Texas Prior Authorization Program
Clinical Criteria

Drug/Drug Class

Biliary Cholangitis Agents

These criteria 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.

Iqirvo (Elafibranor)/Livdelzi (Seladelpar)

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Livmarli (Maralixibat)

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
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Revision Notes

Added criteria for Iqirvo and Livdelzi as approved by the DUR Board

Renamed guide to Biliary Cholangitis Agents (formerly IBAT Inhibitors)

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

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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

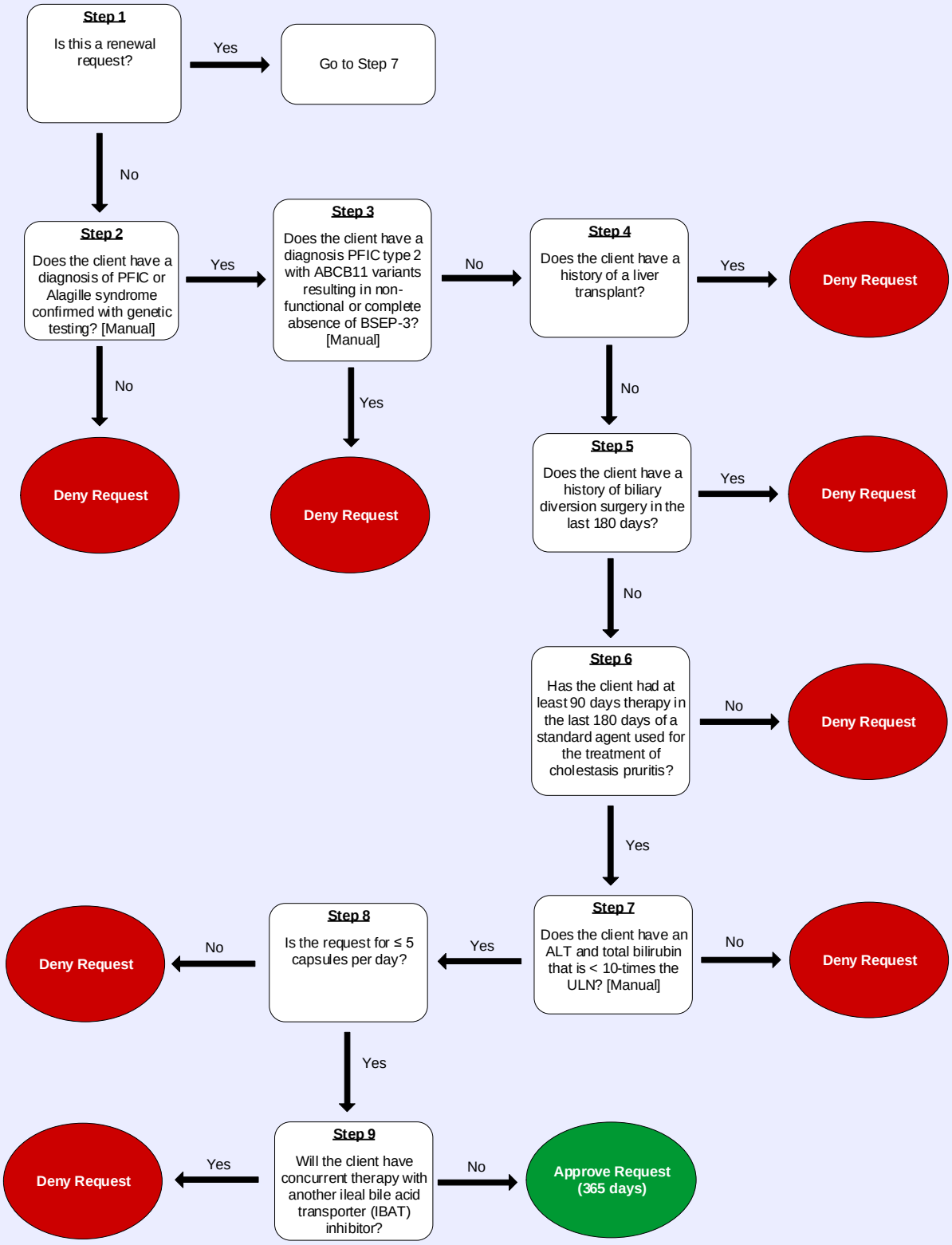
7. Does the client have an ALT and total bilirubin that is less than (<) 10-times the upper limit of normal (ULN)? [Manual]
   [ ] Yes - Go to #8
   [ ] No - Deny

