



**Request for Prior Authorization  
MARALIXIBAT (LIVMARLI)**

(PLEASE PRINT – ACCURACY IS IMPORTANT)

|  |                 |   |
|--|-----------------|---|
| IA Medicaid Member ID #<br> _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _  | Patient name    | DOB                                     |
| Patient address  |                 |   |
| Provider NPI<br> _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _   | Prescriber name | Phone                                   |
| Prescriber address   |                 | Fax                                     |
| Pharmacy name  | Address         | Phone                                   |
| <b>Prescriber must complete all information above. It must be legible, correct, and complete or form will be returned.</b> |                 |   |
| Pharmacy NPI<br> _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _   | Pharmacy fax    | NDC<br> _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ |

**Prior authorization (PA) is required for maralixibat (Livmarli). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:**

- 1) Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
- 2) Is prescribed by or consultation with a hepatologist, gastroenterologist, or a prescriber who specializes in ALGS or PFIC; and
- 3) Patient has a diagnosis of Alagille syndrome (ALGS) confirmed by genetic testing demonstrating a *JAG1* or *NOTCH2* mutation or deletion; and
  - a. Patient has cholestasis with moderate to severe pruritis; and
  - b. Documentation of previous trials and therapy failures, at a therapeutic dose, with at least two of the following agents:
    - i. Ursodeoxycholic acid (ursodiol)
    - ii. Cholestyramine
    - iii. Rifampin; or
- 4) Patient has a diagnosis of genetically confirmed progressive familial intrahepatic cholestasis (PFIC) demonstrating a gene mutation affiliated with PFIC (i.e., *ATP8B1*, *ABCB11*, *ABCB4*, *TJP2*, or *MYO5B*); and
  - a. Genetic testing does not indicate PFIC type 2 with *ABCB11* variants encoding for nonfunction or absence of bile salt export pump protein (*BSEP-3*); and
  - b. Patient has moderate to severe pruritis associated with PFIC; and
- 5) Patient’s current weight in kilograms (kg) is provided.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Request for continuation of therapy will require documentation of an improvement in pruritis symptoms and patient’s current weight in kg.

**Non-Preferred**

Livmarli

|                 |                            |                 |                    |
|-----------------|----------------------------|-----------------|--------------------|
| <b>Strength</b> | <b>Dosage Instructions</b> | <b>Quantity</b> | <b>Days Supply</b> |
| _____           | _____                      | _____           | _____              |

**Request for Prior Authorization  
MARALIXIBAT (LIVMARLI)**

(PLEASE PRINT – ACCURACY IS IMPORTANT)

**Prescriber Specialty:**  Hepatologist  Gastroenterologist  Prescriber specializing in ALGS  
 Prescriber specializing in PFIC  
 Other (specify): \_\_\_\_\_

If other, note consultation with hepatologist, gastroenterologist, or prescriber specializing in ALGS:

Consultation date: \_\_\_\_\_

Physician name, specialty &amp; phone: \_\_\_\_\_

**Alagille syndrome:****Attach genetic testing demonstrating a JAG1 or NOTCH2 mutation or deletion****Does patient have cholestasis with moderate to severe pruritis?**  No  Yes**Patient's current weight in kg:** \_\_\_\_\_**Document trials, at a therapeutic dose, with two of the following agents:****Ursodeoxycholic acid (ursodiol) Trial:**

Dose: \_\_\_\_\_ Trial dates: \_\_\_\_\_

Failure reason: \_\_\_\_\_

**Cholestyramine Trial:**

Dose: \_\_\_\_\_ Trial dates: \_\_\_\_\_

Failure reason: \_\_\_\_\_

**Rifampin Trial:**

Dose: \_\_\_\_\_ Trial dates: \_\_\_\_\_

Failure reason: \_\_\_\_\_

**Progressive Familial Intrahepatic Cholestasis (PFIC):****Attach genetic testing demonstrating a gene mutation affiliated with PFIC****Does genetic testing indicate PFIC type 2 with ABCB11 variants encoding for nonfunction or absence of bile salt export pump protein (BSEP-3)?**  No  Yes**Does patient have moderate to severe pruritis associated with PFIC?**  No  Yes**Renewal Requests:****Patient's current weight in kg:** \_\_\_\_\_**Document an improvement in pruritis symptoms:** \_\_\_\_\_**Attach lab results and other documentation as necessary.**

|  |                    |
|--|--------------------|
| Prescriber signature (Must match prescriber listed above.) | Date of submission |
|--|--------------------|

**IMPORTANT NOTE:** In evaluating requests for prior authorization the consultant will consider the treatment from the standpoint of medical necessity only. If approval of this request is granted, this does not indicate that the member continues to be eligible for Medicaid. It is the responsibility of the provider who initiates the request for prior authorization to establish by inspection of the member's Medicaid eligibility card and, if necessary by contact with the county Department of Health and Human Services, that the member continues to be eligible for Medicaid.