Welcome to the Navigator Program

Start Form

Navigator Program™
Patient Support by Orphalan

A no-cost program created to provide access support to your patients throughout their entire treatment journey with CUVRIOR® (trientine tetrahydrochloride)

From start to finish, you can rely on your dedicated Care Coordinator to be there and help your patients

- Get started on therapy while you and the pharmacy work with their insurance plan to obtain ongoing coverage
- Understand their insurance coverage for CUVRIOR
- Understand the processes required by their insurance to access CUVRIOR (such as prior authorizations)
- Receive information related to co-pay and/or financial assistance programs that may be available

Get started

There are 2 ways to get started in the pursuit of CUVRIOR:

1. Submit a completed Start Form to enroll your patient in the Navigator Program. With this form, the patient will be automatically evaluated for program offerings that they may be eligible for.
2. Submit an eRX or provide a verbal Rx to PANTHERx. This option starts the Benefits Investigation process, but does not specifically enroll the patient in the program. If the patient wants to take advantage of offerings, additional outreach to the physician may be required in order to obtain the appropriate attestations.

Ready to enroll?

Have questions about the Navigator Program?
Patients may contact a Care Coordinator today to discuss how the Navigator Program can support you throughout your treatment journey: **1-877-995-ORPH (6774)**

Orphalan Innovation for Orphan Diseases

US-ORPH-CUVR-079 November 2023

Navigator Program Start Form

Navigator Program™
Patient Support by Orphalan

Submit Completed Start Form to Navigator Program **Phone #**: 1-877-995-ORPH (6774) **Fax #**: 1-866-716-ORPH (6774)

Step 1 Patient Information

First Name:	Middle Initial:	Last Name:
Date of Birth:		Sex: ◯ Male ◯ Female
Primary Address:		
City:	State:	ZIP:
Preferred Phone #:	(*Home or mobile*):	OK to Leave Message: ◯ Yes ◯ No
Alternate Phone #:	Primary Email:	
Caregiver Name:	Caregiver Phone #:	
Relationship to Patient:		

Step 2 Insurance Information *Please include front & back copies of all insurance cards (*medical & pharmacy*)*

PHARMACY BENEFIT INFORMATION:

Prescription Insurance Carrier: _____ PBM Phone #: _____
Member ID #: _____ RX Group ID #: _____
BIN #: _____ PCN #: _____
Policy Holder Name: _____ Relationship to Patient: _____

Secondary Prescription Carrier: _____ PBM Phone #: _____
Member ID #: _____ Group ID #: _____
BIN #: _____ PCN #: _____
Policy Holder Name: _____ Relationship to Patient: _____

MEDICAL INSURANCE INFORMATION:

Primary Medical Insurance: _____ Insurance Phone #: _____
Member ID #: _____ Group ID #: _____
Insurance Type:
◯ Commercial ◯ Medicare ◯ Medicaid ◯ TRICARE/DoD
Policy Holder Name: _____ Relationship to Patient: _____

Secondary Medical Insurance: _____ Insurance Phone #: _____
Member ID #: _____ Group ID #: _____
Insurance Type:
◯ Commercial ◯ Medicare ◯ Medicaid ◯ TRICARE/DoD

Step 3 Diagnosis and Clinical Information

ICD/Diagnostic Code(s): ◯ Wilson Disease (E83.01) ◯ Other Diagnosis: _____

Current Therapy for Wilson Disease:

Medication: _____ Dose: _____ Duration: _____

Medication: _____ Dose: _____ Duration: _____

Previous Therapies (*Check all that apply*):

◯ Cuprimine® ◯ D-Penamine® ◯ Depen Titratabs® ◯ Penicillamine (*generic*)

◯ Syprine® ◯ Trientine (*generic*) ◯ Galzin® ◯ Wilzin®

◯ OTC Zinc ◯ CUVRIOR ◯ Unknown ◯ Other: _____

Medication Allergies:

◯ Known Drug Allergies: _____ _____

◯ No Known Drug Allergies

Step 4 Prescription Information *Each prescription must be completed in its entirety for the prescription to be valid*

First Name: _____ Middle Initial: _____ Last Name: _____

Date of Birth: _____ Sex: ◯ Male ◯ Female

Quick Start Program: an optional program available to eligible patients at no cost (*See Terms of Participation on page 5*)

◯ Prescriber Attestations (*Required for participation in the Quick Start Program*): I confirm that the patient has been diagnosed with Wilson Disease, is age 18 or older, is not treatment naïve (patient has been de-coppered), and has not previously been treated with CUVRIOR.

◯ I understand my patient's eligibility and receipt of free product is not contingent on any purchase obligations from Orphalan, its agents or service providers. I also understand any products distributed under the Navigator Program are provided free of charge, and may not be submitted for reimbursement to any payor, including a federal healthcare program, and may not be sold, traded, distributed for sale or returned for credit; nor may I bill for administration of such product. I agree to assist in efforts to secure coverage for CUVRIOR for my patient.

