Patient Enrollment Form for CHOLBAM® Total Care Hub®

Phone: 844-CHOLBAM (844-246-5226) — Fax 877-473-3171

PATIENT INFORMATION

Patient First Name | MI

Last Name | Gender ☐ M ☐ F

Date of Birth | SS#

Address

City | State | ZIP

Home Phone | Mobile Phone

Preferred Method of Contact ☐ Home Phone ☐ Mobile Phone ☐ E-mail

E-mail

FOR PATIENTS UNDER 18:

Parent/Guardian
First Name | MI

Last Name

Address

City | State | ZIP

Home Phone | Mobile Phone

E-mail

PRIMARY INSURANCE Please attach a copy of both sides of the patient's insurance card(s)

Insurance Carrier

Customer Service Phone

Subscriber Name

Relationship to Patient

Employer Name

Subscriber Date of Birth

Subscriber ID Number

Policy/Employer/Group Number

PHARMACY BENEFITS–PRESCRIPTION DRUG CARD

Insurance Carrier

Customer Service Phone

Subscriber Name | Bin#

Subscriber Date of Birth

Subscriber ID Number

Policy/Employer/Group Number

DIAGNOSIS/MEDICAL INFORMATION (This is for insurance purposes only, not to suggest approved uses for indication)

Diagnosis ☐ Bile Acid Synthesis Disorders (B.A.S.D.) ICD-10-CM Code: _____ ICD-10-CM Code/Description _____

Due to Single Enzyme Defect (check box):
- ☐ Smith Lemli-Opitz Syndrome (SLOS)
- ☐ 3β-HSD or HSD3β7 deficiency
- ☐ AKR1D1 deficiency
- ☐ CYP27A1 deficiency (presenting as cerebrotendinous xanthomatosis, CTX)
- ☐ AMACR deficiency
- ☐ Unknown/Other

Due to Peroxisomal Biogenesis Disorder-Zellweger Spectrum Disorder (PBD-ZSD):
- ☐ PBD-ZSD - Severe
- ☐ PBD-ZSD - Mild - Moderate
- ☐ Unknown/Other

Height_____ inches

Weight _____ kgs

CHOLBAM (cholic acid) ORAL CAPSULES PRESCRIPTION/ORDER

CHOLBAM Total daily dose = _____ mg/day: _____mg _____times a day
(The recommended dosage of CHOLBAM is 10 to 15 mg/kg administered orally once daily, in two divided doses. Refer to the PI for additional information on Dosage & Administration)

Dispense 30 day supply Number of refills _____

Signature: _____

Lab Test Supporting Diagnosis	Results (at least one result)	Date
Genetic Test		
Elevated 7-DHC Levels		
Very Long Chain Fatty Acid		
FAB-MS, Urinary Bile Acid (Atypical)		
Cholestanol		
7A12AC4 or 7AC4, Ketosterols		
Liver Function (ALT/AST/GGT/Bilirubin)		
Other: _____		

PHYSICIAN CERTIFICATION

By signing below, I certify that (a) the above therapy is medically necessary and that I will supervise the patient's treatment accordingly; (b) I have received the necessary authorizations, including those required by state law and the Health Insurance Portability and Accountability Act of 1996 (HIPAA), to release the above information and other health and medical information of the patient to Travere Therapeutics, Inc. and Mirum Pharmaceuticals, Inc., and the company or companies that help Travere Therapeutics and Mirum Pharmaceuticals administer the CHOLBAM Total Care Hub services; (c) I am prescribing the drug listed for the patient listed in this application based upon my independent medical judgment. By my signature below, I agree to receive certain reimbursement support services. I authorize Travere Therapeutics and EVERSANA, acting on behalf of Travere, to use the information contained in the prescription above, my name, and the name, address, and telephon number of my medical practice, and other applicable information, in order to provide me, my practice, and the patient listed in this application with the aforementioned reimbursement support services. I understand that participation in the CHOLBAM Total Care Hub services described does not constitute a guarantee on the part of Travere Therapeutics and Mirum Pharmaceuticals or parties acting on its behalf that (1) the drug I have prescribed will be reimbursed by the patient's or any insurance program, or (2) the patient will be eligible for any patient assistance program. I appoint Travere Therapeutics and its agents to convey this prescription—electronically or otherwise—to the dispensing pharmacy.

