BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

IQIRVO® (elafibranor) oral
LIVDELZI® (seladelpar) oral
OCALIVA™ (obeticholic acid) oral
Generic Equivalent (if available)

Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and/or Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Medical Necessity Requirements for IQIRVO (elafibranor)

Criteria for Initial Therapy

Prescriber Qualifications
- Prescribed by or in consultation with a Hepatologist or Gastroenterologist

ORIGINAL EFFECTIVE DATE: 09/15/2016 | ARCHIVE DATE: | LAST REVIEW DATE: 08/21/2025 | LAST CRITERIA REVISION DATE: 08/21/2025

PHARMACY COVERAGE GUIDELINE

IQIRVO® (elafibranor) oral
LIVDELZI® (seladelpar) oral
OCALIVA™ (obeticholic acid) oral
Generic Equivalent (if available)

Indication

- Primary biliary cholangitis in combination with ursodeoxycholic acid (UDCA) in those with inadequate response to UDCA, or as monotherapy when unable to tolerate ursodeoxycholic acid

Age Requirement

- 18 years or older

Baseline Clinical Evaluation

- **TWO** of the following:
  - Positive antimitochondrial antibodies (AMA) at a titer of 1:40 or more or other primary biliary cholangitis specific autoantibody titer
  - Presence of cholestasis with alkaline phosphatase at least 1.5 times ULN for more than 6 months
  - Liver biopsy consistent with primary biliary cholangitis showing chronic nonsuppurative cholangitis of small and medium bile ducts
- **ALL** the following baseline tests completed:
  - Negative pregnancy test in women of childbearing potential
  - Evaluation for muscle pain or myopathy
  - Liver tests (alanine aminotransferase, aspartate aminotransferase, and total bilirubin)
  - Alkaline phosphatase

Brand Specific Criteria

- Have failure, contraindication, or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the United States Food and Drug Administration (FDA) (see Definitions section)

Safety

- No decompensated cirrhosis (e.g., ascites, variceal bleeding, or hepatic decompensation)
- No biliary obstruction
- No concomitant use with Livdelzi (seladelpar) or Ocaliva (obeticholic acid)

Documentation Requirements

- A completed request form must be submitted, including:
  - Chart notes
  - Lab results
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

ORIGINAL EFFECTIVE DATE: 09/15/2016 | ARCHIVE DATE: | LAST REVIEW DATE: 08/21/2025 | LAST CRITERIA REVISION DATE: 08/21/2025

PHARMACY COVERAGE GUIDELINE

IQIRVO® (elafibranor) oral
LIVDELZI® (seladelpar) oral
OCALIVA™ (obeticholic acid) oral
Generic Equivalent (if available)

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

Prescriber Qualifications

- Continues to be seen by or in consultation with a Hepatologist or Gastroenterologist

Clinical Response

- **ALL** the following:
  - Alkaline phosphatase less than 1.67 times ULN or decreased by at least 15 percent from baseline
  - Total bilirubin less than or equal to ULN

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- Has not developed any contraindications or significant adverse effects such as:
  - New or worsening myalgia, myopathy, or rhabdomyolysis causing acute kidney injury
  - Drug induced liver injury or worsening liver tests
  - Moderate to severe hepatic impairment (Child Pugh Class B or C)
  - Biliary obstruction
  - Severe hypersensitivity reaction or a recurrence of hypersensitivity reaction on rechallenge
- No decompensated cirrhosis (e.g., ascites, variceal bleeding, or hepatic decompensation)
- No concomitant use with Livdelzi (seladelpar) or Ocaliva (obeticholic acid)

Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement
- Lab values confirming safe continued use

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

PHARMACY COVERAGE GUIDELINE

IQIRVO® (elafibranor) oral
LIVDELZI® (seladelpar) oral
OCALIVA™ (obeticholic acid) oral
Generic Equivalent (if available)

Medical Necessity Requirements for LIVDELZI (seladelpar)

Criteria for Initial Therapy

Prescriber Qualifications
- Prescribed by or in consultation with a Hepatologist or Gastroenterologist

Indication
- Primary biliary cholangitis in combination with ursodeoxycholic acid (UDCA) in those with inadequate response to UDCA, or as monotherapy when unable to tolerate ursodeoxycholic acid

