

# Priority Health Medicare prior authorization form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to:  Medicare Part B  Medicare Part D  
 This request is:  Expedited request  Standard request

Your request will be expedited if you haven't gotten the prescription and Priority Health Medicare determines, or your prescriber tells us, that your life or health may be at risk by waiting.

## 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: \_\_\_\_\_

### Drug 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: \_\_\_\_\_

### Prior authorization criteria

The following requirements need to be met before this drug is covered by Priority Health Medicare. These requirements have been approved by the Centers for Medicare and Medicaid Services (CMS), but you may ask us for an exception if you believe one or more of these requirements should be waived.

#### For this drug to be covered, the patient must meet the following criteria:

1. Must be used for a medically-accepted indication\*
  - Bile acid synthesis disorder due to single enzyme defects (SED)
  - Adjunctive treatment of peroxisomal disorders including Zellweger spectrum disorders when liver disease manifestations, steatorrhea, or complications from decreased absorption of fat soluble vitamins are present

#### For continuation, the patient must meet the following criteria:

1. Provide documentation showing the patient has met:
  - 2 of the following laboratory criteria **OR**
  - 1 of the following laboratory criteria **AND** a body weight increase of 10% (or stability at greater than the 50<sup>th</sup> percentile)

#### Laboratory criteria:

1. Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) < 50 U/L (or baseline levels reduced by 80%)
2. Total bilirubin < 1 mg/dL
3. No evidence of cholestasis on liver biopsy

**Medically-accepted indication\***

This drug is only covered under Medicare Part D when it is used for a medically accepted indication. A medically accepted indication is a use of the drug that is *either*:

- approved by the Food and Drug Administration. (That is, the Food and Drug Administration has approved the drug for the diagnosis or condition for which it is being prescribed.)
- — or — supported by certain reference books. (These reference books are the American Hospital Formulary Service Drug Information and the DRUGDEX Information System)

**Additional information**

**Note:** If approved, initial approval will be for 3 months and continuation approvals will be for 1 year.

**Priority Health Precertification Documentation**

**A. What condition is this drug being requested for?**

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

- 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)

**Peroxisomal Disorder**

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

Other – the patient's condition is: \_\_\_\_\_  
**Rationale for Other use:** \_\_\_\_\_

**Request to continue a previously authorized approval  
 Priority Health Precertification Documentation**

**A. Has the patient met any of the following laboratory criteria? Documentation must be provided.**

- Yes (check all that apply)
  - AST or ALT < 50 U/L or level reduced by at least 80% from baseline
  - Total bilirubin level < 1 mg/dL
  - No evidence of cholestasis

No. **Are you requesting an exception to the criteria?**

- Yes. **Rationale for exception:** \_\_\_\_\_
- No

**B. If only 1 laboratory criterion has been met, has the patient's body weight increased by 10% (or remained stable at > 50th percentile)?**

- Yes
- No. **Are you requesting an exception to the criteria?**
  - Yes. **Rationale for exception:** \_\_\_\_\_
  - No

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**Priority Health Medicare Exception Request** (*exceptions to the above criteria*)

**Do you believe one or more of the prior authorization requirements should be waived?**  Yes  No

If yes, you must provide a statement explaining the medical reason why the exception should be approved.

**Would Cholbam likely be the most effective option for this patient?**

No

Yes, because: \_\_\_\_\_

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**If the patient is currently using Cholbam, would changing the patient's current regimen likely result in adverse effects for the patient?**

No

Yes, because: \_\_\_\_\_

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