A LETTER OF MEDICAL NECESSITY TEMPLATE
for payers

Livmarli™ (maralixibat) oral solution

What it is

A Letter of Medical Necessity (LMN) is an important document to help support your rationale for treatment with LIVMARLI to payers. By proactively preparing this document, you can help streamline the authorization process and help patients get their prescribed medication as quickly as possible.

INDICATION
LIVMARLI is indicated for the treatment of cholestatic pruritus in patients who are 3 months of age and older with Alagille syndrome.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
Contraindicated in patients with prior or active hepatic decompensation events (eg, variceal hemorrhage, ascites, or hepatic encephalopathy).

WARNINGS AND PRECAUTIONS
Hepatotoxicity: Treatment-emergent elevations or worsening of liver tests have occurred. Obtain baseline liver tests and monitor during treatment; monitor also for liver-related adverse reactions and signs of hepatic decompensation. Dose reduction or treatment interruption may be considered if abnormalities occur. Permanently discontinue if persistent liver test abnormalities, clinical hepatitis upon rechallenge, or hepatic decompensation occur.

Please see Important Safety Information throughout and full Prescribing Information.

Sample Format: Letter of Medical Necessity

[Insert onto physician letterhead]

[Medical Director]
[Insurance Company]
[Address]
[City, State, ZIP]

RE: **Member Name** [Insert Member Name]
Member Number [Insert Member Number]
Group Number [Insert Group Number]

REQUEST: Authorization for treatment with LIVMARLI® (maralixibat) oral solution
DOSE AND FREQUENCY: [Insert Dose & Frequency]
REQUEST TYPE: EXPEDITED/PRIORITY REVIEW

Dear [Insert Name of Medical Director]:

I am writing to support my request for an **expedited authorization** for my patient mentioned above to receive LIVMARLI® (maralixibat) oral solution. LIVMARLI is the first and only FDA approved medication indicated to treat cholestatic pruritus in Alagille syndrome in patients 3 months of age and older.

Alagille syndrome (ALGS) is a rare, life-threatening multisystem disease that presents in childhood with a range of clinical manifestations, including jaundice (yellowing of the skin), pruritus (itch), failure to thrive (impacted growth in height and weight), xanthomas (disfiguring cholesterol deposits under the skin), and progressive liver disease, which can lead to liver transplantation.

The cholestatic pruritus associated with ALGS is among the most severe of any liver disease. The management of ALGS is challenging as there are no approved therapeutic options to control pruritus.

LIVMARLI is a minimally absorbed, orally administered medication studied in 86 pediatric ALGS patients with cholestasis and pruritus. LIVMARLI inhibits the ileal bile acid transporter (IBAT), resulting in decreased reabsorption of bile acids from the terminal ileum.

This letter serves to document my patient's diagnosis, medical history and to summarize my treatment rationale

Summary of Patient's Diagnosis and History
[Patient Name] is [Age] years old and was initially diagnosed with [Diagnosis] [ICD-10-CM] on [Date]. This diagnosis was confirmed by [insert details of patient's genetic testing and/or 3 of 7 clinical criteria]. [Patient Name] has been in my care since [Date].

[Insert a summary of the patient's clinical history, current symptoms and condition, and relevant lab/test results (i.e. ALT, AST, TB, DB, INR, serum bile acid measurement, FSV). Highlight the factors leading you to recommend use of LIVMARLI and include any relevant previous treatments of pruritus with patient's response to those interventions, such as Ursodiol,Rifampin, and antihistamines.
Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

Rationale for Treatment
[Include your clinical rationale, patient's likely prognosis without treatment with LIVMARLI and your credentials in treating ALGS]

Considering the patient's history, condition, and the full Prescribing Information supporting uses of LIVMARLI, I believe treatment with LIVMARLI at this time is medically necessary and should be a covered treatment for my patient. [Include support for treatment rationale: You may consider including documents that provide additional clinical information to support the recommendation for LIVMARLI for this patient, such as the full Prescribing Information, peer-reviewed journal articles, or clinical guidelines.]

See the next page to learn how to use the LIVMARLI LMN template.

How to use it

The LIVMARLI LMN template is intended to be tailored to your patients' specific clinical situations.

As shown on the previous page, the editable letter includes red text that indicates variable fields that should be replaced with relevant patient, physician, and office information. When submitting the LMN, all brackets in the template should be removed and your office letterhead should be added to the top of the document.

In addition to the LMN, a health plan may also require additional documents to help support your rationale. These may include:

- Patient medical records
- LIVMARLI Prescribing Information
- The ICONIC pivotal study publication

If you have any questions, please contact your Mirum Representative.

To get started, download the

LIVMARLI Letter of Medical Necessity (LMN)

template by visiting **LIVMARLIhcp.com**

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Gastrointestinal Adverse Reactions: Diarrhea and abdominal pain were reported as the most common adverse reactions in patients treated with LIVMARLI. Consider reducing the dosage or interrupting treatment if a patient experiences persistent diarrhea or abdominal pain.

Fat-Soluble Vitamin (FSV) Deficiency: Obtain baseline levels and monitor during treatment. Supplement vitamins if deficiency is observed. Consider interrupting LIVMARLI if bone fractures or bleeding occur.

Risk of Propylene Glycol Toxicity (Pediatric Patients Less Than 5 Years of Age): Total daily intake of propylene glycol should be considered for managing the risk of propylene glycol toxicity. Monitor patients for signs of propylene glycol toxicity. Discontinue LIVMARLI if toxicity is suspected.

Please see Important Safety Information throughout and full Prescribing Information.

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