯ YES	◯ NO
• Previous liver transplant	◯ YES	◯ NO
• Decompensated cirrhosis	◯ YES	◯ NO
• History or presence of other concomitant liver disease	◯ YES	◯ NO

Additional Relevant Clinical Information:

For ALL RENEWAL Requests:

Please select YES or NO to the following:

Patient remains under the care of a hepatologist or gastroenterologist with experience in the diagnosis and management of ALGS.	◯ YES	◯ NO
Has the patient received a liver transplant or biliary diversion surgery?	◯ YES	◯ NO

Please provide ONE of the following (using the same measurement tool used at baseline):
Current average daily ItchRO score: _____ Start Date: _____ End Date: _____
OR
Current average daily CSS score: _____ Start Date: _____ End Date: _____

Additional Relevant Clinical Information:

Prescriber Signature and Date:

☐ **I have discussed with the patient that the purpose of releasing their information to Manitoba Health, Seniors and Long-Term Care is to obtain Exception Drug Status for prescription coverage.**

Date:	Prescriber Signature: