Patient Enrollment Form Guide

The Patient Enrollment Form (PEF) must be completely filled out in order to get your patients started on PROCYSBI® (cysteamine bitartrate) delayed-release capsules and delayed-release oral granule and initiate their enrollment in Amgen By Your Side, a patient support program. This guide is designed to help you understand the different fields on the form and how to complete the form accurately for submission.

Three easy steps to initiate the patient enrollment process for PROCYSBI:

Fill out all required fields on pages 1 and 2 as indicated by the asterisks, including the prescriber signature and date within the Prescriber section

Obtain the patient consent ("I Consent" check box), patient signature and date within the Patient Consent and Authorization section at the top of page 2, if possible

Send both the front and back of the patient's insurance card(s) along with all 4 pages of the PEF

Two ways to submit the Patient Enrollment Form:

- Email: PROCYSBIABYS@amgen.com
- Fax: 1-877-773-9411

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.

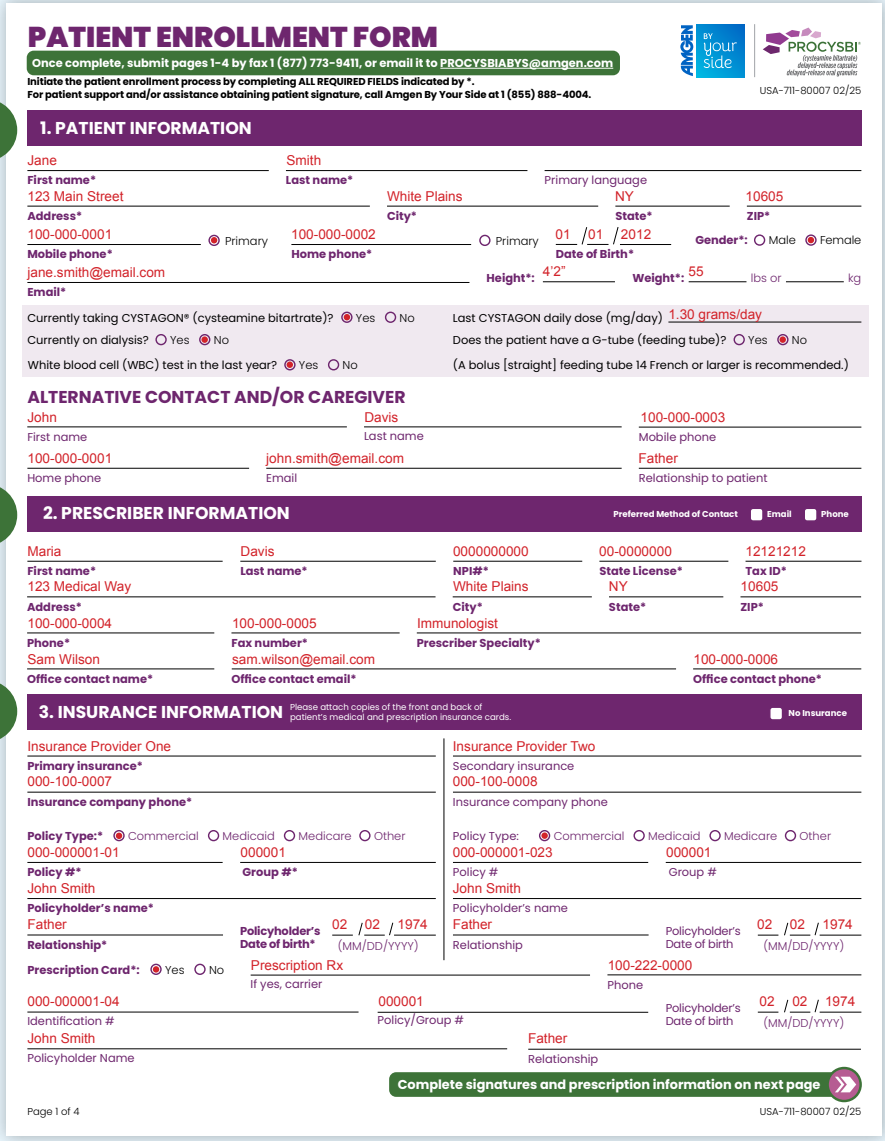
IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

Please see additional Important Safety Information throughout.

If you have any questions while completing the form, please contact Amgen By Your Side at 1-855-888-4004.



