

SENTARA HEALTH PLANS

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; fax to **1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. If information provided is not complete, correct, or legible, authorization may be delayed.

Drug Requested: Livmarli® (maralixibat)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code: _____

Weight: _____ Date: _____

Recommended Dosage: 380 mcg/kg once daily, taken 30 minutes before the first meal of the day.
Maximum dosage is 760 mcg/kg per day

Dose Volume Recommendations Based on Patient Body Weight				
Patient weight	Days 1 to 7 (190 mcg/kg once daily)		Beginning day 8 (380 mcg/kg once daily)	
	Volume (once daily)	Dosing dispenser size	Volume (once daily)	Dosing dispenser size
5 to 6 kg	0.1 mL	0.5 mL	0.2 mL	0.5 mL
7 to 9 kg	0.15 mL	0.5 mL	0.3 mL	0.5 mL
10 to 12 kg	0.2 mL	0.5 mL	0.45 mL	0.5 mL
13 to 15 kg	0.3 mL	0.5 mL	0.6 mL	1 mL
16 to 19 kg	0.35 mL	0.5 mL	0.7 mL	1 mL

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Dose Volume Recommendations Based on Patient Body Weight				
Patient weight	Days 1 to 7 (190 mcg/kg once daily)		Beginning day 8 (380 mcg/kg once daily)	
	Volume (once daily)	Dosing dispenser size	Volume (once daily)	Dosing dispenser size
20 to 24 kg	0.45 mL	0.5 mL	0.9 mL	1 mL
25 to 29 kg	0.5 mL	0.5 mL	1 mL	1 mL
30 to 34 kg	0.6 mL	1 mL	1.25 mL	3 mL
35 to 39 kg	0.7 mL	1 mL	1.5 mL	3 mL
40 to 49 kg	0.9 mL	1 mL	1.75 mL	3 mL
50 to 59 kg	1 mL	1 mL	2.25 mL	3 mL
60 to 69 kg	1.25 mL	3 mL	2.5 mL	3 mL
≥70 kg	1.5 mL	3 mL	3 mL	3 mL

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

DIAGNOSIS: Cholestatic pruritus due to Alagille syndrome

Initial Authorization: 6 months

- ☐ Medication is prescribed by or in consultation with a hepatologist, gastroenterologist, cardiologist or a physician who specializes in Alagille syndrome
- ☐ Member is 3 months of age or older
- ☐ Member has been diagnosed with Alagille syndrome
- ☐ Provider has submitted the results of genetic testing confirming a JAG1 or NOTCH2 deletion or mutation (**submit results**)
- ☐ Provider has submitted clinical confirmation of disease met by **ALL** the following (**submit labs and/or chart notes**):
 - ☐ Bile duct paucity on liver biopsy
 - ☐ THREE (3) or more of the following major criteria:
 - ☐ Liver/cholestasis
 - ☐ Dysmorphic facies
 - ☐ Heart disease
 - ☐ Axial skeleton/vertebral anomalies
 - ☐ Eye/posterior embryotoxin

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- ☐ Member is experiencing evidence of cholestasis confirmed by **TWO** of the following (**submit labs and/or chart notes**):
 - ☐ Total serum bile acid > 3 x ULN for age
 - ☐ Conjugated bilirubin > 1 mg/dL
 - ☐ Fat soluble vitamin deficiency otherwise unexplainable
 - ☐ GGT > 3 x ULN for age
 - ☐ Intractable pruritus explainable only by liver disease
- ☐ Member has an average daily score >2 on the itch-reported outcome (ItchRO™)
- ☐ Member does **NOT** have any of the following:
 - ☐ Surgical interruption of the enterohepatic circulation
 - ☐ Liver transplantation
 - ☐ Decompensated liver cirrhosis
- ☐ Member has failed an adequate trial, is intolerant to, or has a contraindication to **ONE** of the following (**verified by pharmacy paid claims; documentation of failure as evidenced by labs/ItchRO™ MUST be submitted**):
 - ☐ ursodeoxycholic acid (ursodiol)
 - ☐ rifampin

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ☐ Provider has submitted documentation of ItchRO™ score decrease from baseline by <1 and serum bile acid decrease
- ☐ Member does **NOT** have any of the following:
 - ☐ Surgical interruption of the enterohepatic circulation
 - ☐ Liver transplantation
 - ☐ Decompensated liver cirrhosis

Medication being provided by Specialty Pharmacy - PropriumRx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****