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



Iqirvo (Elafibranor)/Livdelzi (Seladelpar)

Drugs Requiring Prior Authorization

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Drugs Requiring Prior Authorization	
Label Name	**GCN**
IQIRVO 80 MG TABLET	54888
LIVDELZI 10 MG CAPSULE	56144

Iqirvo (Elafibranor)/Livdelzi (Seladelpar)

Clinical Criteria Logic

Initial criteria:

1. Is the client greater than or equal to (≥) 18 years of age?
   [ ] Yes – Go to #2
   [ ] No – Deny

2. Does the client have a diagnosis of **primary biliary cholangitis (PBC)** in the last 730 days?
   [ ] Yes – Go to #3
   [ ] No – Deny

3. Will the client have concurrent therapy with **ursodeoxycholic acid (UDCA/ursodiol)**?
   [ ] Yes – Go to #5
   [ ] No – Go to #4

4. Is the client unable to tolerate therapy with **ursodeoxycholic acid (UDCA/ursodiol)**? [Manual]
   [ ] Yes – Go to #5
   [ ] No – Deny

5. Does the client have a diagnosis of **decompensated cirrhosis or moderate to severe hepatic impairment** in the last 365 days?
   [ ] Yes – Deny
   [ ] No – And the request is for Iqirvo, go to #6
   [ ] No – And the request is for Livdelzi, go to #7

6. Is the requested dose less than or equal to (≤) 80 mg daily?
   [ ] Yes – Approve (365 days)
   [ ] No – Deny

7. Will the client have concurrent therapy with an **OAT3 inhibitor** or a **strong CYP2C9 inhibitor**?
   [ ] Yes – Deny
   [ ] No – Go to #8

8. Is the requested dose less than or equal to (≤) 10 mg daily?
   [ ] Yes – Approve (365 days)
   [ ] No – Deny

Iqirvo (Elafibranor)/Livdelzi (Seladelpar)

Clinical Criteria Logic

Renewal criteria:

1. Will the client have concurrent therapy with **ursodeoxycholic acid (UDCA/ursodiol)**?
   [ ] Yes – Go to #3
   [ ] No – Go to #2

2. Is the client unable to tolerate therapy with **ursodeoxycholic acid (UDCA/ursodiol)**? [Manual]
   [ ] Yes – Go to #3
   [ ] No – Deny

3. Does the client have a diagnosis of **decompensated cirrhosis or moderate to severe liver impairment** in the last 365 days?
   [ ] Yes – Deny
   [ ] No – And the request is for Iqirvo, go to #4
   [ ] No – And the request is for Livdelzi, go to #5