PATIENT ENROLLMENT FORM

Once complete, submit pages 1-4 by fax 1 (877) 773-9411, or email it to PROCYSBIABYS@amgen.com

Initiate the patient enrollment process by completing ALL REQUIRED FIELDS indicated by *.
For patient support and/or assistance obtaining patient signature, call Amgen By Your Side at 1 (855) 888-4004.

AMGEN BY your side | PROCYSBI (cysteamine bitartrate) delayed-release capsules, delayed-release oral granules

USA-711-80007 02/25

1. PATIENT INFORMATION

First name*: Jane | Last name*: Smith | Primary language:
Address*: 123 Main Street | City*: White Plains | State*: NY | ZIP*: 10605
Mobile phone*: 100-000-0001 (Primary) | Home phone*: 100-000-0002 (Primary) | Date of Birth*: 01/01/2012 | Gender*: (Male) (Female)
Email*: jane.smith@email.com | Height*: 4'2" | Weight*: 55 lbs or kg

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: Davis | Mobile phone: 100-000-0003
Home phone: 100-000-0001 | Email: john.smith@email.com | Relationship to patient: Father

2. PRESCRIBER INFORMATION

Preferred Method of Contact: (Email) (Phone)

First name*: Maria | Last name*: Davis | NPI#*: 0000000000 | State License*: 00-0000000 | Tax ID*: 12121212
Address*: 123 Medical Way | City*: White Plains | State*: NY | ZIP*: 10605
Phone*: 100-000-0004 | Fax number*: 100-000-0005 | Prescriber Specialty*: Immunologist
Office contact name*: Sam Wilson | Office contact email*: sam.wilson@email.com | Office contact phone*: 100-000-0006

3. INSURANCE INFORMATION

Please attach copies of the front and back of patient's medical and prescription insurance cards. (No Insurance)

Primary insurance*	Secondary insurance
Insurance Provider One	Insurance Provider Two
Insurance company phone*: 000-100-0007	Insurance company phone: 000-100-0008
Policy Type:* (Commercial) (Medicaid) (Medicare) (Other)	Policy Type: (Commercial) (Medicaid) (Medicare) (Other)
Policy #*: 000-000001-01	Policy #: 000-000001-023
Group #*: 000001	Group #: 000001
Policyholder's name*: John Smith	Policyholder's name: John Smith
Relationship*: Father	Relationship: Father
Policyholder's Date of birth*: 02/02/1974 (MM/DD/YYYY)	Policyholder's Date of birth: 02/02/1974 (MM/DD/YYYY)

Prescription Card*: (Yes) (No) | If yes, carrier: Prescription Rx | Phone: 100-222-0000
Identification #: 000-000001-04 | Policy/Group #: 000001 | Policyholder's Date of birth: 02/02/1974 (MM/DD/YYYY)
Policyholder Name: John Smith | Relationship: Father

Complete signatures and prescription information on next page

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1 Patient Information

Provide the patient's demographic and contact information; only one patient phone number required, mobile OR home

- Required fields are needed to conduct a benefits investigation, contact the patient for any follow-up, and provide support from Amgen By Your Side
- Alternate contact information is optional
  - It may help to include a caregiver's contact information
- Include 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)

2 Prescriber Information

Provide the prescriber's name, contact information, NPI, tax ID, and state license numbers, which are required for processing

3 Insurance Information

Provide the patient's primary insurance information (required to conduct a benefits investigation)

Include secondary insurance information, if applicable, to improve the accuracy of the benefits investigation

If the patient does not have any insurance, fill in the circle next to "Patient is uninsured to my knowledge"