Quick Start Prescription:

CUVRIOR® (trientine tetrahydrochloride) 300 mg Tablets

Dispense Quantity: _____ Days' Supply: **30-day supply** Refill(s): **1 refill** Directions for Use: _____

Ongoing Prescription:

CUVRIOR® (trientine tetrahydrochloride) 300 mg Tablets

Dispense Quantity: _____ Days' Supply: _____ Refills: _____

Directions for Use: _____

Step 5 Prescriber Information

Prescriber First Name: _____ Prescriber Last Name: _____

Prescriber Specialty: _____ NPI #: _____ Practice Name: _____

Street Address: _____ City: _____ State: _____ ZIP: _____

Prescriber Phone: _____ Prescriber Fax: _____

Office Contact Name: _____ Office Contact Title: _____

Office Contact Phone: _____ Office Contact Email: _____

Prescriber Authorization:

I certify that I am the prescriber mentioned above, therapy with CUVRIOR is medically necessary and appropriate for my patient, and the medical necessity information included on this Start Form and attestations (*as applicable*) are true, accurate, and complete. I further certify that I have prescribed CUVRIOR therapy for an FDA-approved indication and I will be supervising the patient's treatment accordingly. I certify that I have obtained the patient's written authorization to provide the information in this Start Form, and such other information as may be necessary to administer the Navigator Program, to Orphalan, its agents and service providers in accordance with all applicable federal and state laws. I authorize PANTHERx Rare, as the dedicated specialty pharmacy agent and on behalf of my patient, to (1) forward the above statement of medical necessity to the patient's insurance plan if permitted by the policies of that plan and (2) coordinate medication delivery with the patient. Finally, I certify that I am licensed to prescribe the product listed on this form and the prescription complies with my state-specific prescribing requirements. If I am practicing in a state with official prescription requirements, I will attach the actual prescription along with this form.

Prescriber Signature: _____ ◯ Dispense as Written ◯ Substitution Allowed Date: _____

(*Signature stamps are not acceptable*)

Please see Quick Start Program Terms of Participation on page 5.
Please see Important Safety Information on page 6 and full Prescribing Information on www.cuvrior.com.

Step 6 AUTHORIZATION FOR USE AND DISCLOSURE OF PERSONAL INFORMATION

I would like to enroll in the Navigator Program. By signing this Enrollment Form ("Authorization") I authorize Orphalan, Inc., and its affiliated companies, agents and service providers (collectively, "Orphalan") to provide me with support under the Navigator Program.

I authorize Orphalan, my health care providers, and their staff ("HCPs"), my health insurer(s), patient assistance organizations, and my pharmacy providers ("Authorized Parties") to use, process and share: (1) my personal health information (e.g., information about my diagnosis, treatment and medical condition), (2) information that identifies me (e.g., my name, address, phone number, date of birth), and (3) my insurance information (collectively my "Personal Information").

I understand this sharing of my Personal Information is necessary to enable the Authorized Parties to enroll me in the Navigator Program, provide Navigator Program services to me, operate the Navigator Program, conduct other business activities, and meet legal requirements. For example, Orphalan must use my Personal Information to communicate with me, investigate insurance matters, determine my eligibility for patient support services, and coordinate with my HCP about my enrollment. I understand that Orphalan may use "de-identified" data from the Navigator Program, meaning it may remove elements of my Personal Information that identify me, combine my data with other patients' information and use this "de-identified" data for business purposes such as analysis and reporting. I understand that once my Personal Information is shared, federal privacy laws may no longer protect it, and may not prevent re-disclosure by Orphalan or the Navigator Program. However, I understand Orphalan and the Navigator Program have agreed to use, process and disclose my Personal Information only for the purposes described in this Authorization. For more information about how Orphalan collects, uses, and protects my Personal Information, I can visit www.cuvrior.com to review the Privacy Policy.

I understand the Navigator Program is optional. If I choose not to sign this Authorization, I am still able to receive the medication that has been prescribed to me by my HCP. But not signing this Authorization will mean I cannot participate in the Navigator Program.

This Authorization expires five (5) years from the date of my signature below unless a shorter period is required by state law or I cancel my participation in the Navigator Program.

California Residents: I have the right to access my Personal Information, update my Personal Information if it is incorrect, or to request that Orphalan delete or limit the use of my Personal Information. I understand that deletion may not be possible or required under certain circumstances. To exercise the use of this right, I must send a written notice by mail to the address provided below.

I understand that I may revoke this authorization by sending a written notice to the Navigator Program at **Navigator Program, 24 Summit Park Dr., Pittsburgh, PA 15275** or faxing a written request to **1-866-716-6774**. I understand that if I revoke this Authorization, my revocation will not invalidate any uses or disclosures of my Personal Information made in reliance on this Authorization prior to the Navigator Program's receipt of this notice.

