Texas Prior Authorization Program
Clinical Criteria

Drug/Drug Class

Ileal Bile Acid Transporter (IBAT) Inhibitors

These criterion were recommended for review by Kepro and an MCO to ensure appropriate and safe utilization

Clinical Information Included in this Document

Bylvay (Odevixibat)

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- **Logic diagram:** a visual depiction of the clinical criteria logic
- **Supporting tables**: a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes); provided when applicable
- **References**: clinical publications and sources relevant to this clinical criteria

Note: Click the hyperlink to navigate directly to that section.

Livmarli (Maralixibat)

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- **Logic diagram:** a visual depiction of the clinical criteria logic
- **Supporting tables:** a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes); provided when applicable
- **References:** clinical publications and sources relevant to this clinical criteria

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Revision Notes

Annual review by staff

Updated age to ≥ 1 year for a diagnosis of PFIC for Livmarli

Updated references

Bylvay (Odevixibat)

Drugs Requiring Prior Authorization

The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.

Drugs Requiring Prior Authorization	
Label Name	**GCN**
BYLVAY 200 MCG PELLET	49976
BYLVAY 400 MCG CAPSULE	49978
BYLVAY 600 MCG PELLET	49977
BYLVAY 1,200 MCG CAPSULE	49979

RxPERT PAxpress™

Bylvay (Odevixibat)

Clinical Criteria Logic

1. Is this a renewal request?
   [ ] Yes (Go to #7)
   [ ] No (Go to #2)

2. Does the client have diagnosis of **progressive familial intrahepatic cholestasis (PFIC)** or **Alagille syndrome** confirmed with genetic testing? [Manual]
   [ ] Yes (Go to #3)
   [ ] No (Deny)

3. Does the client have a diagnosis of PFIC type 2 with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3)? [Manual]
   [ ] Yes (Deny)
   [ ] No (Go to #4)

4. Does the client have a history of a **liver transplant**?
   [ ] Yes (Deny)
   [ ] No (Go to #5)

5. Does the client have a history of **biliary diversion surgery** in the last 180 days?
   [ ] Yes (Deny)
   [ ] No (Go to #6)

6. Has the client had at least 90 days therapy in the last 180 days of a **standard agent used for the treatment of cholestasis pruritis**?
   [ ] Yes (Go to #7)
   [ ] No (Deny)

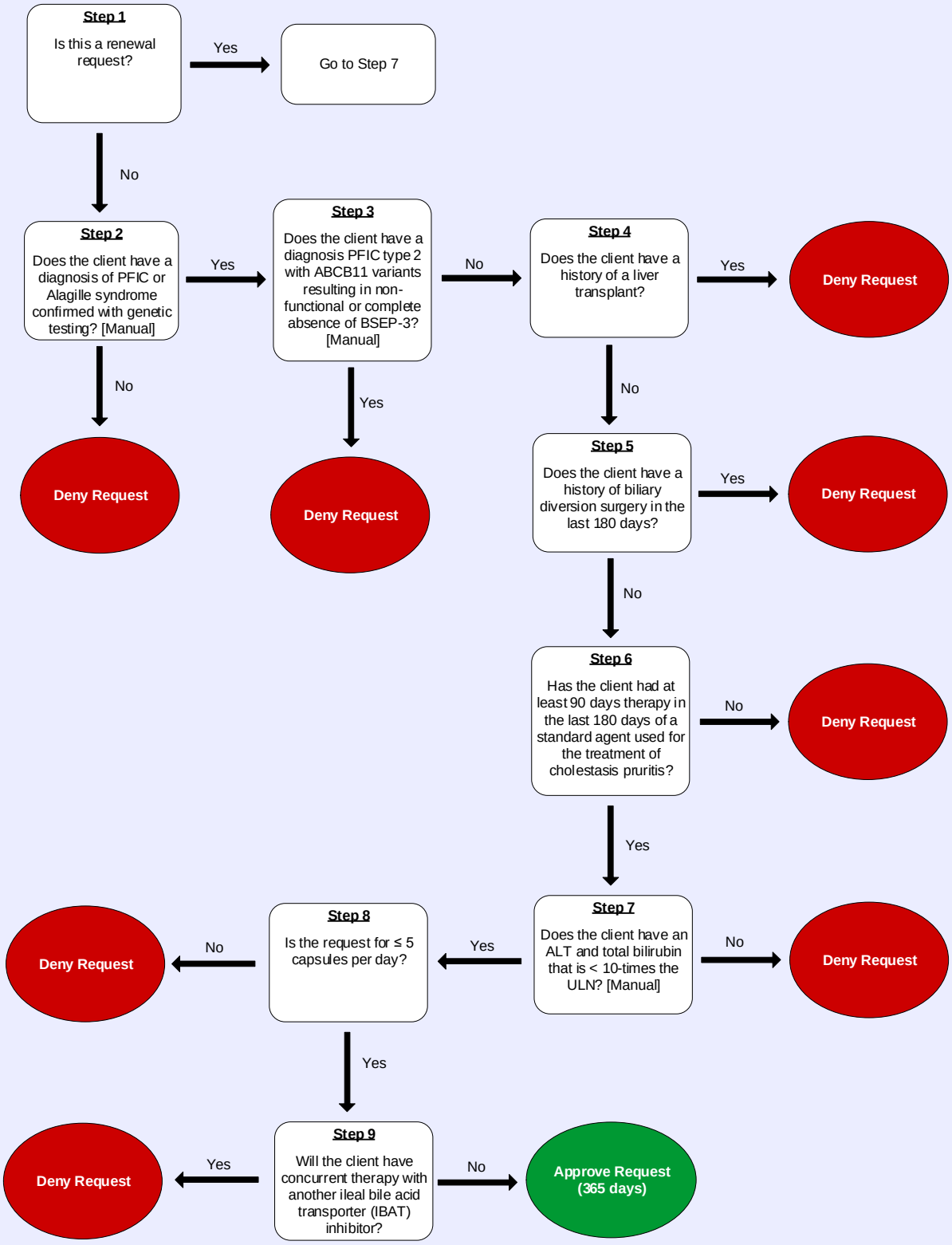
7. Does the client have an ALT and total bilirubin that is less than (<) 10-times the upper limit of normal (ULN)? [Manual]
   [ ] Yes (Go to #8)
   [ ] No (Deny)

