

Patient Enrollment Form Guide

Initiate process to enroll patients prescribed PROCYSBI® (cysteamine bitartrate) delayed-release capsules and delayed-release oral granules in Horizon By Your Side



Fill out all required fields to ensure a thorough benefits investigation



Complete the prescriber signature and date within the Patient Enrollment Form. Make sure your patient or their legally authorized representative has completed, signed, and dated the Patient Authorization Form for Horizon By Your Side, a patient support program



Send copies of both sides of the patient's insurance card(s) and both completed forms to Horizon By Your Side

1 PATIENT INFORMATION

- **Fill out all patient information**, including the most recent results of a white blood cell cystine level test, recent history with Cystagon® (cysteamine bitartrate) capsules, and the use of a gastrostomy tube (G-tube)
 - Required fields are needed to **conduct a benefits investigation, to contact the patient for any follow-up, and to provide support from Horizon By Your Side**
- Please include caregiver's contact information

2 PRESCRIBER INFORMATION

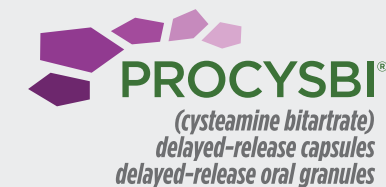
- **Fill out all prescriber information**, including prescriber name, contact information, and NPI number
 - Include the office contact name, phone number, and email address

3 INSURANCE INFORMATION

- **Provide the patient's primary insurance information**
 - Select the "No Insurance" box if the patient does not have any insurance
 - Include secondary insurance plan information, if applicable
- **Please include copies of both sides of your patient's insurance card(s), if available, along with the completed Patient Enrollment Form**
 - If not available, or if the patient is uninsured, you may attach the electronic medical record demographics page as an alternative to the image of the cards

Ensure that you submit **pages 1 and 2 of the Patient Enrollment Form**, along with copies of **both sides of the patient's insurance card(s)**. Retain a copy of this form in the patient's records.

NPI, National Provider Identifier.



**PROCYSBI® (CYSTEAMINE BITARTRATE)
DELAYED-RELEASE CAPSULES AND DELAYED-RELEASE
ORAL GRANULES PATIENT ENROLLMENT FORM**

Please fax completed form to 1-877-773-9411, or email it to PROHBYS@horizontherapeutics.com.

Phone: 1-855-888-4004
Fax: 1-877-773-9411
PROCYSBI.com

1. PATIENT INFORMATION

First Name Jane MI A Last Name Smith
 Address 123 Main Street City White Plains State NY Zip 10605
 Home Phone 100-001-0001 Mobile Phone 100-001-0002
 Date of Birth 01/01/2012 Gender M F Height 4'2" Weight 55lbs
 Email jane.smith@email.com Preferred Method of Contact Home Mobile Email Mail

Currently taking CYSTAGON® (cysteamine bitartrate)? Yes No Last CYSTAGON daily dose (mg/day) 1.30 grams/day
 Currently on dialysis? Yes No Does the patient have a G-tube (feeding tube)? Yes No
 White blood cell (WBC) test in the last year? Yes No (A bolus [straight] feeding tube 14 French or larger is recommended.)

ALTERNATIVE CONTACT AND/OR CAREGIVER
 First Name John Last Name Smith Home Phone 100-001-0001
 Mobile Phone 100-001-0002 Email john.smith@email.com Preferred Method of Contact Home Mobile Email

2. PRESCRIBER INFORMATION

Prescriber First Name Maria MI A Last Name Davis Prescriber NPI# 000000000
 Address 123 Medical Way City White Plains State NY Zip 10605
 Phone 100-001-0004 Fax 100-001-0005 Physician Specialty Nephrologist
 Office Contact Name Sam Wilson Email sam.wilson@email.com Phone 100-001-0006
 Preferred Method of Contact Email Phone

3. INSURANCE INFORMATION — Please attach a copy of both sides of the patient's insurance card(s). No Insurance

PRIMARY INSURANCE	SECONDARY INSURANCE (if any)
Insurance Carrier <u>Insurance Provider One</u>	Insurance Carrier <u>Insurance Provider Two</u>
Customer Service Phone <u>100-001-0007</u>	Customer Service Phone <u>100-001-0008</u>
Subscriber Name <u>John Smith</u>	Subscriber Name <u>John Smith</u>
Patient's Relationship to Subscriber <u>Child</u>	Patient's Relationship to Subscriber <u>Child</u>
Subscriber Date of Birth <u>02/02/1974</u>	Subscriber Date of Birth <u>02/02/1974</u>
Subscriber ID Number <u>000-000001-01</u>	Subscriber ID Number <u>000-000001-23</u>
Policy/Employer/Group Number <u>000001</u>	Policy/Employer/Group Number <u>000001</u>
Prescription Card? <input checked="" type="checkbox"/> Yes If Yes, Carrier: <u>Prescription Rx</u>	Phone <u>100-222-0000</u>

