Iowa Department of Human Services

Request for Prior Authorization
CHOLIC ACID (CHOLBAM®)

FAX Completed Form To
1 (800) 574-2515

Provider Help Desk
1 (877) 776-1567

(PLEASE PRINT – ACCURACY IS IMPORTANT)

IA Medicaid Member ID #	Patient name	DOB
Patient address		
Provider NPI	Prescriber name	Phone
Prescriber address		Fax
Pharmacy name	Address	Phone
Prescriber must complete all information above. It must be legible, correct, and complete or form will be returned.		
Pharmacy NPI	Pharmacy fax	NDC

Prior authorization is required for cholic acid (Cholbam®). Payment will be considered under the following conditions:

1) **Is prescribed by a hepatologist or pediatric gastroenterologist; and**
2) **Is prescribed for a diagnosis of bile acid synthesis disorder due to a single enzyme defect (SED) including:**
   - **3-beta-hydroxy-delta-5c27-steroid oxidoreductase deficiency (3-βHSD),**
   - **Aldo-keto reductase 1D1 (AKR1D1),**
   - **Alpha-methylacyl-CoA racemase deficiency (AMACR deficiency),**
   - **Sterol 27-hydroxylase deficiency (cerebrotendinous xanthomatosis [CTX]),**
   - **Cytochrome P450 7A1 (CYP7A1),**
   - **25-hydroxylation pathway (Smith-Lemli-Opitz), OR**
3) **Is prescribed as an adjunctive treatment of peroxisomal disorder (PD) in patients who exhibit manifestations of liver disease, steatorrhea, or complications from fat soluble vitamin absorption. Peroxisomal disorders include Zellweger syndrome (ZWS), neonatal adrenoleukodystrophy (NALD), or infatile refsum disease (IRD); and**
4) **Diagnosis is confirmed by mass spectrometry or other biochemical testing or genetic testing (attach results); and**
5) **Baseline liver function tests are taken prior to initiation of therapy (AST. ALT, GGT, ALP, total bilirubin, INR) and provided with request; and**
6) **Patient must have elevated serum aminotransferases (AST and ALT) with normal serum gamma glutamyltransferase (GTT); and**
7) **Patient is at least 3 weeks old.**

When criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be granted for 12 months at a time requiring documentation of response to therapy by meeting two of the following criteria:

- **Body weight has increased by 10% or is stable at ≥50th percentile,**
- **Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) < 50 U/L or baseline levels reduced by 80%,**
- **Total bilirubin level reduced to ≤1mg/dL.**

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Non-Preferred

☐ Cholbam

Strength	Dosage Instructions	Quantity	Days Supply
_____	_____	_____	_____

Diagnosis:

☐ **Bile Acid Synthesis Disorder due to SED**

○ 3β-HSD ○ AKR1D1 ○ AMACR deficiency ○ CTX ○ CYP7A1 ○ Smith-Lemli-Opitz

☐ **Peroxisomal Disorder (PD)**

○ ZWS ○ NALD ○ IRD

☐ **Other:**_____

☐ **Attach results of diagnosis confirmation by mass spectrometry, biochemical testing, or genetic testing**

☐ **Provider specialty:**_____

☐ **Attach baseline liver function tests prior to initiation of therapy (AST, ALT, GGT, ALP, total bilirubin, INR)**

☐ **Renewal requests:** Provide documentation of adequate response to treatment by meeting two of the following criteria (attach lab results and/or chart notes):

○ Body weight has increased by 10% or is stable at ≥50th percentile

○ ALT or AST < 50 U/L or baseline levels reduced by 80%

○ Total bilirubin level reduced to ≤ 1mg/dL

Attach lab results and other documentation as necessary.

Prescriber signature (Must match prescriber listed above.)	Date of submission

IMPORTANT NOTE: *In evaluating requests for prior authorization the consultant will consider the treatment from the standpoint of medical necessity only. If approval of this request is granted, this does not indicate that the member continues to be eligible for Medicaid. It is the responsibility of the provider who initiates the request for prior authorization to establish by inspection of the member's Medicaid eligibility card and, if necessary by contact with the county Department of Human Services, that the member continues to be eligible for Medicaid.*