Age Requirement
- 18 years or older

Baseline Clinical Evaluation
- **TWO** of the following:
  - Positive antimitochondrial antibodies (AMA) at a titer of 1:40 or more or other primary biliary cholangitis specific autoantibody titer
  - Presence of cholestasis with alkaline phosphatase at least 1.5 times ULN for more than 6 months
  - Liver biopsy consistent with primary biliary cholangitis showing chronic nonsuppurative cholangitis of small and medium bile ducts
- **ALL** the following baseline tests completed:
  - Liver tests (alanine aminotransferase, aspartate aminotransferase, and total bilirubin)
  - Alkaline phosphatase

Brand Specific Criteria
- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- No concomitant use of:
  - OAT3 inhibitors (e.g., probenecid)
  - Strong CYP2C9 inhibitors (e.g., nicardipine, delavirdine, gemfibrozil, capecitabine, others)
  - Iqirvo (elafibranor) or Ocaliva (obeticholic acid)
- No biliary obstruction
- No decompensated cirrhosis (e.g., ascites, variceal bleeding, or hepatic decompensation)

PHARMACY COVERAGE GUIDELINE

IQIRVO® (elafibranor) oral
LIVDELZI® (seladelpar) oral
OCALIVA™ (obeticholic acid) oral
Generic Equivalent (if available)

Documentation Requirements
- A completed request form must be submitted, including:
  - Chart notes
  - Lab results
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration
- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):
Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

Prescriber Qualifications
- Continues to be seen by or in consultation with a Hepatologist or Gastroenterologist

Clinical Response
- **ALL** of the following:
  - Alkaline phosphatase less than one point six seven times upper limit of normal or decreased by at least fifteen percent
  - Total bilirubin less than or equal to upper limit of normal

Adherence
- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria
- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- Has not developed any significant adverse effects such as:
  - Drug induced liver injury or worsening liver tests
  - Moderate to severe hepatic impairment (Child Pugh Class B or C)
  - Biliary obstruction
- No significant drug interactions
- No worsening liver injury
- No moderate or severe hepatic impairment
- No concomitant use of:

  - OAT3 inhibitors (e.g., probenecid)
  - Strong CYP2C9 inhibitors (e.g., nicardipine, delavirdine, gemfibrozil, capecitabine, others)
  - Iqirvo (elafibranor) or Ocaliva (obeticholic acid)
- No decompensated cirrhosis (e.g., ascites, variceal bleeding, or hepatic decompensation)

Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement
- Lab values confirming safe continued use

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Medical Necessity Requirements for OCALIVA (obeticholic acid)

Criteria for Initial Therapy

Prescriber Qualifications

- Prescribed or in consultation with a Hepatologist or Gastroenterologist

Indication

- Primary biliary cholangitis without cirrhosis or with compensated cirrhosis but without portal hypertension with **ONE** of the following:
  - In combination with ursodeoxycholic acid (UDCA) after inadequate response following one year
  - As monotherapy when unable to tolerate UDCA

Age Requirement

- 18 years or older

Baseline Clinical Evaluation

- **TWO** of the following:
  - Positive antimitochondrial antibodies (AMA) at a titer of 1:40 or more or other primary biliary cholangitis specific autoantibody titer
  - Presence of cholestasis with alkaline phosphatase at least 1.5 times ULN for more than 6 months
  - Liver biopsy consistent with primary biliary cholangitis showing chronic nonsuppurative cholangitis of small and medium bile ducts

PHARMACY COVERAGE GUIDELINE

IQIRVO® (elafibranor) oral
LIVDELZI® (seladelpar) oral
OCALIVA™ (obeticholic acid) oral
Generic Equivalent (if available)

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- No Food and Drug Administration label contraindications including:
  - Decompensated cirrhosis (e.g., Child Pugh Class B or C)
  - Prior decompensation event
  - Compensated cirrhosis with evidence or portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia)
  - Complete biliary obstruction
- No concomitant use with Iqirvo (elafibranor) or Livdelzi (seladelpar)

Documentation Requirements

- A completed request form must be submitted, including:
  - Chart notes
  - Lab results
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

