UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1373-5
Program	Prior Authorization/Notification
Medication	Livmarli™ (maralixibat)
P&T Approval Date	11/2021, 11/2022, 5/2023, 5/2024, 9/2024
Effective Date	12/1/2024

1. Background:

Livmarli (maralixibat) is an ileal bile acid transporter inhibitor indicated for the treatment of cholestatic pruritis in patients 12 months of age and older with progressive familial intrahepatic cholestasis (PFIC). Livmarli is also indicated for the treatment of cholestatic pruritis in patients 3 months of age and older with Alagille syndrome (ALGS).

Limitation of Use:
Livmarli is not recommended in a subgroup of PFIC type 2 patients with specific ABCB11 variants resulting in non-functional or complete absence of bile salt export pump (BSEP) protein.

2. Coverage Criteria[a]:

A. Progressive Familial Intrahepatic Cholestasis

1. **Initial Authorization**

a. **Livmarli** will be approved based upon **both** of the following criteria:

(1) Diagnosis of progressive familial intrahepatic cholestasis (PFIC)

-AND-

(2) Patient is experiencing pruritus associated with PFIC.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Livmarli** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Livmarli therapy

Authorization will be issued for 12 months.

B. Alagille Syndrome

1. **Initial Authorization**

a. **Livmarli** will be approved based upon **both** of the following criteria:

(1) Diagnosis of Alagille syndrome (ALGS).

-AND-

(2) Patient is experiencing pruritus associated with ALGS.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Livmarli** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Livmarli therapy

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. Reference:

1. Livmarli [package insert]. Foster City, CA: Mirum Pharmaceuticals, Inc.; July 2024.

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Change Control	
11/2021	New program
11/2022	Annual review with no changes to coverage criteria. Added state mandate footnote.
5/2023	Updated background with expanded indication in ALGS patients 3 months of age and older. No change to coverage criteria. Updated reference.
5/2024	Annual review. Added coverage criteria for new PFIC indication. Updated initial authorization duration to 12 months for ALGS indication. Updated background and reference.
9/2024	Updated background with expanded PFIC indication in patients 12 months to 4 years of age. Updated reference.