Prescriber's Signature _____ Date _____

(No stamps permitted; prescription will be dispensed as written unless otherwise noted)

Prescriber NPI# | Prescriber State License #

Prescriber's full, usual, and actual signature is required – no stamps. This form cannot be processed without the prescriber's signature.

Prescriber's First Name | MI | Last Name

Address | City | State | ZIP

Phone | Fax | E-mail

Office Contact Name | Phone

Please Note: If you are faxing a prescription, it must be faxed from prescriber's facility to fax number (877) 473-3171.

Please return this form to the CHOLBAM (cholic acid) Total Care Hub by faxing it to (877) 473-3171.

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PATIENT AUTHORIZATION AND RELEASE TO COLLECT, USE, AND DISCLOSE PROTECTED HEALTH INFORMATION

Before signing, the patient and/or patient's authorized representative should review and understand the terms of this Authorization and Release ("Authorization") before signing. If an authorized representative signs for the patient, please indicate the relationship to the patient.

I understand that the collection, use, and disclosure of the patient's health information are protected under law. Information contained in this Enrollment Form, such as the patient's name, address, insurance, prescription, and medical information, is "protected health information" ("PHI")." By signing this Authorization, the patient agrees to the collection, use, and disclosure of the patient's PHI as described below.

I understand that I may decline to sign this Authorization, and that doing so will not affect the patient's ability to receive CHOLBAM® (cholic acid) or obtain insurance or insurance benefits.

I understand that once PHI about the patient is released, based on this Authorization, federal privacy laws may not prevent Travere Therapeutics and Mirum Pharmaceuticals and company or companies who administer the CHOLBAM® (cholic acid) Total Care Hub® Support Services ("Services") from further disclosing my information. However, I understand that such entities have agreed to use or disclose PHI they receive only for the purposes described in this Authorization or as required by law. I also understand that I may revoke (withdraw) this Authorization at any time by sending a signed, written statement to the CHOLBAM Total Care Hub and faxing it to (877) 473-3167.

Revoking this Authorization will prohibit PHI disclosures after the date the written revocation is received by the CHOLBAM Total Care Hub, except to the extent that action has been taken already in on this Authorization. After I revoke this Authorization, the patient's PHI may be disclosed among Travere Therapeutics and the company or companies that help Travere Therapeutics and Mirum Pharmaceuticals administer the Services in order to maintain records of the patient's participation, but it will not be otherwise disclosed or used.

By signing below, I authorize Travere Therapeutics and the company or companies that help Travere Therapeutics and Mirum Pharmaceuticals administer the Services, to do the following:

1. Request and receive information from the patient's treating physician, healthcare provider, health insurer, or pharmacist necessary to investigate and resolve the patient's insurance coverage, coding, or reimbursement inquiry or to provide the reimbursement support service that I have requested. Information may include the patient's medical diagnosis, condition, and treatment (including prescription information), the patient's health insurance, name, address and telephone number;
2. Collect, use, and disclose to each other any patient information including PHI provided to Travere Therapeutics for the purpose of investigating and resolving the patient's insurance coverage, coding, or reimbursement inquiry or to administer the Services, including entering and maintaining the patient's PHI in a database;
3. Contact me by mail, email, telephone, text or alternative communication to discuss and receive marketing communications, invitations to participate in research, educational materials, treatment support services and patient engagement initiatives designed for people taking CHOLBAM, including nutritional support and counseling;
4. Communicate with my healthcare providers and health plans about my benefit and coverage status and product administration (e.g., prescription, dosing, refills);
5. Disclose information to the patient's treating physician, healthcare professional, or pharmacist that I have provided to Travere Therapeutics as necessary to resolve patient insurance coverage, coding, or reimbursement inquiry. By signing below, I also authorize the insurer, treating physician, healthcare provider, and pharmacist to release PHI about the patient's prescribed medications and medical condition requested by Travere Therapeutics and the company or companies that help Travere Therapeutics and Mirum Pharmaceuticals administer the Services.
6. Contact the patient's insurer, other potential funding sources, social workers, patient advocacy organizations, or patient assistance programs (e.g., the CHOLBAM Total Care Hub) on the patient's behalf to determine if the patient may be eligible for health insurance coverage or other funds, and disclose to them PHI about the patient's prescribed medications and medical condition that has been provided by the patient or patient's authorized representative or physician, healthcare provider, or pharmacist; and
7. Disclose any PHI obtained from the sources listed above to third parties, if required by law, and to conduct surveys to evaluate the effectiveness of CHOLBAM Total Care Hub program.

