Louisiana Medicaid
Digestive Disorders – Bile Acid Salts

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request:

- Prior authorization for non-preferred bile acid salts; **AND**
- Clinical authorization for maralixibat (Livmarli®); **AND**
- Clinical authorization for odevixibat (Bylvay®).

Additional Point-of-Sale edits may apply.

By submitting the authorization request, the prescriber attests to the conditions available HERE.

Approval Criteria for Initiation and Continuation of Therapy (Except Livmarli® and Bylvay®)

- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- Previous use of a preferred product - **ONE** of the following is required:
    - The recipient has had a *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
    - The prescriber states that the recipient is currently using the requested medication**.**

Duration of approval for initiation and continuation of therapy: 12 months

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Maralixibat (Livmarli®)

Approval Criteria for Initiation of Therapy

- The recipient is at least 12 months~~5 years~~ of age or older on the date of the request; **AND**
- The recipient has a diagnosis of pruritus associated with progressive familial intrahepatic cholestasis (PFIC) [must be **stated on the request**]; **AND**
- This medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a gastroenterologist or hepatologist; **AND**
- The recipient has failed treatment with, is intolerant to, or has a contraindication to at least **ONE** pruritus therapy;

OR

- The recipient is at least 3 months of age or older on the date of the request; **AND**
- The recipient has a diagnosis of Alagille syndrome; **AND**
- The recipient has evidence of cholestasis (must be **stated on the request**); **AND**

- The recipient experiences persistent moderate to severe pruritus (must be **stated on the request**); **AND**
- This medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a gastroenterologist or hepatologist; **AND**
- The recipient has failed treatment with, is intolerant to, or has a contraindication to at least **ONE** pruritus therapy;

AND

- If request is for a non-preferred agent **– ONE** of the following is required:
  - The recipient has had a *treatment failure* with at least one preferred product; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
  - There is *no preferred product that is appropriate* to use for the condition being treated**.**

Duration of approval for initiation of therapy: 6 months

Approval Criteria for Continuation of Therapy

- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of approval for continuation of therapy: 12 months

Odevixibat (Bylvay®)

Approval Criteria for Initiation of Therapy

- The recipient is at least 3 months of age or older on the date of the request; **AND**
- The recipient has a diagnosis of pruritus associated with progressive familial intrahepatic cholestasis (PFIC) [must be **stated on the request**]; **AND**
- This medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a gastroenterologist or hepatologist; **AND**
- The recipient has failed treatment with, intolerant to, or has a contraindication to at least **ONE** pruritus therapy;

OR

- The recipient is at least 12 months of age or older on the date of the request; **AND**
- The recipient has a diagnosis of Alagille syndrome; **AND**
- The recipient has evidence of cholestasis (must be **stated on the request**); **AND**
- The recipient experiences persistent moderate to severe pruritus (must be **stated on the request**); **AND**

- This medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a gastroenterologist or hepatologist; **AND**
- The recipient has failed treatment with, intolerant to, or has a contraindication to at least **ONE** pruritus therapy;

AND

- If request is for a non-preferred agent **– ONE** of the following is required:
  - The recipient has had a *treatment failure* with at least one preferred product; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
  - There is *no preferred product that is appropriate* to use for the condition being treated**.**

Duration of approval for initiation of therapy: 6 months

Approval Criteria for Continuation of Therapy

- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of approval for continuation of therapy: 12 months

References

Bylvay (odevixibat) [package insert]. Boston, MA: Albireo Pharma, Inc; January 2024. https://bylvay.com/pdf/Bylvay_PI.pdf

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; https://www.clinicalkey.com/pharmacology/

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. Pharmacotherapy: A Pathophysiologic Approach, 10e New York, NY: McGraw-Hill; https://accesspharmacy.mhmedical.com/book.aspx?bookid=1861

Livmarli (maralixibat) [package insert]. Foster City, CA: Mirum Pharmaceuticals, Inc; July~~March~~ 2024. https://files.mirumpharma.com/livmarli/livmarli-prescribinginformation.pdf

Revision / Date	Implementation Date
Single PDL Implementation	May 2019
Separated “Select Therapeutic Classes (Established)” into individual therapeutic class documents / November 2019	January 2020
Formatting changes / September 2021	January 2022
Added clinical authorization for Livmarli® and Bylvay® / July 2022	April 2023
Updated age requirement for Livmarli® / March 2023	April 2023
Updated criteria for Bylvay® to include new indication, updated references / July 2023	January 2024
Added indication of pruritus due to PFIC for Livmarli®, formatting changes, updated references / April 2024	October 2024
Updated age limit of pruritus due to PFIC for Livmarli®, updated references / August 2024	January 2025