



**GEORGIA MEDICAID FEE-FOR-SERVICE  
BILE SALTS PA SUMMARY**

Preferred	Non-Preferred
Cholbam (cholic acid)* Ocaliva (obeticholic acid)* Ursodiol 250 mg, 500 mg tablets generic Ursodiol 300 mg capsules generic	Bylvay (odevixibat) Chenodal (chenodiol) Iqirvo (elafibranor) Livdelzi (seladelpar) Livmarli (maralixibat) Reltone (ursodiol 200 mg, 400 mg capsules)

\*preferred but requires PA

**LENGTH OF AUTHORIZATION:** Varies

**NOTE:** Cholbam and Ocaliva are preferred but require prior authorization.

**PA CRITERIA:**

*Bylvay*

- ❖ Approvable for members 3 months of age and older with a confirmed diagnosis of progressive familial intrahepatic cholestasis (PFIC) who are experiencing moderate to severe cholestatic pruritis and have experienced inadequate response, allergies, contraindications, drug-drug interactions or intolerable side effects with two of the following:
  - ursodeoxycholic acid (UDCA)/ursodiol (Actigall, Urso)
  - rifampin
  - cholestyramine (Questran) or colestipol (Colestid)
  - naltrexone (Vivitrol).
- ❖ Approvable for members 12 months of age and older with a confirmed diagnosis of Alagille syndrome (ALGS) who are experiencing moderate to severe cholestatic pruritis and have experienced inadequate response, allergies, contraindications, drug-drug interactions or intolerable side effects with two of the following:
  - ursodeoxycholic acid (UDCA)/ursodiol (Actigall, Urso)
  - rifampin
  - cholestyramine (Questran) or colestipol (Colestid)
  - naltrexone (Vivitrol).
- ❖ Must be prescribed by or in consultation with a gastroenterologist, hepatologist or specialist in managing cholestatic pruritus.

*Chenodal*

- ❖ Approvable for members 18 years of age and older with a diagnosis of cholelithiasis who have small (<15 mm [1.5 cm]) radiolucent (non-calcified) cholesterol gallstones, have a normally functioning gallbladder, are not eligible for surgery due to disease or age and have experienced an inadequate response, allergy, contraindication, drug-drug interaction or intolerable side effect with ursodiol (Actigall, Urso).
- ❖ Approvable for members with a diagnosis of cerebrotendinous xanthomatosis.



- ❖ Must be prescribed by or in consultation with a gastroenterologist, hepatologist or specialist in managing gallstones.

### Cholbam

- ❖ Approvable for members with bile acid synthesis disorder due to one of the following single enzyme defects (SEDs):
  - 3-beta-hydroxy-delta-5-C27-steroid oxidoreductase deficiency (3 $\beta$ -HSD)
  - Aldo-keto reductase 1D1 (AKR1D1)
  - Alpha-methylacyl-CoA racemase deficiency (AMACR deficiency)
  - Sterol 27-hydroxylase deficiency (cerebrotendinous xanthomatosis [CTX])
  - Cytochrome P450 7A1 (CYP7A1)
- ❖ Approvable for members with one of the following peroxisomal disorders confirmed by mass spectrometry, biochemical testing or genetic testing and when used with adjunctive therapy:
  - Neonatal Adrenoleukodystrophy
  - Generalized Peroxisomal Disorder
  - Refsum Disease
  - Zellweger Syndrome
  - Peroxisomal Disorder, Type Unknown
- ❖ Must be prescribed by or in consultation with a gastroenterologist, hepatologist or specialist in managing bile acid synthesis or peroxisomal disorders.

### Iqirvo and Livdelzi

- ❖ Approvable for members 18 years of age or older with primary biliary cholangitis/primary biliary cirrhosis (PBC) when member has tried and failed to achieve an adequate biochemical response or member has allergies, contraindications, drug-drug interactions or intolerable side effects with ursodiol (Actigall, Urso) and Ocaliva (obeticholic acid).

AND

- ❖ Must be used in combination with or member must be unable to take ursodiol (Actigall, Urso)

AND

- ❖ Must be prescribed by or in consultation with a gastroenterologist, hepatologist or specialist in managing primary biliary cholangitis/primary biliary cirrhosis.

### Livmarli

- ❖ Approvable for members 3 months of age and older with a confirmed diagnosis of Alagille syndrome (ALGS) who are experiencing moderate to severe cholestatic pruritis and have experienced inadequate response, allergies, contraindications, drug-drug interactions or intolerable side effects with two of the following
  - ursodeoxycholic acid (UDCA)/ursodiol (Actigall, Urso)
  - rifampin
  - cholestyramine (Questran) or colestipol (Colestid)
  - naltrexone (Vivitrol).
- ❖ Approvable for members 12 months of age and older with a confirmed diagnosis of progressive familial intrahepatic cholestasis (PFIC) who are experiencing moderate to severe cholestatic pruritis and have experienced inadequate response, allergies, contraindications, drug-drug interactions or intolerable side effects with two of the following:
  - ursodeoxycholic acid (UDCA)/ursodiol (Actigall, Urso)
  - rifampin



- cholestyramine (Questran) or colestipol (Colestid)
- naltrexone (Vivitrol).
- ❖ Must be prescribed by or in consultation with a gastroenterologist, hepatologist or specialist in managing cholestatic pruritus.

#### Ocaliva

- ❖ Approvable for members 18 years of age or older with primary biliary cholangitis/primary biliary cirrhosis (PBC) when member has tried ursodiol for at least 1 year and failed to achieve an adequate biochemical response or member has an allergy, contraindication, drug-drug interaction or intolerable side effect with ursodiol (Actigall, Urso)

#### AND

- ❖ Must be used in combination with or member must be unable to take ursodiol (Actigall, Urso)

#### AND

- ❖ Must be prescribed by or in consultation with a gastroenterologist, hepatologist or specialist in managing primary biliary cholangitis/primary biliary cirrhosis.

#### Reltone

- ❖ Prescriber must submit a written letter of medical necessity stating the reasons the preferred products, generic ursodiol capsules and tablets, are not appropriate for the member

#### **EXCEPTIONS:**

- Exceptions to these conditions of coverage are considered through the prior authorization process.
- The Prior Authorization process may be initiated by calling **OptumRx at 1-866-525-5827**.

#### **PREFERRED DRUG LIST:**

- For online access to the Preferred Drug List (PDL), please go to <http://dch.georgia.gov/preferred-drug-lists>.

#### **PA AND APPEAL PROCESS:**

- For online access to the PA process, please go to [www.dch.georgia.gov/prior-authorization-process-and-criteria](http://www.dch.georgia.gov/prior-authorization-process-and-criteria) and click on Prior Authorization (PA) Request Process Guide.

#### **QUANTITY LEVEL LIMITATIONS:**

- For online access to the current Quantity Level Limits (QLL), please go to [www.mmis.georgia.gov/portal](http://www.mmis.georgia.gov/portal), highlight Pharmacy and click on [Other Documents](#), then select the most recent quarters QLL list.