8. Is the request for less than or equal to (≤) 5 capsules per day?
   [ ] Yes (Go to #9)
   [ ] No (Deny)

9. Will the client have concurrent therapy with another **ileal bile acid transporter (IBAT) inhibitor**?
   [ ] Yes (Deny)
   [ ] No (Approve – 365 days)

Bylvay (Odevixibat)

Clinical Criteria Logic Diagram



Livmarli (Maralixibat)

Drugs Requiring Prior Authorization

The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.

Drugs Requiring Prior Authorization	
Label Name	**GCN**
LIVMARLI 9.5 MG/ML ORAL SOLUTION	51256

RxPERT PAxpress

Livmarli (Maralixibat)

Clinical Criteria Logic

1. Is this a renewal request?
   [ ] Yes (Go to #11)
   [ ] No (Go to #2)

2. Does the client have diagnosis of **Alagille syndrome (ALGS)** confirmed with genetic testing? [Manual]
   [ ] Yes (Go to #5)
   [ ] No (Go to #3)

3. Does the client have a diagnosis of **progressive familial intrahepatic cholestatis (PFIC)** confirmed with genetic testing? [Manual]
   [ ] Yes (Go to #4)
   [ ] No (Deny)

4. Is the client greater than or equal to (≥) 1 year of age?
   [ ] Yes (Go to #6)
   [ ] No (Deny)

5. Is the requested dose less than or equal to (≤) 28.5 mg per day?
   [ ] Yes (Go to #7)
   [ ] No (Deny)

6. Is the requested dose less than or equal to (≤) 38 mg per day?
   [ ] Yes (Go to #7)
   [ ] No (Deny)

7. Does the client have a history of a **liver transplant**?
   [ ] Yes (Deny)
   [ ] No (Go to #8)

8. Does the client have a history of **biliary diversion surgery** in the last 180 days?
   [ ] Yes (Deny)
   [ ] No (Go to #9)