By signing below, I acknowledge that the Navigator Program provided by Orphalan will make payments to third-party providers for processing my Personal Information. I also understand that each patient support offering under the Navigator Program is subject to its own terms and conditions, and these terms and conditions may change over time. If I am eligible to receive one or more of the Navigator Program's patient support offering(s), I will be required to abide by all applicable terms and conditions; and I agree to do so. I acknowledge that my eligibility for each patient support offering under the Navigator Program depends on my insurance situation, and if my insurance information changes at any time, I will notify the Navigator Program as soon as possible.

By signing below, I certify that I have read and agree to the above.

Patient's Name (*Printed*): _____ Date: _____

Patient, or Personal Representative Signature: _____

Personal Representative's Description of Authority (*If applicable*): _____

◯ **Call and Text Opt-in (*Optional*):** By checking this box, I further authorize the Navigator Program to send text messages to the number(s) I provide.* I understand I may revoke my consent to receive automated calls or text messages by replying STOP to any text from the Navigator Program or by contacting the Navigator Program in writing at the address above.

◯ **Marketing Opt-in (*Optional*):** I authorize Orphalan to contact me by mail, email, fax, and/or telephone regarding other potential topics of interest to me, customer surveys, or occasionally for market research purposes. I understand that I am not required to provide this consent as a condition of receiving any Orphalan medicine or patient support services.

Patient Phone #: _____ Patient Email Address: _____

*I understand texts I receive may be subject to fees imposed by my telecommunications provider, and I will be responsible for paying these fees.

Step 7 QUICK START TERMS OF PARTICIPATION

The Quick Start Program (Quick Start) is available for insured patients who are U.S. residents, age 18 and older, new to CUVRIOR®, and experiencing a coverage delay that has lasted at least five days. Additional eligibility criteria may apply. Quick Start provides a 30-day supply of CUVRIOR® to eligible patients while they work with their health care provider (HCP) and insurer to obtain coverage. A one-month refill is available if coverage delays persist. Patients and HCPs have a responsibility to pursue coverage diligently. Patients may be asked to reverify their insurance coverage status during the course of their participation in Quick Start.

Quick Start is not insurance, nor is participation a guarantee that insurance coverage will be obtained successfully. Participation in Quick Start does not require the patient or prescriber to make any future purchases from Orphalan or PANTHERx. Free product received under Quick Start may not be submitted to any third-party payor for reimbursement, and may not be sold, traded or distributed to anyone other than the patient for whom it was intended. For Medicare Patients: Quick Start product is administered outside the Medicare benefit and should not be counted toward the patient's true out-of-pocket ("TrOOP") cost for any Part D enrollee.

Participation in Quick Start concludes at the earlier of successful coverage or exhaustion of permitted refills. Patients may not re-enroll. Orphalan may change or terminate Quick Start at any time without notice.

CUVRIOR® (trientine tetrahydrochloride) Tablets

INDICATION

CUVRIOR is a copper chelator indicated for the treatment of adult patients with stable Wilson Disease who are de-coppered and tolerant to penicillamine.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- CUVRIOR is contraindicated in patients with hypersensitivity to trientine or to any of the excipients in CUVRIOR.

WARNINGS AND PRECAUTIONS

- **Potential for Worsening of Clinical Symptoms at Initiation of Therapy**, including neurological deterioration, may occur at the beginning of CUVRIOR therapy due to mobilization of excess stores of copper. Adjust the dosage or discontinue therapy if clinical condition worsens. Evaluate serum non-ceruloplasmin copper (NCC) levels or 24-hour urinary copper excretion (UCE) when initiating treatment, after 3 months, and approximately every 6 months thereafter.
- **Copper Deficiency** may develop following treatment with CUVRIOR. Periodic monitoring is required.
- **Iron Deficiency** may develop following treatment with CUVRIOR. If iron deficiency develops, a short course of iron supplementation may be given.
- **Hypersensitivity Reactions**, characterized by rash, have been reported with the use of trientine. Rash was reported in 12% (3/26) of CUVRIOR-treated patients, and one patient discontinued treatment due to rash. If rash or other hypersensitivity reaction occurs, consider discontinuing CUVRIOR.

ADVERSE REACTIONS

The most common adverse reactions (>5%) are abdominal pain, change of bowel habits, rash, alopecia, and mood swings.

DRUG INTERACTIONS

- **Mineral Supplements (e.g. iron, zinc, calcium, magnesium)**: Avoid concomitant use. If concomitant use is unavoidable, take CUVRIOR at least 2 hours before or 2 hours after iron and take CUVRIOR at least 1 hour before or 2 hours after other mineral supplements.
- **Other Drugs for Oral Administration**: Take CUVRIOR at least 1 hour apart from any other oral drug.

Please see full Prescribing Information at www.cuvrior.com.

To report SUSPECTED ADVERSE REACTIONS, contact Orphalan at 1-800-961-8320 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.