4. Is the requested dose less than or equal to (≤) 80 mg daily?
   [ ] Yes – Approve (365 days)
   [ ] No – Deny

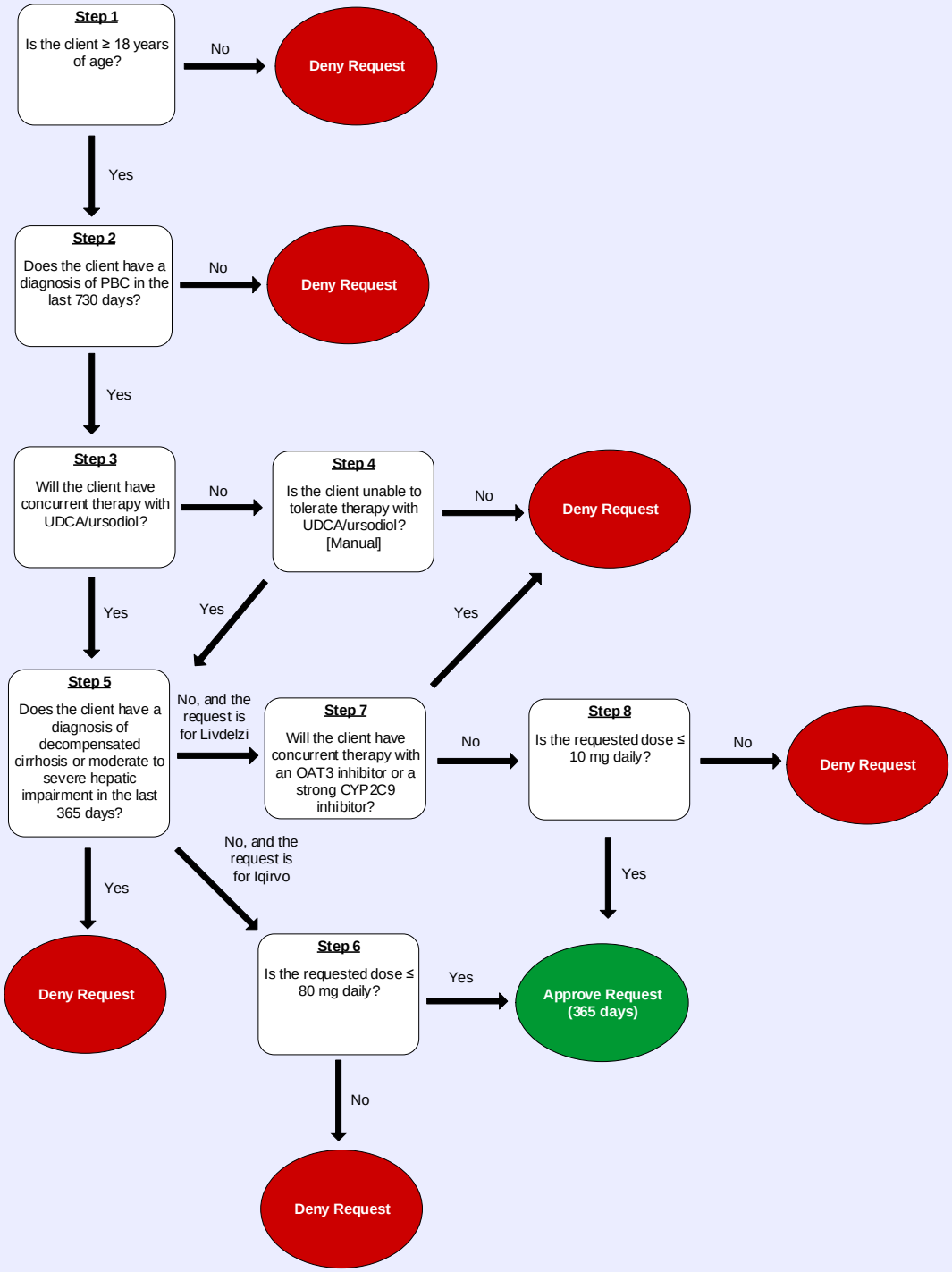
5. Will the client have concurrent therapy with an **OAT3 inhibitor** or a **strong CYP2C9 inhibitor**?
   [ ] Yes – Deny
   [ ] No – Go to #6

6. Is the requested dose less than or equal to (≤) 10 mg daily?
   [ ] Yes – Approve (365 days)
   [ ] No – Deny

Iqirvo (Elafibranor)/Livdelzi (Seladelpar)

