Pharmacy Prior Authorization Form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to: ☒ **Commercial** ☒ **Commercial Individual (PPACA)** ☐ **Medicaid**

This request is: ☐ **Urgent** (life threatening) ☐ **Non-Urgent** (standard review)

Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function. The standard review time averages between 1 and 3 business days.

Cholbam® (cholic acid)

Member

Last Name: _____ First Name: _____

ID #: _____ DOB: _____ Gender: _____

Primary Care Physician: _____

Requesting Provider: _____ Prov. Phone: _____ Prov. Fax: _____

Provider Address: _____

Provider NPI: _____ Contact Name: _____

Provider Signature: _____ Date: _____

Product Information

☐ New request ☐ Continuation request

Drug product: ☐ Cholbam 50 mg capsule ☐ Cholbam 250 mg capsule

Start date (or date of next dose): _____

Date of last dose (if applicable): _____

Dosing frequency: _____

Drug cost information

The wholesale acquisition cost for Cholbam is up to $830.00 for each capsule. The cost of treatment with this drug will vary depending on the patient's circumstances, but may cost more than $13,284 each year.

Precertification Requirements

Before this drug is covered for an initial 8 weeks, the patient must meet all of the following requirements:

1. Must have a diagnosis of bile acid synthesis disorder due to single enzyme defects (SED) or peroxisomal disorder (PD).
2. Must provide a serum very long chain fatty acid value (VLCFA).
3. Must provide baseline liver function tests.

For continued coverage, patient must have met the following requirements:

1. Body weight increased by 10% or is stable at ≥ 50th percentile.
2. Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) < 50 U/L or baseline levels reduced by 80%.
3. Total bilirubin level reduced to ≤ 1mg/dL.
4. Must not have evidence of cholestasis on liver biopsy.

All fields must be complete and legible for review. Your office will receive a response via fax.

New 07/2015
Last reviewed 07/2017

Note: Authorization for indications not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the drug's use for the identified indication.

New request
Priority Health Precertification Documentation

A. Has the patient been diagnosed with bile acid synthesis disorder due to SED or a peroxisomal disorder?

Bile Acid Synthesis Disorders due to SED:

- ☐ 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)

Peroxisomal Disorders

- ☐ Zellweger syndrome (ZWS)
- ☐ Neonatal adrenoleukodystrophy (NALD)
- ☐ Infantile Refsum disease (IRD)

☐ Other – the patient's condition is: _____

Rationale for use: _____

B. Provide VLCFA lab results?

Lab Date	Result	Interpretation		
_____	_____ umol/L	☐ high	☐ low	☐ within normal limits
_____	_____ umol/L	☐ high	☐ low	☐ within normal limits
_____	_____ umol/L	☐ high	☐ low	☐ within normal limits
_____	_____ umol/L	☐ high	☐ low	☐ within normal limits
_____	_____ umol/L	☐ high	☐ low	☐ within normal limits

C. Provide liver function lab results?

Lab Date	Result	Interpretation		
_____	_____ U/L	☐ high	☐ low	☐ within normal limits
_____	_____ U/L	☐ high	☐ low	☐ within normal limits
_____	_____ U/L	☐ high	☐ low	☐ within normal limits
_____	_____ U/L	☐ high	☐ low	☐ within normal limits

Request to continue a previously authorized approval
Priority Health Precertification Documentation

A. Has the patient's body weight increased by 10% or remained stable at, or greater than, the 50th percentile?

☐ Yes ☐ No - Rationale for use: _____

B. Are the patient's AST or ALT less than 50 U/L or has the level been reduced by at least 80% from baseline?

☐ Yes ☐ No - Rationale for use: _____

C. Is the total bilirubin level less than or equal to 1 mg/dL?

☐ Yes ☐ No - Rationale for use: _____

D. Does the patient have evidence of cholestasis?

☐ No ☐ Yes - Rationale for use: _____

All fields must be complete and legible for review. Your office will receive a response via fax.

New 07/2015
Last reviewed 07/2017