Prescriber Qualifications

- Continues to be seen by a physician specializing in the diagnosis or in consultation with a Hepatologist or Gastroenterologist

Clinical Response

- **ALL** of the following:
  - Alkaline phosphatase less than one point six seven times upper limit of normal or decreased by at least fifteen percent
  - Total bilirubin less than or equal to upper limit of normal

Adherence

- Adherence to the prescribed therapy regimen has been documented

PHARMACY COVERAGE GUIDELINE

IQIRVO® (elafibranor) oral
LIVDELZI® (seladelpar) oral
OCALIVA™ (obeticholic acid) oral
Generic Equivalent (if available)

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- No Food and Drug Administration label contraindications including:
  - Decompensated cirrhosis (e.g., Child Pugh Class B or C)
  - Prior decompensation event
  - Compensated cirrhosis with evidence or portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia)
  - Complete biliary obstruction
  - Severe, persistent, intolerable pruritus that is intense or widespread, interfering with activities of daily living, or causes severe sleep disturbances or discomfort despite management strategies
  - Significant liver adverse reactions (e.g., increased direct and indirect bilirubin, new or worsening jaundice)
- No concomitant use with Iqirvo (elafibranor) or Livdelzi (seladelpar)

Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement
- Lab values confirming safe continued use

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Criteria for Off-Label Use Requests:

Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. Off-Label Use of Non-Cancer Medications

2. Off-Label Use of Cancer Medications

Description:

Iqirvo (elafibranor) is indicated for the treatment of **primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have had an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA.** This indication is approved under accelerated approval

based on reduction of alkaline phosphatase (ALP). Improvement in survival or prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). Use of Iqirvo is not recommended in patients who have or develop decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy).

Livdelzi (seladelpar) is indicated for the treatment of **primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have had an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA**. This indication is approved under accelerated approval based on a reduction of alkaline phosphatase (ALP). Improvement in survival or prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). Use of Livdelzi is not recommended in patients who have or develop decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy)
Ocaliva (obeticholic acid) is indicated for the treatment of **primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA**. This indication was approved based on a reduction in alkaline phosphatase (ALP). An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Treatment with Ocaliva (obeticholic acid) in patients with moderate and severe hepatic impairment should be initiated and monitored by a healthcare provider with experience managing PBC.

Ursodeoxycholic acid (UDCA) is a naturally occurring hydrophilic bile acid, derived from cholesterol, is found in small quantities in normal human bile. Oral administration of UDCA increases this fraction in a dose related manner, to become the major biliary acid, replacing/displacing toxic concentrations of endogenous hydrophobic bile acids that tend to accumulate in cholestatic liver disease. In addition to the replacement and displacement of toxic bile acids, other mechanisms of action include cytoprotection of the injured bile duct epithelial cells (cholangiocytes) against toxic effects of bile acids, inhibition of apotosis of hepatocytes, immunomodulatory effects, and stimulation of bile secretion by hepatocytes and cholangiocytes.

PBC (previously referred to as primary biliary cirrhosis) is an autoimmune disease that is characterized by progressive destruction of the small and medium sized intrahepatic biliary ducts. With ongoing inflammation and scarring of the bile ducts, bile cannot be carried from the liver to the intestine. There is progressive impairment of bile flow, increased hepatocellular bile concentration, and cellular injury. As a result, bile builds up in the liver causing cholestasis and jaundice (obstructive jaundice). Fibrosis and cirrhosis occur as the disease advances over a few years or in some a few decades. Most patients are asymptomatic at the time of their diagnosis, and it is often diagnosed based on elevated alkaline phosphatase (ALP). PBC was initially known as primary biliary cirrhosis but the name was changed due to cirrhosis being an advanced feature of the disease.

PBC is a relatively rare disease affecting 1 in 4,000 individuals and it is seen more commonly in females in a ratio of 9:1 with a peak incidence in the fifth decade of life. The diagnosis of PBC can be made by two of the following 3 American Association for the Study of Liver Diseases (AASLD) 2009 criteria: positive antimitochoindrial antibodies (AMA), presence of cholestasis with a history of increased ALP levels for more than 6 months, or liver biopsy consistent with PBC that shows chronic suppurative cholangitis of the small and medium size bile ducts. A liver biopsy is typically not required.

