**Sample Format: Letter of Medical Necessity**

[Insert onto physician letterhead]

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| --- | --- |
| [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.]

Given the urgent nature of this request, please provide an expedited priority review and authorization. Contact my office at [insert phone number] if I can provide you with any additional information.

Sincerely,

[Insert Physician Name and Participating Provider Number]

Enclosures: [include full Prescribing Information and the additional support noted above].

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