Clinical Criteria Logic Diagram

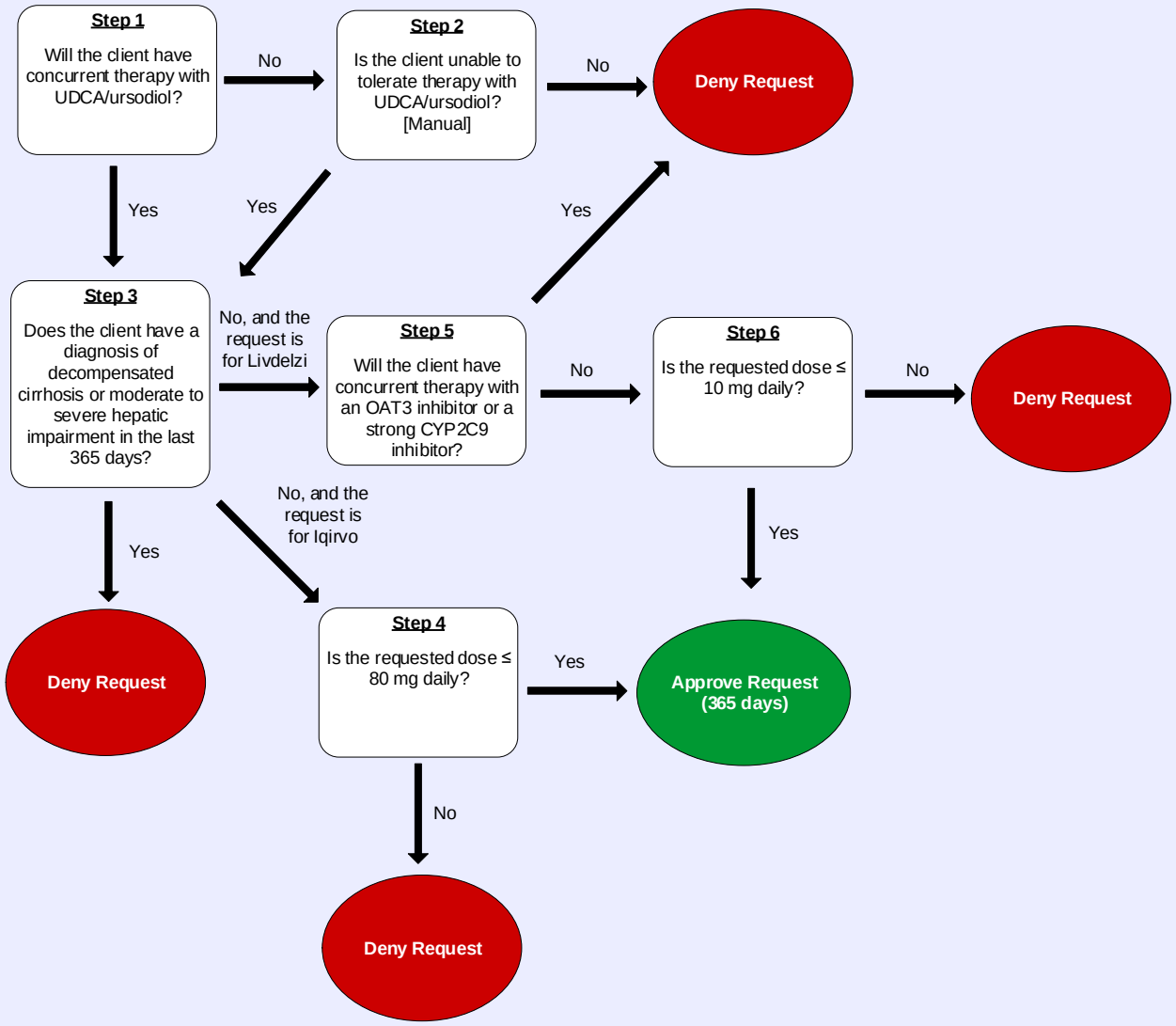
Initial criteria:



Iqirvo (Elafibranor)/Livdelzi (Seladelpar)

Clinical Criteria Logic Diagram

Renewal criteria:



Livmarli (Maralixibat)

Drugs Requiring Prior Authorization

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

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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