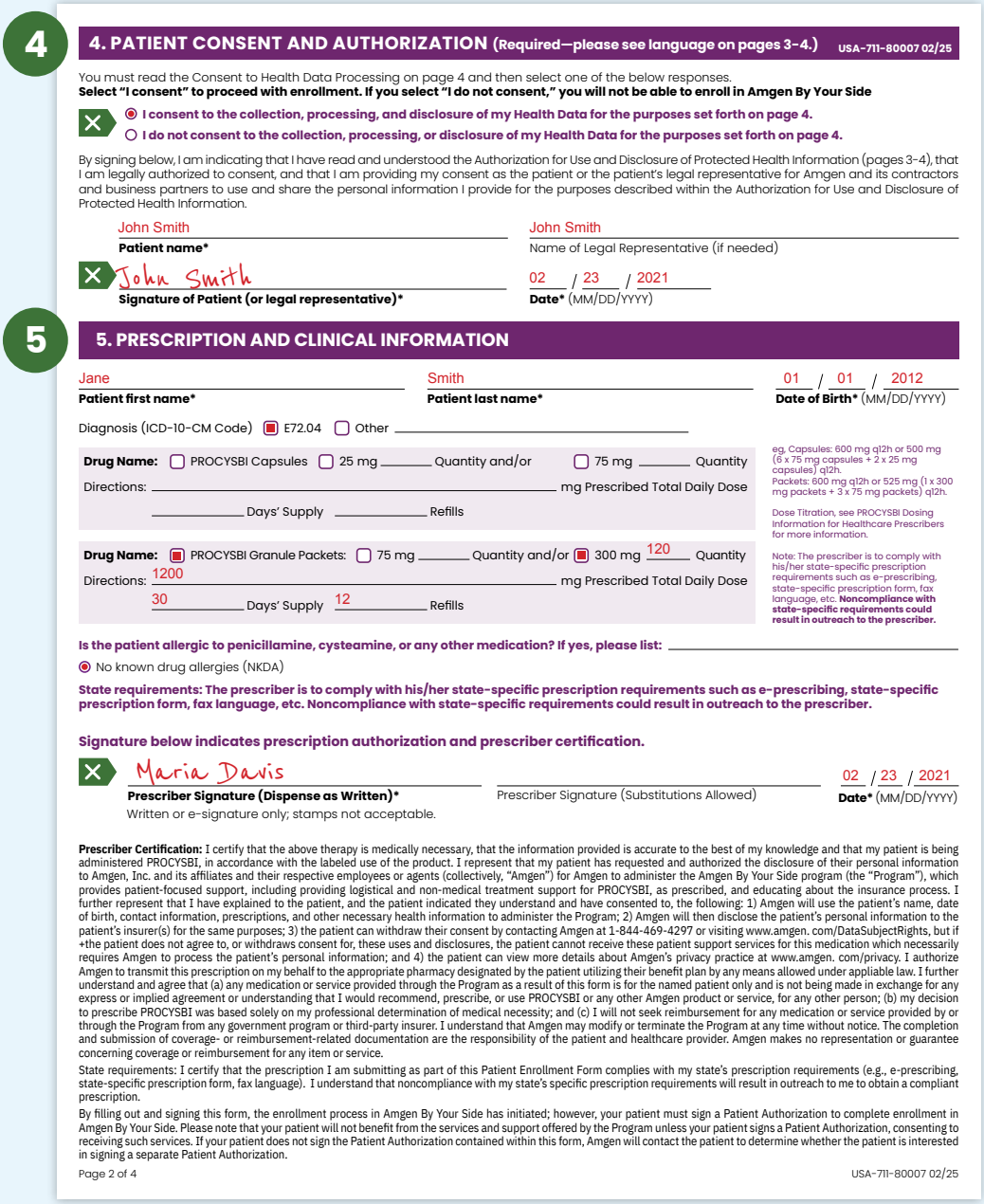
Please include the front and back of your patient's insurance card(s), if available, along with the completed Patient Enrollment Form

Disclaimer: The information provided on this form is for demonstration purposes only and does not represent any real person.

IMPORTANT SAFETY INFORMATION (CONT'D)
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.

Please see additional Important Safety Information throughout.



4. PATIENT CONSENT AND AUTHORIZATION (Required—please see language on pages 3-4.) USA-711-80007 02/25

You must read the Consent to Health Data Processing on page 4 and then select one of the below responses.
Select "I consent" to proceed with enrollment. If you select "I do not consent," you will not be able to enroll in Amgen By Your Side

- (●) **I consent to the collection, processing, and disclosure of my Health Data for the purposes set forth on page 4.**
- ( ) **I do not consent to the collection, processing, or disclosure of my Health Data for the purposes set forth on page 4.**

By signing below, I am indicating that I have read and understood the Authorization for Use and Disclosure of Protected Health Information (pages 3-4), that I am legally authorized to consent, and that I am providing my consent as the patient or the patient's legal representative for Amgen and its contractors and business partners to use and share the personal information I provide for the purposes described within the Authorization for Use and Disclosure of Protected Health Information.