4. PRESCRIPTION AND CLINICAL INFORMATION

Diagnosis (ICD-10-CM Code) E72.04 Other _____

Drug Name: PROCYSBI Capsules: 25 mg _____ Quantity and/or 75 mg _____ Quantity
 Directions: _____ mg Prescribed Total Daily Dose _____
 _____ Days' Supply _____ Refills _____

Drug Name: PROCYSBI Granule Packets: 75 mg _____ Quantity and/or 300 mg 120 Quantity
 Directions: 1200 _____ mg Prescribed Total Daily Dose _____
30 Days' Supply 12 Refills _____

eg. Capsules: 600 mg q12h or 500 mg (6 x 75 mg capsules + 2 x 25 mg capsules) q12h. Packets: 600 mg q12h or 525 mg (1 x 300 mg packets + 3 x 75 mg packets) q12h.
 Dose Titration, see PROCYSBI Dosing Information for Healthcare Prescribers on page 3 for more information.
 Note: The prescriber is to comply with his/her state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc.

Is the patient allergic to penicillamine, cysteamine, or any other medication? If yes, please list: None

Prescriber Certification
 I certify that the above therapy is medically necessary, that the information provided is accurate to the best of my knowledge and that my patient is being administered PROCYSBI in accordance with the labeled use of the product. I understand that Horizon Therapeutics USA, Inc. and its affiliates and their respective employees or agents (collectively, "Horizon") will use this information to administer the Horizon By Your Side program (the "Program"), which provides a wide array of patient-focused services, including providing logistical and non-medical treatment support for PROCYSBI, as prescribed, and educating about the insurance process. By my signature, I also certify that (1) my patient or his/her personal representative has provided a signed HIPAA authorization that allows me to share protected health information with Horizon for purposes of the Program and (2) I have obtained the patient's authorization to release such information as may be required for Accredited Health Group, Inc. (or another party acting on behalf of Horizon) to assess insurance coverage for PROCYSBI and assistance in initiating or continuing PROCYSBI as prescribed. I further understand and agree that (a) any medication or service provided through the Program as a result of this form is for the named patient only and is not being made in exchange for any express or implied agreement or understanding that I would recommend, prescribe, or use PROCYSBI or any other Horizon product or service, for any other person; (b) my decision to prescribe PROCYSBI was based solely on my professional determination of medical necessity; and (c) I will not seek reimbursement for any medication or service provided by or through the Program from any government program or third-party insurer. I understand that Horizon may modify or terminate the Program at any time without notice. The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and healthcare provider. Horizon makes no representation or guarantee concerning coverage or reimbursement for any item or service. State requirements: The prescriber is to comply with his/her state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Noncompliance with state-specific requirements could result in outreach to the prescriber.
 By filling out and signing this form, the enrollment process in Horizon By Your Side has initiated; however, your patient must sign a Patient Authorization to complete enrollment in Horizon By Your Side. Please note that your patient will not benefit from the services and support offered by Horizon By Your Side unless your patient signs a Patient Authorization, consenting to receiving such services. If your patient does not sign the Patient Authorization contained within this form, Horizon will contact the patient to determine whether the patient is interested in signing a separate Patient Authorization.

Prescriber Signature Maria Davis Date 01/01/2022
Written signature only; stamps not acceptable. (Dispense as Written) (Substitution Permitted)

Please see complete IMPORTANT SAFETY INFORMATION on last page and [click here for the PROCYSBI Full Prescribing Information](#). P-PYB-US-00033 02/22

4 PRESCRIPTION AND CLINICAL INFORMATION

- **Provide diagnosis code**
 - If there is no box for the primary diagnosis, select "Other" and note the primary diagnosis code
- **Fill out all prescription information**
 - Reference the select PROCYSBI dosing instructions included in the Patient Enrollment Form or the [Full Prescribing Information](#) for complete dosing information
- **Review, sign, and date the prescriber certification.** In signing, you are indicating that PROCYSBI should be dispensed as written. If a substitution is allowed, it should be noted
 - Must be a written signature; stamps and digital signatures are not accepted



All prescription fields must be fully completed based on HCP's description. Incomplete prescriptions may result in delays at specialty pharmacies and require additional outreach for prescription clarification.

5 PATIENT CONSENT

- **The Patient Authorization is located on the second page of the Patient Enrollment Form**
 - A patient or patient's legally authorized representative signature **is required** for the team at Horizon By Your Side to provide nonmedical logistical support to the patient
- If the patient/legally authorized representative is not available to sign the form at your office, the Horizon By Your Side team can follow up to obtain HIPAA consent

Submit the Patient Enrollment Form using one of the methods below:



FAX to Horizon By Your Side
1-877-773-9411



EMAIL
HPSPRO@horizontherapeutics.com

HCP, healthcare provider; HIPAA, Health Insurance Portability and Accountability Act.

Please see Important Safety Information on page 3 and see accompanying [Full Prescribing Information](#) or visit PROCYSBIhcp.com.

