

Texas Prior Authorization Program
Clinical Criteria

Drug/Drug Class

Biliary Cholangitis Agents

Clinical Criteria Information Included in this Document

Iqirvo (Elafibranor) / Livdelzi (Seladelpar)

- [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.

Revision Notes

Initial publication and presentation to the DUR Board



Biliary Cholangitis Agents

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
IQIRVO 80 MG TABLET	54888
LIVDELZI 10 MG CAPSULE	56144

**Biliary Cholangitis Agents****Clinical Criteria Logic**

Initial criteria:

1. Is the client greater than or equal to (\geq) 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 (\leq) 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 (\leq) 10 mg daily?
 - Yes – Approve (365 days)
 - No – Deny

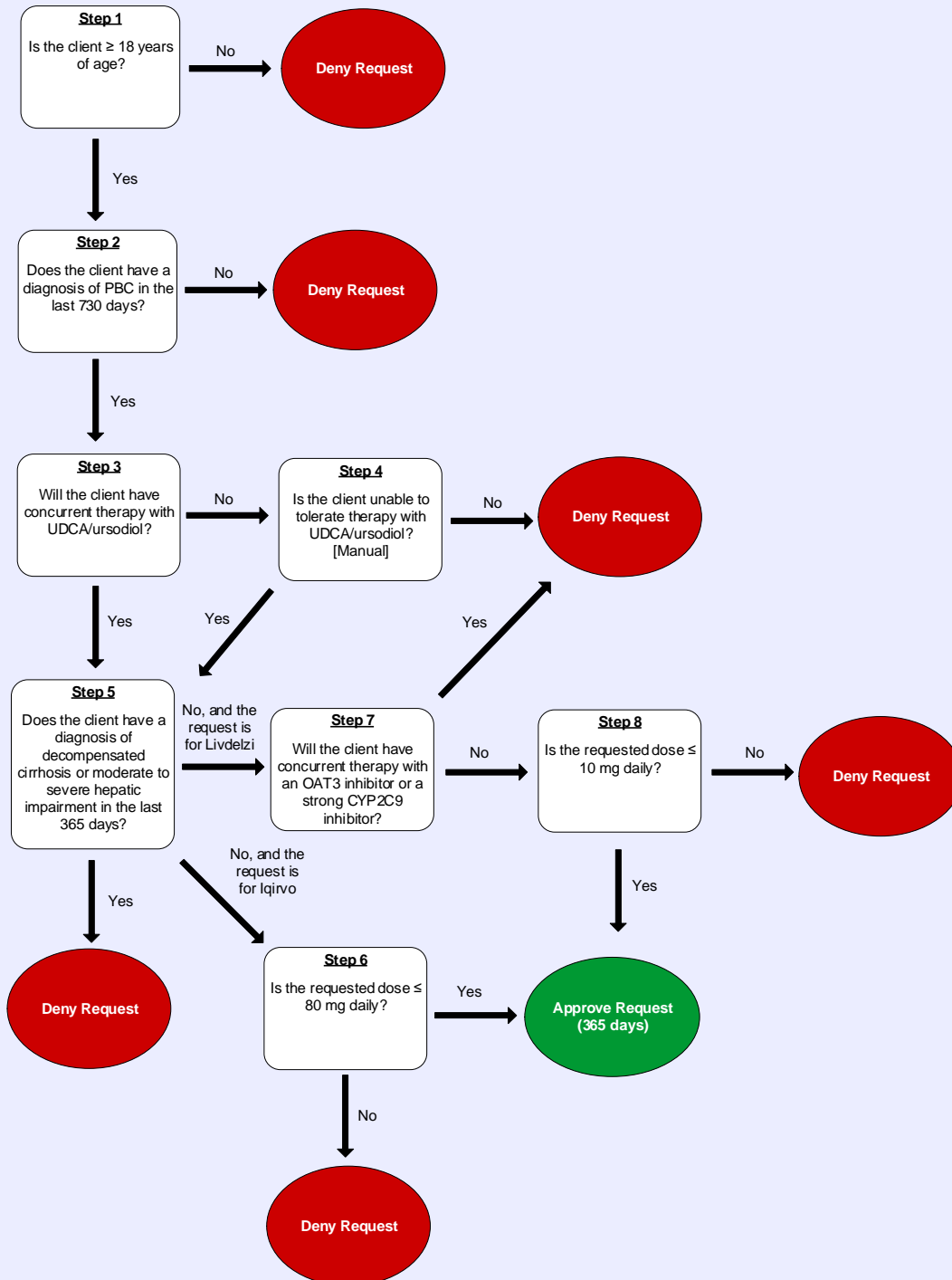
**Biliary Cholangitis Agents****Clinical Criteria Logic**