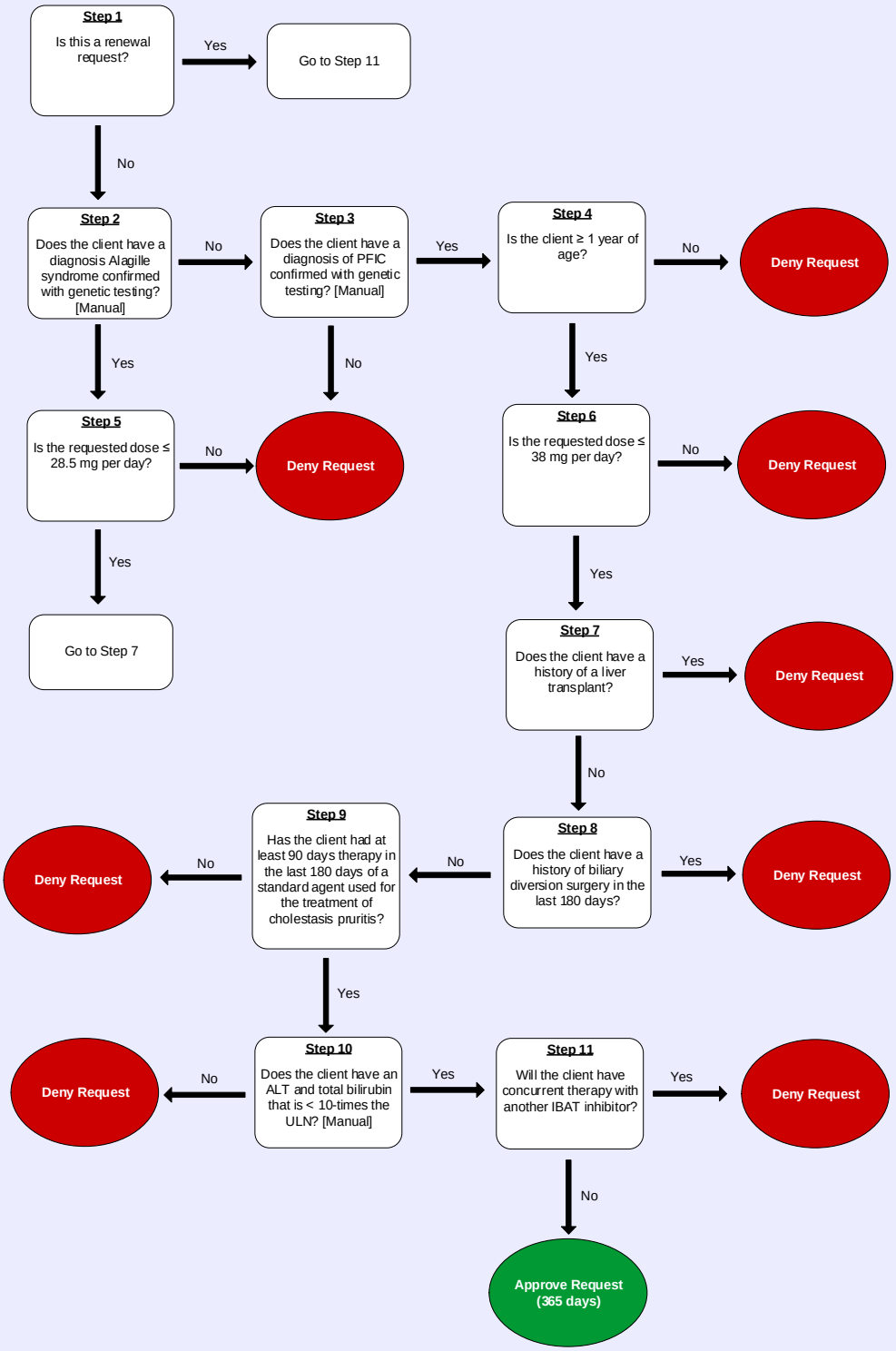
9. Has the client had at least 90 days therapy in the last 180 days of a **standard agent used for the treatment of cholestasis pruritis**?
   [ ] Yes (Go to #10)
   [ ] No (Deny)

10. Does the client have an ALT and total bilirubin that is less than (<) 10-times the upper limit of normal (ULN)? [Manual]
    [ ] Yes (Go to #11)
    [ ] No (Deny)

11. Will the client have concurrent therapy with another **ileal bile acid transporter (IBAT) inhibitor**?
    [ ] Yes (Deny)
    [ ] No (Approve – 365 days)

Livmarli (Maralixibat)

Clinical Criteria Logic Diagram



IBAT Inhibitors

Clinical Criteria Supporting Tables

Alagille Syndrome	
ICD-10 Code	**Description**
Q4471	ALAGILLE SYNDROME

Biliary Diversion Surgery	
CPT Code	**Description**
47533	PLACEMENT OF BILIARY DRAINAGE CATHETER, PERCUTANEOUS, INCLUDING DIAGNOSTIC CHOLANGIOGRAPHY WHEN PERFORMED, IMAGING GUIDANCE, AND ALL ASSOCIATED RADIOLOGICAL SUPERVISION AND INTERPRETATION; EXTERNAL
47534	PLACEMENT OF BILIARY DRAINAGE CATHETER, PERCUTANEOUS, INCLUDING DIAGNOSTIC CHOLANGIOGRAPHY WHEN PERFORMED, IMAGING GUIDANCE, AND ALL ASSOCIATED RADIOLOGICAL SUPERVISION AND INTERPRETATION; INTERNAL