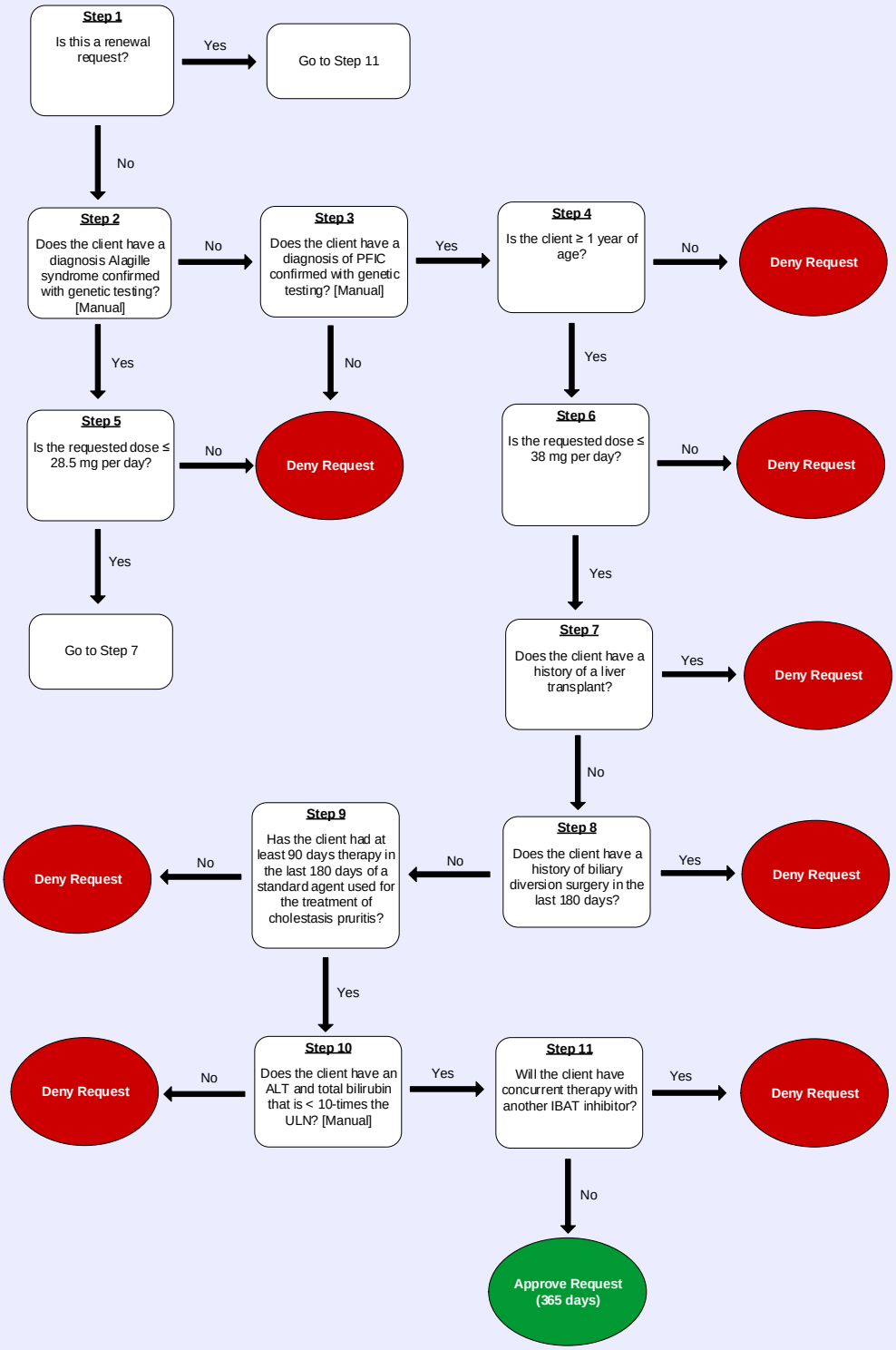
9. Has the client had at least 90 days therapy in the last 180 days of a **standard agent used for the treatment of cholestasis pruritis**?
   [ ] Yes - Go to #10
   [ ] No - Deny

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



Biliary Cholangitis Agents

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

Decompensated Cirrhosis/Moderate to Severe Hepatic Impairment	
ICD-10 Code	**Description**
B160	ACUTE HEPATITIS B WITH DELTA-AGENT WITH HEPATIC COMA
B161	ACUTE HEPATITIS B WITH DELTA-AGENT WITHOUT HEPATIC COMA
B162	ACUTE HEPATITIS B WITHOUT DELTA-AGENT WITH HEPATIC COMA
B169	ACUTE HEPATITIS B WITHOUT DELTA-AGENT AND WITHOUT HEPATIC COMA
B170	ACUTE DELTA-(SUPER) INFECTION OF HEPATITIS B CARRIER
B1710	ACUTE HEPATITIS C WITHOUT HEPATIC COMA
B1711	ACUTE HEPATITIS C WITH HEPATIC COMA
B172	ACUTE HEPATITIS E
B178	OTHER SPECIFIED ACUTE VIRAL HEPATITIS
B179	ACUTE VIRAL HEPATITIS, UNSPECIFIED
B180	CHRONIC VIRAL HEPATITIS B WITH DELTA-AGENT
B181	CHRONIC VIRAL HEPATITIS B WITHOUT DELTA-AGENT
B182	CHRONIC VIRAL HEPATITIS C
B188	OTHER CHRONIC VIRAL HEPATITIS