Date: 01/01/2022

Patient's Printed Name: John Smith

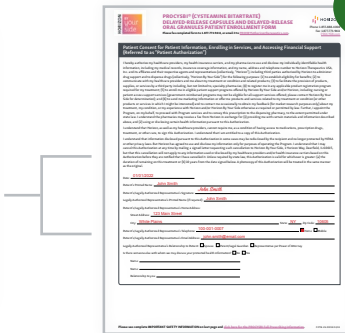
Patient's/Legally Authorized Representative's Signature: John Smith

Legally Authorized Representative's Printed Name (if required): John Smith

Patient's/Legally Authorized Representative's Home Address:
 Street Address: 123 Main Street
 City: White Plains State: NY Zip Code: 10605

Patient's/Legally Authorized Representative's Telephone: 100-001-0007 Home Mobile

Patient's/Legally Authorized Representative's Email Address: john.smith@email.com



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INDICATION and IMPORTANT SAFETY INFORMATION

INDICATION

PROCYSBI (cysteamine bitartrate) delayed-release capsules and delayed-release oral granules is a cystine-depleting agent indicated for the treatment of nephropathic cystinosis in adults and pediatric patients 1 year of age and older.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- Patients with serious hypersensitivity reaction, including anaphylaxis to penicillamine or cysteamine.

WARNINGS AND PRECAUTIONS

- **Ehlers-Danlos-like Syndrome:** Skin and bone lesions that resemble clinical findings for Ehlers-Danlos-like syndrome have been reported in patients treated with high doses of immediate-release cysteamine bitartrate or other cysteamine salts. Monitor patients for development of skin or bone lesions and reduce PROCYSBI dosing if patients develop these lesions.
- **Skin Rash:** Severe skin rashes such as erythema multiforme bullosa or toxic epidermal necrolysis have been reported in patients receiving immediate-release cysteamine bitartrate. Discontinue use if severe skin rash occurs.
- **Gastrointestinal (GI) Ulcers and Bleeding:** GI ulceration and bleeding have been reported in patients receiving immediate-release cysteamine bitartrate. Monitor for GI symptoms and consider decreasing the dose if severe symptoms occur.
- **Fibrosing Colonopathy:** Fibrosing colonopathy has been reported with postmarketing use of PROCYSBI. Evaluate patients with severe, persistent, and/or worsening abdominal symptoms for fibrosing colonopathy. If the diagnosis is confirmed, permanently discontinue PROCYSBI and switch to immediate-release cysteamine bitartrate capsules.
- **Central Nervous System (CNS) Symptoms:** CNS symptoms such as seizures, lethargy, somnolence, depression, and encephalopathy have been associated with immediate-release cysteamine. Monitor for CNS symptoms; interrupt or reduce the dose for severe symptoms or those that persist or progress.
- **Leukopenia and/or Elevated Alkaline Phosphatase Levels:** Cysteamine has been associated with reversible leukopenia and elevated alkaline phosphatase levels. Monitor white blood cell counts and alkaline phosphatase levels; decrease or discontinue the dose until values revert to normal.
- **Benign Intracranial Hypertension:** Benign intracranial hypertension (pseudotumor cerebri; PTC) and/or papilledema has been reported in patients receiving immediate-release cysteamine bitartrate treatment. Monitor for signs and symptoms of PTC; interrupt or reduce the dose for signs/symptoms that persist, or discontinue if diagnosis is confirmed.

ADVERSE REACTIONS

The most common adverse reactions reported in PROCYSBI clinical trials ($\geq 5\%$): were:

- *Patients 2 years of age and older previously treated with cysteamine:* vomiting, nausea, abdominal pain, headache, conjunctivitis, influenza, gastroenteritis, nasopharyngitis, dehydration, ear infection, upper respiratory tract infection, fatigue, arthralgia, cough, and pain in extremity.
- *Patients 1 year of age and older naïve to cysteamine treatment:* vomiting, gastroenteritis/viral gastroenteritis, diarrhea, breath odor, nausea, electrolyte imbalance, headache.

DRUG INTERACTIONS

- Drugs that increase gastric pH may alter the pharmacokinetics of cysteamine due to the premature release of cysteamine from PROCYSBI and increase WBC cystine concentration. Monitor WBC cystine concentration with concomitant use.
- Consumption of alcohol with PROCYSBI may increase the rate of cysteamine release and/or adversely alter the pharmacokinetic properties, as well as the effectiveness and safety of PROCYSBI.
- PROCYSBI can be administered with electrolyte (except bicarbonate) and mineral replacements necessary for management of Fanconi Syndrome as well as vitamin D and thyroid hormone.

USE IN SPECIFIC POPULATIONS

- **Lactation:** Because of the potential risk for serious adverse reactions in breastfed children from cysteamine, breastfeeding is not recommended during treatment with PROCYSBI.

Please see accompanying [Full Prescribing Information](#) or visit PROCYSBIhcp.com.



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