Travere Therapeutics and Mirum Pharmaceuticals and Services administer agree to protect the patient's PHI by using and disclosing the patient's PHI only for the reasons listed above or as required by law

Patient's Signature	**Date**
Print Patient's Name	
Legally Authorized Representative's Signature (if needed)	
Print Legally Authorized Representative's Name	
Relationship to Patient ☐ **Spouse** ☐ **Legal Guardian** ☐ **Representative per Power of Attorney**	
Representative's Address	
Phone	**Mobile Phone**

Fax this form, along with both sides of the patient's Medical and Prescription Drug Benefit Cards to CHOLBAM Total Care Hub at (877) 473-3171

Retain a copy of this form in the patient's records.

Please see Important Safety Information on next page and accompanying full Prescribing Information.

CHOLBAM® (CHOLIC ACID) INDICATION & SAFETY INFORMATION

INDICATION

CHOLBAM® (cholic acid) is a bile acid indicated for

- Treatment of bile acid synthesis disorders due to single enzyme defects
- Adjunctive treatment of peroxisomal disorders, including Zellweger spectrum disorders, in patients who exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption.

LIMITATION OF USE

The safety and effectiveness of CHOLBAM on extrahepatic manifestations of bile acid synthesis disorders due to single enzyme defects or peroxisomal disorders, including Zellweger spectrum disorders, have not been established.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS – Exacerbation of liver impairment

- Monitor liver function and discontinue CHOLBAM in patients who develop worsening of liver function while on treatment.
- Concurrent elevations of serum gamma glutamyltransferase (GGT) and alanine aminotransferase (ALT) may indicate CHOLBAM overdose.
- Discontinue treatment with CHOLBAM at any time if there are clinical or laboratory indicators of worsening liver function or cholestasis.

ADVERSE REACTIONS

- The most common adverse reactions(≥1%) are diarrhea, reflux esophagitis, malaise, jaundice, skin lesion, nausea, abdominal pain, intestinal polyp, urinary tract infection, and peripheral neuropathy.

DRUG INTERACTIONS

- Inhibitors of Bile Acid Transporters: Avoid concomitant use of inhibitors of the bile salt efflux pump (BSEP) such as cyclosporine. Concomitant medications that inhibit canalicular membrane bile acid transporters such as the BSEP may exacerbate accumulation of conjugated bile salts in the liver and result in clinical symptoms. If concomitant use is deemed necessary, monitoring of serum transaminases and bilirubin is recommended.
- Bile Acid Binding Resins: Bile acid binding resins such as cholestyramine, colestipol, or colesevelam adsorb and reduce bile acid absorption and may reduce the efficacy of CHOLBAM. Take CHOLBAM at least 1 hour before or 4 to 6 hours (or at as great an interval as possible) after a bile acid binding resin.
- Aluminum-Based Antacids: Aluminum-based antacids have been shown to adsorb bile acids in vitro and can reduce the bioavailability of CHOLBAM. Take CHOLBAM at least 1 hour before or 4 to 6 hours (or at as great an interval as possible) after an aluminum-based antacid.

PREGNANCY

No studies in pregnant women or animal reproduction studies have been conducted with CHOLBAM.

LACTATION

Endogenous cholic acid is present in human milk. Clinical lactation studies have not been conducted to assess the presence of CHOLBAM in human milk, the effects of CHOLBAM on the breastfed infant, or the effects of CHOLBAM on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for CHOLBAM and any potential adverse effects on the breastfed infant from CHOLBAM or from the underlying maternal condition.

GERIATRIC USE

It is not known if elderly patients respond differently from younger patients.

HEPATIC IMPAIRMENT

- Discontinue treatment with CHOLBAM if liver function does not improve within 3 months of the start of treatment.
- Discontinue treatment with CHOLBAM at any time if there are clinical or laboratory indicators of worsening liver function or cholestasis. Continue to monitor laboratory parameters of liver function and consider restarting at a lower dose when the parameters return to baseline.

OVERDOSAGE

Concurrent elevations of serum GGT and serum ALT may indicate CHOLBAM overdose. In the event of overdose, the patient should be monitored and treated symptomatically. Continue to monitor laboratory parameters of liver function and consider restarting at a lower dose when the parameters return to baseline.

To report SUSPECTED ADVERSE REACTIONS, contact Mirum Pharmaceuticals at 1-855-MRM-4YOU or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. Please see accompanying full Prescribing Information.