Decompensated Cirrhosis/Moderate to Severe Hepatic Impairment	
ICD-10 Code	**Description**
B189	CHRONIC VIRAL HEPATITIS, UNSPECIFIED
B190	UNSPECIFIFED VIRAL HEPATITIS WITH HEPATIC COMA
B1910	UNSPECIFIED VIRAL HEPATITIS B WITHOUT HEPATIC COMA
B1911	UNSPECIFIED VIRAL HEPATITIS B WITH HEPATIC COMA
B1920	UNSPECIFIED VIRAL HEPATITIS C WITHOUT HEPATIC COMA
B1921	UNSPECIFIED VIRAL HEPATITIS C WITH HEPATIC COMA
B199	UNSPECIFIED VIRAL HEPATITIS WITHOUT HEPATIC COMA
K700	ALCOHOLIC FATTY LIVER
K7010	ALCOHOLIC HEPATITIS WITHOUT ASCITES
K7011	ALCOHOLIC HEPATITIS WITH ASCITES
K702	ALCOHOLIC FIBROSIS AND SCLEROSIS OF LIVER
K7030	ALCOHOLIC CIRRHOSIS OF LIVER WITHOUT ASCITES
K7031	ALCOHOLIC CIRRHOSIS OF LIVER WITH ASCITES
K7040	ALCOHOLIC HEPATIC FAILURE WITHOUT COMA
K7041	ALCOHOLIC HEPATIC FAILURE WITH COMA
K709	ALCOHOLIC LIVER DISEASE, UNSPECIFIED
K710	TOXIC LIVER DISEASE WITH CHOLESTASIS
K7110	TOXIC LIVER DISEASE WITH HEPATIC NECROSIS WITHOUT COMA
K7111	TOXIC LIVER DISEASE WITH HEPATIC NECROSIS WITH COMA
K712	TOXIC LIVER DISEASE WITH ACUTE HEPATITIS
K713	TOXIC LIVER DISEASE WITH CHRONIC PERSISTENT HEPATITIS
K714	TOXIC LIVER DISEASE WITH CHRONIC LOBULAR HEPATITIS
K7150	TOXIC LIVER DISEASE WITH CHRONIC ACTIVE HEPATITIS WITHOUT ASCITES
K7151	TOXIC LIVER DISEASE WITH CHRONIC ACTIVE HEPATITIS WITH ASCITES
K716	TOXIC LIVER DISEASE WITH HEPATITIS, NOT ELSEWHERE CLASSIFIED
K717	TOXIC LIVER DISEASE WITH FIBROSIS AND CIRRHOSIS OF LIVER
K718	TOXIC LIVER DISEASE WITH OTHER DISORDERS OF LIVER
K719	TOXIC LIVER DISEASE, UNSPECIFIED
K7200	ACUTE AND SUBACUTE HEPATIC FAILURE WITHOUT COMA
K7201	ACUTE AND SUBACUTE HEPATIC FAILURE WITH COMA
K7210	CHRONIC HEPATIC FAILURE WITHOUT COMA
K7211	CHRONIC HEPATIC FAILURE WITH COMA
K7290	HEPATIC FAILURE, UNSPECIFIED WITHOUT COMA
K7291	HEPATIC FAILURE, UNSPECIFIED WITH COMA