John Smith — **Patient name***

John Smith — Name of Legal Representative (if needed)

John Smith — **Signature of Patient (or legal representative)***

02 / 23 / 2021 — **Date*** (MM/DD/YYYY)

5. PRESCRIPTION AND CLINICAL INFORMATION

Jane — **Patient first name***

Smith — **Patient last name***

01 / 01 / 2012 — **Date of Birth*** (MM/DD/YYYY)

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

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 for more information.

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

Note: 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.**

Is the patient allergic to penicillamine, cysteamine, or any other medication? If yes, please list: _____

(●) No known drug allergies (NKDA)

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.

Signature below indicates prescription authorization and prescriber certification.

Maria Davis — **Prescriber Signature (Dispense as Written)***
Written or e-signature only; stamps not acceptable.

Prescriber Signature (Substitutions Allowed)

02 / 23 / 2021 — **Date*** (MM/DD/YYYY)

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 represent that my patient has requested and authorized the disclosure of their personal information to Amgen, Inc. and its affiliates and their respective employees or agents (collectively, "Amgen") for Amgen to administer the Amgen By Your Side program (the "Program"), which provides patient-focused support, including providing logistical and non-medical treatment support for PROCYSBI, as prescribed, and educating about the insurance process. I further represent that I have explained to the patient, and the patient indicated they understand and have consented to, the following: 1) Amgen will use the patient's name, date of birth, contact information, prescriptions, and other necessary health information to administer the Program; 2) Amgen will then disclose the patient's personal information to the patient's insurer(s) for the same purposes; 3) the patient can withdraw their consent by contacting Amgen at 1-844-469-4297 or visiting www.amgen. com/DataSubjectRights, but if +the patient does not agree to, or withdraws consent for, these uses and disclosures, the patient cannot receive these patient support services for this medication which necessarily requires Amgen to process the patient's personal information; and 4) the patient can view more details about Amgen's privacy practice at www.amgen. com/privacy. I authorize Amgen to transmit this prescription on my behalf to the appropriate pharmacy designated by the patient utilizing their benefit plan by any means allowed under appliable law. 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 Amgen 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 Amgen 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. Amgen makes no representation or guarantee concerning coverage or reimbursement for any item or service.

State requirements: I certify that the prescription I am submitting as part of this Patient Enrollment Form complies with my state's prescription requirements (e.g., e-prescribing, state-specific prescription form, fax language). I understand that noncompliance with my state's specific prescription requirements will result in outreach to me to obtain a compliant prescription.

By filling out and signing this form, the enrollment process in Amgen By Your Side has initiated; however, your patient must sign a Patient Authorization to complete enrollment in Amgen By Your Side. Please note that your patient will not benefit from the services and support offered by the Program 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, Amgen will contact the patient to determine whether the patient is interested in signing a separate Patient Authorization.

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4 Patient Consent and Authorization

- Patient must sign and date form
- Patient must check "I consent" circle in order to be enrolled in Amgen By Your Side
- If the patient can't sign the form at your office, Amgen By Your Side can follow up to obtain consent

5 Prescription, Clinical Information and Prescriber Signature

Complete in full the prescription and clinical information section

- Include patient name and date of birth within prescription section along with prescription information
- Provide diagnosis code
  - -If there is no box for the primary diagnosis, select "Other" and note the primary diagnosis code
- Prescriber signature is required for processing the Patient Enrollment Form
  - Must be a written signature; stamps and digital signatures are not accepted

**Pages 3-4 of the PEF include the patient authorization and consent language.
Once the PEF is submitted, you can provide these 2 pages to the patient for their reference.**

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS

- 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.

Please see additional Important Safety Information throughout.

Connecting Patients with their Amgen By Your Side PAL

The Patient Access Liaison (PAL) is a dedicated support partner who helps investigate, explain, and educate on the steps in your patient's treatment experience. They are your patient's point of contact and champion while your patient is accomplishing their treatment goals.

- ☐ Make sure the patient is aware their PAL will be calling them in the next few days to provide information on next steps and getting started on PROCYSBI
- ☐ Have the patient save their PAL's contact in their phone
  - **It is important that a patient answers the PAL's call**

PAL Name: _____ **Phone Number:** _____

Please ensure that all four pages of the enrollment forms are submitted by fax to 1-877-773-9411 or emailed to PROCYSBIABYS@amgen.com. Incomplete forms may delay enrollment.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS

- 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 (≥ 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 Full Prescribing Information.

AMGEN Rare Disease

PROCYSBI® (cysteamine bitartrate) delayed-release capsules delayed-release oral granules