PHARMACY COVERAGE GUIDELINE

IQIRVO® (elafibranor) oral
LIVDELZI® (seladelpar) oral
OCALIVA™ (obeticholic acid) oral
Generic Equivalent (if available)

Bile acids are ligands of the nuclear receptor, farnesoid X receptor (FXR). The FXR is a member of the nuclear receptor superfamily that is highly expressed in liver, intestine, kidney, and adrenal glands. The most potent natural FXR ligand is chenodeoxycholic acid (CDCA, chenodiol), but other bile acids, cholic, lithocholic, and deoxycholic also activate FXR.

Obeticholic acid is an agonist for FXR. FXR is a key regulator of bile acid, inflammatory, fibrotic, and metabolic pathways. Recent studies show that FXR is the primary sensor of bile acids and is involved in every aspect of bile acid metabolism, including bile acid synthesis, transport, detoxification, and excretion in the liver and intestine. FXR activation decreases the intracellular hepatocyte concentrations of bile acids by suppressing *de novo* synthesis from cholesterol as well as by increased transport of bile acids out of the hepatocytes. These mechanisms limit the overall size of the circulating bile acid pool while promoting choleresis, thus reducing hepatic exposure to bile acids.

In clinical trials, administration of Ocaliva (obeticholic acid) 10 mg once daily was also associated with an increase from baseline in concentrations of fibroblast growth factor (FGF)-19, an FXR-inducible enterokine involved in bile acid homeostasis. Concentrations of cholic acid and CDCA were reduced from baseline also. Fibroblast growth factors (FGFs) represent a large gene family of proteins involved in cell growth and differentiation, embryonic development, angiogenesis, and wound healing. FGF-19 is involved in controlling the enterohepatic bile acid/cholesterol system. FGF-19 also exerts important regulatory effects on glucose, protein, and lipid metabolism. The clinical relevance of these findings is unknown.

Obeticholic acid is a modified bile acid with structural similarity to endogenous CDCA. Obeticholic acid is conjugated with glycine or taurine in the liver and secreted into bile. These glycine and taurine conjugates of obeticholic acid are pharmacologically active and are absorbed in the small intestine leading to enterohepatic recirculation. The conjugates can be deconjugated in the ileum and colon by intestinal microbiota, leading to the conversion to obeticholic acid that can be reabsorbed or excreted in feces. A third obeticholic acid metabolite, 3-glucuronide, is formed but is considered to have minimal pharmacologic activity.

Iqivo (elafibranor) and its main active metabolite GFT1007 are peroxisome proliferator-activated receptor (PPAR) agonists both of which activate PPAR-alpha, PPAR-gamma, and PPAR-delta. However, the mechanism by which elafibranor exerts its therapeutic effects in patients with PBC is not well understood. Pharmacological activity that is potentially relevant to therapeutic effects includes inhibition of bile acid synthesis through activation of PPAR-alpha and PPAR-delta. The signaling pathway for PPAR-delta was reported to include Fibroblast Growth Factor 21 (FGF21)-dependent downregulation of CYP7A1, the key enzyme for the synthesis of bile acids from cholesterol.

Livdelzi (seladelpar) is a peroxisome proliferator-activated receptor (PPAR)-delta agonist. However, the mechanism by which seladelpar exerts its therapeutic effects in patients with PBC is not well understood. Pharmacological activity that is potentially relevant to therapeutic effects includes inhibition of bile acid synthesis through activation of PPAR-delta, which is a nuclear receptor expressed in most tissues, including the liver. Published studies show that PPAR-delta activation by seladelpar reduces bile acid synthesis through Fibroblast Growth Factor 21 (FGF21)-dependent downregulation of CYP7A1, the key enzyme for the synthesis of bile acids from cholesterol.

PHARMACY COVERAGE GUIDELINE

IQIRVO® (elafibranor) oral
LIVDELZI® (seladelpar) oral
OCALIVA™ (obeticholic acid) oral
Generic Equivalent (if available)

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Diagnostic criteria for PBC: (from American Association for the Study of Liver Disease 2009)

Two of the following three criteria:

- Positive antimitochondrial antibodies (AMA)
- Presence of cholestasis with a history of increased ALP levels of at least 1.5x ULN for more than 6 months
- Liver biopsy consistent with PBC that shows chronic non-suppurative cholangitis of the small and medium size bile ducts. A liver biopsy is typically not required.