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 (\leq) 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 (\leq) 10 mg daily?
 - Yes – Approve (365 days)
 - No – Deny

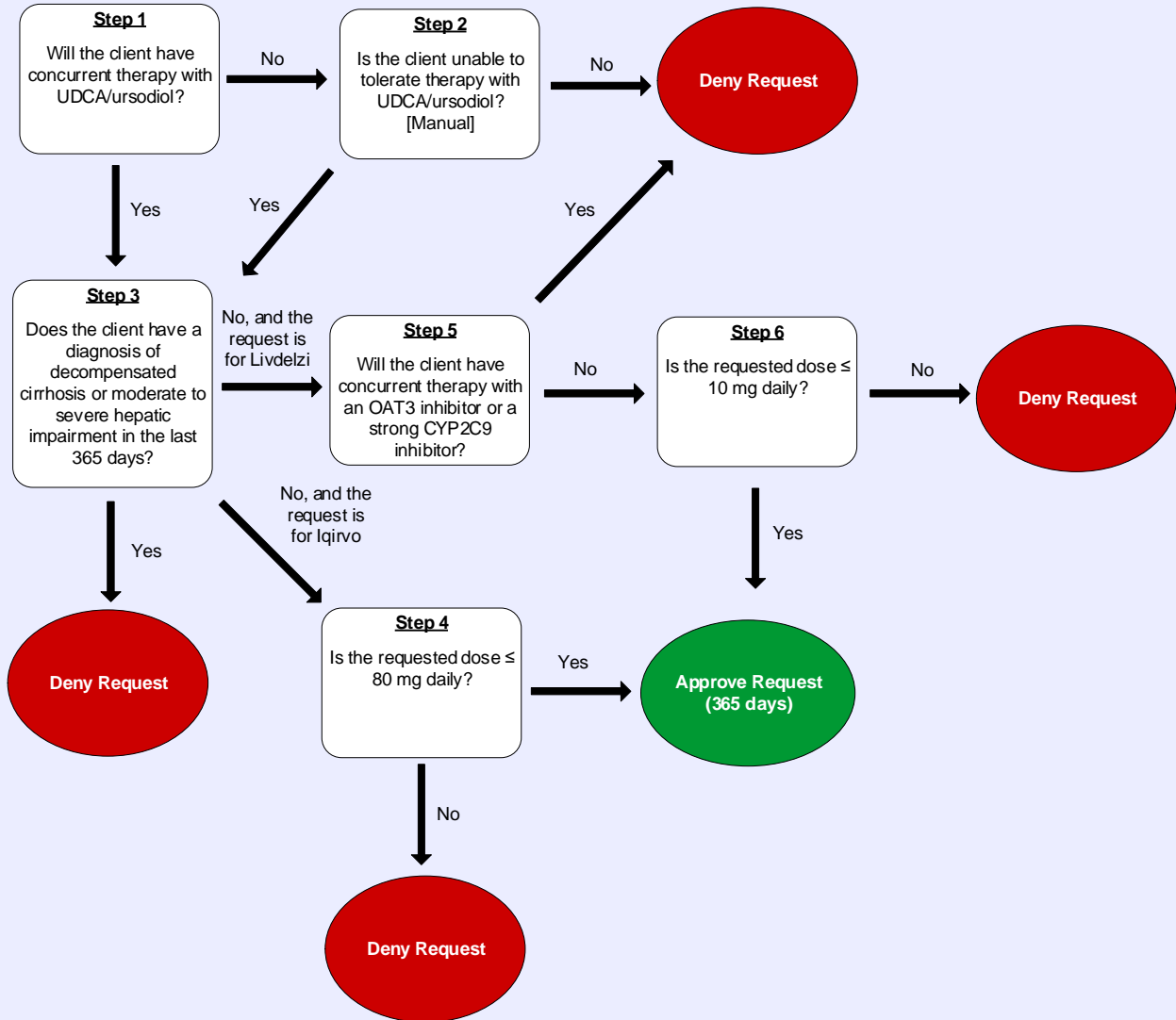
PAYPRESS™ **Biliary Cholangitis Agents**
Clinical Criteria Logic Diagram

