GEORGIA MEDICAID FEE-FOR-SERVICE
BILE SALTS PA SUMMARY

<table>
<thead>
<tr>
<th>Preferred</th>
<th>Non-Preferred</th>
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<tbody>
<tr>
<td>Cholbam (cholic acid)*</td>
<td>Chenodal (chenodiol)</td>
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<td>Ocaliva (obeticholic acid)*</td>
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<tr>
<td>Ursodiol generic</td>
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*preferred but requires PA

LENGTH OF AUTHORIZATION: Varies

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

PA CRITERIA:

**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 (3β-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.

**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.
- If the member has moderate to severe hepatic impairment (Child-Pugh B or C) or has had a prior hepatic decompensation event, the dosing frequency must be limited to a maximum of 10 mg twice weekly at least 3 days apart.

**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](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.