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~~ursodiol agents; **AND**
- Clinical authorization for bile acid salts (except ursodiol)~~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 Non-Preferred Ursodiol Agents ~~(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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Chenodiol (Chenodal®)

Approval Criteria for Initiation of Therapy

- The recipient is 18 years of age or older on the date of the request; **AND**
- The prescriber **states on the request** that the recipient has the presence of radiolucent stones in a well-opacifying gallbladder; **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 had a treatment failure of a 6-month trial of ursodiol, unless contraindicated or clinically significant adverse effects were experienced; **AND**
- The prescriber has obtained baseline liver laboratory assessments prior to starting therapy~~.~~; **AND**
- If the 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; **AND**
- The prescriber **states on the request** that the recipient has had recent liver test monitoring to identify new or worsening liver function based on risks with medication (provide most recent date of test on the request); **AND**
- The prescriber **states on the request** that the recipient has had recent serum cholesterol test monitoring (provide most recent date of test on the request); **AND**
- Total treatment duration does not exceed 24 months.

Duration of approval for continuation of therapy: 12 months, any subsequent continuation of therapy approvals should not exceed a total of 24 months of therapy

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Chenodiol (Ctexli™)

Approval Criteria for Initiation of Therapy

- The recipient is 18 years of age or older on the date of the request; **AND**
- The recipient has a diagnosis of cerebrotendinous xanthomatosis (CTX) genetically confirmed by a mutation in the *CYP27A1* gene; **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 prescriber has obtained baseline liver laboratory assessments prior to starting therapy; **AND**
- If the 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; **AND**

- The prescriber **states on the request** that the recipient has had recent liver test monitoring to identify new or worsening liver function based on risks with medication (provide most recent date of test on the request).

Duration of approval for continuation of therapy: 12 months

Cholic Acid (Cholbam®)

Approval Criteria for Initiation of Therapy

- The recipient has **ONE** of the following diagnosis; **AND**
  - Bile acid synthesis disorder due to single enzyme defects (SEDs); **OR**
  - Peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea or complications from decreased fat-soluble vitamin absorption; **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 prescriber has obtained baseline liver laboratory assessments prior to starting therapy; **AND**
- If the 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; **AND**
- The prescriber **states on the request** that the recipient has had recent liver test monitoring to identify new or worsening liver function based on risks with medication (provide most recent date of test on the request).

Duration of approval for continuation of therapy: 12 months

Elafibranor (Iqirvo®)

Approval Criteria for Initiation of Therapy

- The recipient is 18 years of age or older on the date of the request; **AND**
- The recipient has a diagnosis of primary biliary cholangitis (PBC); **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 ursodeoxycholic acid (UDCA) at the maximum tolerated dose (**dates of medication trial stated on request**); **AND**
- The medication is prescribed in combination with UDCA, unless contraindicated or clinically significant adverse effects are experienced; **AND**
- The prescriber has obtained baseline liver laboratory assessments prior to starting therapy; **AND**
- If the 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; **AND**
- The prescriber **states on the request** that the recipient has had recent liver test monitoring to identify new or worsening liver function based on risks with medication (provide most recent date of test on the request).

Duration of approval for continuation of therapy: 12 months

Maralixibat (Livmarli®)

Approval Criteria for Initiation of Therapy

- The recipient is at least 12 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, 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

Obeticholic Acid (Ocaliva®)

Approval Criteria for Initiation of Therapy

- The recipient is 18 years of age or older on the date of the request; **AND**
- The recipient has a diagnosis of primary biliary cholangitis (PBC); **AND**
- **ONE** of the following is true and **stated on the request**:
  - The recipient does not have cirrhosis; **OR**
  - The recipient has compensated cirrhosis **WITHOUT** evidence of portal hypertension (e.g., ascites, gastroesophageal varices, or persistent thrombocytopenia); **AND**
- The recipient has failed treatment with, intolerant to, or has a contraindication to ursodeoxycholic acid (UDCA) at the maximum tolerated dose (**dates of medication trial stated on request**); **AND**
- The medication is prescribed in combination with UDCA, unless contraindicated or clinically significant adverse effects are experienced; **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 prescriber has obtained baseline liver laboratory assessments prior to starting therapy; **AND**
- If the 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; **AND**
- The prescriber **states on the request** that the recipient has had recent liver test monitoring to identify new or worsening liver function based on risks with medication (provide most recent date of test on the request).

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 the 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

Seladelpar (Livdelzi®)

Approval Criteria for Initiation of Therapy

- The recipient is 18 years of age or older on the date of the request; **AND**
- The recipient has a diagnosis of primary biliary cholangitis (PBC); **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 ursodeoxycholic acid (UDCA) at the maximum tolerated dose (**dates of medication trial stated on request**); **AND**
- The medication is prescribed in combination with UDCA, unless contraindicated or clinically significant adverse effects are experienced; **AND**
- The prescriber has obtained baseline liver laboratory assessments prior to starting therapy; **AND**
- If the 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; **AND**
- The prescriber **states on the request** that the recipient has had recent liver test monitoring to identify new or worsening liver function based on risks with medication (provide most recent date of test on the request).

Duration of approval for continuation of therapy: 12 months

References

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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
Added clinical criteria for Chenodal®, Cholbam®, Ctexli™, Iqirvo®, Livdelzi®, and Ocaliva®, updated references / March 2025	August 2025