GEORGIA MEDICAID FEE-FOR-SERVICE
CHOLBAM PA SUMMARY

<table>
<thead>
<tr>
<th>Preferred</th>
<th>Non-Preferred</th>
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<td>Cholbam (cholic acid)</td>
<td>n/a</td>
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LENGTH OF AUTHORIZATION: Initial 3 months; repeat 1 year

PA CRITERIA:

- 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 hepatologist or gastroenterologist.

- Member’s serum aspartate aminotransferase (AST), serum alanine aminotransferase (ALT), serum gamma glutamyltransferase (GGT), alkaline phosphatase (ALP), bilirubin and international normalized ratio (INR) must be routinely monitored.

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.

Revised 4/13/2016
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 Provider Information and click on Provider Manuals. Scroll to the page with Pharmacy Services and select that manual.