**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 LIVMARLITM (maralixibat) oral solution

**DIAGNOSIS:** [Insert Diagnosis] [Insert ICD]

**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 the above-mentioned patient to receive LIVMARLITM (maralixibat) oral solution for the treatment of cholestatic pruritus in patients with Alagille syndrome 1 year of age and older. LIVMARLI is the first and only FDA approved medication indicated to treat cholestatic pruritus in Alagille syndrome in patients age 1 year 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 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.

My request is supported by the following:

**Summary of Patient’s Diagnosis**

[insert patient’s diagnosis, date of diagnosis, lab results and date, current condition and symptoms]

**Summary of Patient’s History**

[Insert summary of patient history per your medical judgment. You may want to include:

* Brief description of the patient’s recent condition, including severity of symptoms, and relevant test results
* Previous treatment of pruritus and patient’s response to those interventions
* History of patient’s routine and non-routine visits
* Summary of your professional opinion of the patient’s likely prognosis without treatment with LIVMARLI
* Summary of your credentials in treating ALGS

Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient’s medical condition.]

**Rationale for Treatment**

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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