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.

*These agents may have **Black Box Warnings** and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Approval Criteria for Initial and Reauthorization Requests (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; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of initial and reauthorization approval: 12 months

Maralixibat (Livmarli®)

Approval Criteria

- 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, 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; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of initial approval: 6 months

Reauthorization Criteria

- The recipient continues to meet initial criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of reauthorization approval: 12 months

Odevixibat (Bylvay®)

Approval Criteria

- 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; **AND**

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**

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; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested

medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of initial approval: 6 months

Reauthorization Criteria

- The recipient continues to meet initial criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of reauthorization approval: 12 months

References

Bylvay (odevixibat) [package insert]. Boston, MA: Albireo Pharma, Inc; June ~~April~~ 2023~~2~~. 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; March 2023. 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