Child-Pugh Classification:

Child-Pugh Classification of severity of liver disease			
Child-Pugh Classification	Points		
A: Well compensated	5-6		
B: Significant functional compromise	7-9		
C: Decompensated	10-15		
Parameter/Factor	1 point each	2 points each	3 points each
Total Bilirubin: (mg/dL) or (µmol/L)	< 2 (or < 34)	2-3 (or 34-50)	> 3 or (> 50)
Albumin (g/dL) or (g/L)	>3.5 (or > 35)	2.8-3.5 (or 28-35)	< 2.8 (or < 28)
Prothrombin time			
Seconds over control	1-3	4-6	> 6
INR	< 1.7	1.71-2.3	> 2.3
Ascites	Absent	Slight/Mild	Moderate to severe
Encephalopathy	None	Grade 1-2 (or suppressed with medication)	Grade 3-4 (or refractory)

Decompensation events:

Appearance of ascites
Gastroesophageal variceal bleeding
New or worsening jaundice
Encephalopathy
Spontaneous bacterial peritonitis

The appearance of ascites, variceal bleeding, jaundice, or encephalopathy, the major clinical manifestations of liver cirrhosis, marks the transition from the ***compensated*** phase into the ***decompensated*** phase of cirrhosis

PHARMACY COVERAGE GUIDELINE

IQIRVO® (elafibranor) oral
LIVDELZI® (seladelpar) oral
OCALIVA™ (obeticholic acid) oral
Generic Equivalent (if available)

Encephalopathy Grades:

Grade 0	• Minimal hepatic encephalopathy (also known as covert hepatic encephalopathy and previously known as subclinical hepatic encephalopathy) • Lack of detectable changes in personality or behavior • Minimal changes in memory, concentration, intellectual function, and coordination • Asterixis is absent
Grade 1	• Trivial lack of awareness • Shortened attention span • Impaired performance with addition or subtraction • Hypersomnia, insomnia, or inversion of sleep pattern • Euphoria or anxiety, depression, or irritability • Mild confusion • Slowing of ability to perform mental tasks
Grade 2	• Lethargy or apathy • Minimal disorientation for time and place • Inappropriate behavior • Impaired performance with subtraction • Slurred speech • Obvious asterixis • Drowsiness • Gross deficits in ability to perform mental tasks • Obvious personality changes
Grade 3	• Somnolence to semi-stupor, but responsive to verbal stimuli • Marked confusion • Gross disorientation • Unable to perform mental tasks • Amnesia • Occasional fits of rage • Incomprehensible speech
Grade 4	• Coma (unresponsive to verbal or noxious stimuli) • Coma with or without response to painful stimuli

Resources:

Ocaliva (obeticholic acid) product information, revised by Intercept Pharmaceuticals, Inc. 05-2022. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed May 12, 2025.

Iqirvo (elafibranor) product information, revised by Ipsen Biopharmaceuticals, Inc. 06-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed May 12, 2025.

Livdelzi (seladelpar) product information, revised by Gilead Sciences, Inc. 08-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed May 12, 2025.

ORIGINAL EFFECTIVE DATE: 09/15/2016 | ARCHIVE DATE: | LAST REVIEW DATE: 08/21/2025 | LAST CRITERIA REVISION DATE: 08/21/2025

Poupon R. Clinical manifestations, diagnosis, and prognosis of primary biliary cholangitis. In: UpToDate, Lindor KD, Robson KM (Eds), UpToDate, Waltham, MA.: UpToDate Inc. Available at Inc. http://uptodate.com. Literature current through May 2025. Topic last updated April 25, 2025. Accessed June 18, 2025.

Poupon R. Overview of the management of primary biliary cholangitis. In: UpToDate, Lindor KD, Robson KM (Eds), UpToDate, Waltham, MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through May 2025. Topic last updated February 14, 2025. Accessed June 18, 2025.