Decompensated Cirrhosis/Moderate to Severe Hepatic Impairment	
ICD-10 Code	**Description**
K730	CHRONIC PERSISTENT HEPATITIS, NOT ELSEWHERE CLASSIFIED
K731	CHRONIC LOBULAR HEPATITIS, NOT ELSEWHERE CLASSIFIED
K732	CHRONIC ACTIVE HEPATITIS, NOT ELSEWHERE CLASSIFIED
K738	OTHER CHRONIC HEPATITIS, NOT ELSEWHERE CLASSIFIED
K739	CHRONIC HEPATITIS, UNSPECIFIED
K740	HEPATIC FIBROSIS
K741	HEPATIC SCLEROSIS
K742	HEPATIC FIBROSIS WITH HEPATIC SCLEROSIS
K743	PRIMARY BILIARY CIRRHOSIS
K744	SECONDARY BILIARY CIRRHOSIS
K745	BILIARY CIRRHOSIS, UNSPECIFIED
K7460	UNSPECIFIED CIRRHOSIS OF LIVER
K7469	OTHER CIRRHOSIS OF LIVER
K750	ABSCESS OF LIVER
K751	PHLEBITIS OF PORTAL VEIN
K752	NONSPECIFIC REACTIVE HEPATITIS
K753	GRANULOMATOUS HEPATITIS, NOT ELSEWHERE CLASSIFIED
K754	AUTOIMMUNE HEPATITIS
K7581	NONALCOHOLIC STEATOHEPATITIS (NASH)
K7589	OTHER SPECIFIED INFLAMMATORY LIVER DISEASES
K759	INFLAMMATORY LIVER DISEASE, UNSPECIFIED
K761	CHRONIC PASSIVE CONGESTION OF LIVER
K763	INFARCTION OF LIVER
K7689	OTHER SPECIFIED DISEASES OF LIVER
K769	LIVER DISEASE, UNSPECIFIED
K77	LIVER DISORDERS IN DISEASES CLASSIFIED ELSEWHERE

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

OAT3 Inhibitors	
Label Name	**GCN**
ARAVA 10 MG TABLET	67031
ARAVA 20 MG TABLET	67032
AUBAGIO 14 MG TABLET	33262
AUBAGIO 7 MG TABLET	33259
JYNARQUE 45-15 MG TABLET	39957
JYNARQUE 60-30 MG TABLET	39958
JYNARQUE 90-30 MG TABLET	39956
LEFLUNOMIDE 10 MG TABLET	67031
LEFLUNOMIDE 20 MG TABLET	67032
PROBENECID 500 MG TABLET	35072
PROBENECID-COLCHICINE TABS	14029
SAMSCA 15 MG TABLET	24294
SAMSCA 30 MG TABLET	24302
TOLVAPTAN 15 MG TABLET	24294
TOLVAPTAN 30 MG TABLET	24294

Primary Biliary Cholangitis	
ICD-10 Code	**Description**
K743	PRIMARY BILIARY CIRRHOSIS

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

Strong CYP2C9 Inhibitors	
Label Name	**GCN**
DIFLUCAN 10 MG/ML SUSPENSION	60822
DIFLUCAN 100 MG TABLET	42190
DIFLUCAN 150 MG TABLET	42193
DIFLUCAN 200 MG TABLET	42191
DIFLUCAN 40 MG/ML SUSPENSION	60821
DIFLUCAN 50 MG TABLET	48192
FLUCONAZOLE 10 MG/ML SUSP	60822
FLUCONAZOLE 100 MG TABLET	42190
FLUCONAZOLE 150 MG TABLET	42193
FLUCONAZOLE 200 MG TABLET	42191
FLUCONAZOLE 40 MG/ML SUSP	60821
FLUCONAZOLE 50 MG TABLET	42192
FLUCONAZOLE-NACL 200 MG/100 ML	69790
FLUCONAZOLE-NACL 400 MG/200 ML	69791

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

Ursodeoxycholic Acid	
Label Name	**GCN**
URSO FORTE 500 MG TABLET	17730
URSODIOL 250 MG CAPSULE	01072
URSODIOL 300 MG CAPSULE	01070
URSODIOL 500 MG TABLET	17730

Biliary Cholangitis Agents

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).
9. Iqirvo Prescribing Information. Cambridge, MA. Ipsen Biopharmaceuticals, Inc. June 2024.
10. Livdelzi Prescribing Information. Foster City, CA. Gilead Sciences, Inc. August 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
10/25/2024	• Added criteria for Iqirvo and Livdelzi as approved by the DUR Board • Renamed guide to Biliary Cholangitis Agents (formerly IBAT Inhibitors)