Liver Transplant	
ICD-10 Code	**Description**
Z944	LIVER TRANSPLANT STATUS

PFIC	
ICD-10 Code	**Description**
K7689	OTHER SPECIFIED DISEASES OF LIVER

Standard Agent for Cholestasis Pruritis	
Label Name	**GCN**
CHOLESTYRAMINE LIGHT PACKET	09850
CHOLESTYRAMINE LIGHT POWDER	98654
CHOLESTYRAMINE PACKET	09920
CHOLESTYRAMINE POWDER	14295
NALTREXONE 50 MG TABLET	17070
PREVALITE PACKET	09850
PREVALITE POWDER	98654
QUESTRAN LIGHT POWDER	98654
QUESTRAN PACKET	09920
QUESTRAN POWDER	14295
RIFAMPIN 150 MG CAPSULE	41260
RIFAMPIN 300 MG CAPSULE	41261
SERTRALINE 20 MG/ML ORAL CONC	16376
SERTRALINE HCL 100 MG TABLET	16375
SERTRALINE HCL 25 MG TABLET	16373
SERTRALINE HCL 50 MG TABLET	16374
URSO 250 MG TABLET	01072
URSO FORTE 500 MG TABLET	17730
URSODIOL 250 MG TABLET	01072
URSODIOL 300 MG CAPSULE	01070
URSODIOL 500 MG TABLET	17730
ZOLOFT 100 MG TABLET	16375
ZOLOFT 25 MG TABLET	16373
ZOLOFT 50 MG TABLET	16374

IBAT inhibitor	
Label Name	**GCN**
BYLVAY 200 MCG PELLET	49976
BYLVAY 400 MCG CAPSULE	49978
BYLVAY 600 MCG PELLET	49977
BYLVAY 1,200 MCG CAPSULE	49979

IBAT Inhibitors

Clinical Criteria References

1. 2022 ICD-10-CM Diagnosis Codes. 2022. Available at **www.icd10data.com**. Accessed on January 21, 2022.
2. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2024. Available at **www.clinicalpharmacology.com**. Accessed on August 31, 2024.
3. Micromedex [online database]. Available at **www.micromedexsolutions.com**. Accessed on August 31, 2024.
4. Bylvay Prescribing Information. Cambridge, MA. Ipsen Biopharmaceuticals, Inc. February 2024.
5. Livmarli Prescribing Information. Foster City, CA. Mirum Pharmaceuticals, Inc. March 2023.
6. Kohut TJ, Loomes KM. Alagille Syndrome. In: UpToDate, Post, TW (Ed), UpToDate, Waltham, MA. (Accessed on December 4, 2023.)
7. Poupon R, Chopra S. Pruritus associated with cholestasis. In: UpToDate, Post, TW (Ed), UpToDate, Waltham, MA. (Accessed on August 31, 2024).
8. Kohut TJ, Loomes KM. Alagille syndrome. In: UpToDate, Post, TW (Ed), UpToDate, Waltham, MA. (Accessed on August 31, 2024).

Publication History

The Publication History records the publication iterations and revisions to this document. Notes for the *most current revision* are also provided in the **Revision Notes** on the first page of this document.

Publication Date	Notes
01/21/2022	• Initial publication and presentation to the DUR Board
04/28/2022	• Combined Bylvay and Livmarli criteria guides into Cholestatic Pruritis Agents criteria guide • Removed INR check for Bylvay and Livmarli
10/20/2022	• Updated Bylvay criteria question 2 to read "Does the client have a diagnosis of PFIC type 2 with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3)?"
12/01/2022	• Annual review by staff • Updated references
03/30/2023	• Changed guide name to Ileal Bile Acid Transporter (IBAT) Inhibitors • Removed age check for Livmarli
01/09/2024	• Annual review by staff • Added diagnosis of Alagille syndrome for Bylvay and add check for concurrent therapy with another IBAT inhibitor (already in the criteria for Livmarli) • Updated references
05/07/2024	• Added diagnosis of PFIC for Livmarli • Added age check for PFIC diagnosis for Livmarli • Added dosage checks for Livmarli
08/31/2024	• Annual review by staff • Updated age to ≥ 1 year for a diagnosis of PFIC for Livmarli • Updated references