Initial criteria:



PAXPRESS™ **Biliary Cholangitis Agents**
Clinical Criteria Logic Diagram

Renewal criteria:





Biliary Cholangitis Agents

Clinical Criteria Supporting Tables

Primary Biliary Cholangitis Required quantity: 1 Look back timeframe: 730 days	
ICD-10 Code	Description
K743	PRIMARY BILIARY CIRRHOSIS

Ursodeoxycholic Acid Required quantity: 1 Look back timeframe: concurrent therapy	
GCN	Label Name
17730	URSO FORTE 500 MG TABLET
01072	URSODIOL 250 MG CAPSULE
01070	URSODIOL 300 MG CAPSULE
17730	URSODIOL 500 MG TABLET

Decompensated Cirrhosis/Moderate to Severe Hepatic Impairment Required quantity: 1 Look back timeframe: 365 days	
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

Decompensated Cirrhosis/Moderate to Severe Hepatic Impairment	
Required quantity: 1	
Look back timeframe: 365 days	
ICD-10 Code	Description
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
B189	CHRONIC VIRAL HEPATITIS, UNSPECIFIED
B190	UNSPECIFIED 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

Decompensated Cirrhosis/Moderate to Severe Hepatic Impairment	
Required quantity: 1	
Look back timeframe: 365 days	
ICD-10 Code	Description
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
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

Decompensated Cirrhosis/Moderate to Severe Hepatic Impairment	
Required quantity: 1	
Look back timeframe: 365 days	
ICD-10 Code	Description
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	ABSCCESS 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

OAT3 Inhibitors	
Required quantity: 1	
Look back timeframe: concurrent therapy	
GCN	Label Name
67031	ARAVA 10 MG TABLET
67032	ARAVA 20 MG TABLET
33262	AUBAGIO 14 MG TABLET
33259	AUBAGIO 7 MG TABLET
39957	JYNARQUE 45-15 MG TABLET
39958	JYNARQUE 60-30 MG TABLET
39956	JYNARQUE 90-30 MG TABLET
67031	LEFLUNOMIDE 10 MG TABLET
67032	LEFLUNOMIDE 20 MG TABLET
35072	PROBENECID 500 MG TABLET
14029	PROBENECID-COLCHICINE TABS
24294	SAMSCA 15 MG TABLET
24302	SAMSCA 30 MG TABLET
24294	TOLVAPTAN 15 MG TABLET
24294	TOLVAPTAN 30 MG TABLET

Strong CYP2C9 Inhibitor	
Required quantity: 1	
Look back timeframe: concurrent therapy	
GCN	Label Name
60822	DIFLUCAN 10 MG/ML SUSPENSION
42190	DIFLUCAN 100 MG TABLET
42193	DIFLUCAN 150 MG TABLET
42191	DIFLUCAN 200 MG TABLET

Strong CYP2C9 Inhibitor	
Required quantity: 1	
Look back timeframe: concurrent therapy	
GCN	Label Name
60821	DIFLUCAN 40 MG/ML SUSPENSION
48192	DIFLUCAN 50 MG TABLET
60822	FLUCONAZOLE 10 MG/ML SUSP
42190	FLUCONAZOLE 100 MG TABLET
42193	FLUCONAZOLE 150 MG TABLET
42191	FLUCONAZOLE 200 MG TABLET
60821	FLUCONAZOLE 40 MG/ML SUSP
42192	FLUCONAZOLE 50 MG TABLET
69790	FLUCONAZOLE-NACL 200 MG/100 ML
69791	FLUCONAZOLE-NACL 400 MG/200 ML

**Biliary Cholangitis Agents****Clinical Criteria References**

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2024. Available at www.clinicalpharmacology.com. Accessed on October 25, 2024.
2. Micromedex [online database]. Available at www.micromedexsolutions.com. Accessed on October 25, 2024.
3. Iqirvo Prescribing Information. Cambridge, MA. Ipsen Biopharmaceuticals, Inc. June 2024.
4. Livdelzi Prescribing Information. Foster City, CA. Gilead Sciences, Inc. August 2024.

**Biliary Cholangitis Agents****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
10/25/2024	<ul style="list-style-type: none">Initial Publication and Presentation to the DUR Board