



Amgen By Your Side

is a support program for patients prescribed **PROCYSBI®** (cysteamine bitartrate)

Our dedicated team is your patient's partner, committed to providing nonmedical support to help patients as they start and continue on treatment as you prescribe.



Patient Support



Financial Assistance



Insurance Benefits Investigation



Initiate your patient's enrollment in Amgen By Your Side by submitting the Patient Enrollment Form.

OPTIONS AVAILABLE AT:



amgenbyside.com/procysbi/hcp



Our mission is to connect, coordinate, and champion your patient at the most important steps along the way:



Connect

Your patient will be connected to one person dedicated to partnering with them throughout their treatment experience



Coordinate

Your patient will receive educational support on insurance, financial assistance options, important appointment-related information, and more



Champion

Your patient's dedicated partner will empower them to be confident self-advocates for maintaining treatment goals

When you are ready to prescribe:

Simplify access to treatment for your patients

The Amgen By Your Side team is here to assist your patients every step of the way

Amgen By Your Side offers a wide range of patient-focused services:



Patient Support

- Provide dedicated, one-on-one support for your patients
- Work directly with individual patients to answer nonmedical, logistical questions and provide support upon enrollment



Insurance Benefits Investigation

- Provide education to you and your staff about product coding and billing
- Educate you and your staff about insurance processes, including specific payor requirements and examples



Financial Assistance

- Educate patients on the results of their benefits investigation and review their insurance coverage
- Help patients understand potential out-of-pocket costs and financial assistance options

Meet the Amgen By Your Side team

Initiate your patient's enrollment in Amgen By Your Side by submitting the Patient Enrollment Form at amgenbyyourside.com/procysbi/hcp. Your patient must complete enrollment to access our patient-focused services and resources.



Patient Access Liaison (PAL)

The PAL provides dedicated, one-on-one support for your patient.

- They work directly with individual patients to answer nonmedical, logistical questions and provide support upon enrollment
- Additionally, the PAL educates about navigating insurance processes and accessing treatment on your patient's behalf
- The PAL has the expertise and tools to support the patient by educating on patient benefits, prior authorization requirements, payor policies, and coding and claim submissions



Case Manager

Case Managers work on behalf of the patient and interact with the doctor's office to ensure insurance information is accurate and to inform the office on insurance criteria for the submission of a prior authorization. These comprehensive services are free of charge to your patient.

In addition, a Case Manager:

- May reach out to the doctor's office after a prescriber initiates enrollment and inquire about missing information on the enrollment form
- Has the expertise and knowledge to educate the doctor's office on payor policies and insurance criteria for access to Amgen products

The team at Amgen By Your Side is available by phone at 1-855-888-4004

We believe patients should pay the lowest amount possible

Patients with commercial insurance may be eligible for a \$0 co-pay for medication through our Amgen Commercial Co-Pay Program.*



PALS can speak with patients prescribed PROCYSBI about the insurance approval process and help them understand coverage options

*The Amgen Commercial Co-Pay Program may be available to patients who meet the following minimum criteria:

- Patient's prescription cannot be paid in part or in full by any government-funded program including but not limited to: Medicare, Medicare Part D, Medicaid, Medigap, VA, CHAMPUS, Department of Defense (DOD), TRICARE, or any state, patient foundation, or other pharmaceutical program.
- Patient is prescribed a covered Amgen rare disease medication for an indication approved by the Food and Drug Administration; the indication for each product is shown in its prescribing information.
- Patient is a resident of the United States.
- Patient must be commercially insured and have financial responsibility for a portion of the drug and/or infusion cost if applicable.

The assistance offered under this co-pay program is subject to additional terms and conditions, including but not limited to the following:

Terms and Conditions: Offer cannot be combined with any other rebate or coupon, free trial, or similar offer for the specified prescription. Not valid for prescriptions reimbursed in whole or in part by any government-funded program including but not limited to: Medicare, Medicare Part D, Medicaid, Medigap, VA, CHAMPUS, DOD, TRICARE, or any state, patient foundation, or other pharmaceutical program. Offer good only in the United States at participating specialty pharmacies or sites of care. Offer not valid where otherwise prohibited by law, for example by applicable state law prohibiting co-pay cards. Amgen reserves the right to rescind, revoke, or amend offer without notice. The selling, purchasing, trading, or counterfeiting of any co-pay card or benefits is prohibited by law. This co-pay program is not insurance and is not intended to substitute for insurance.

Participating Pharmacies or Healthcare Providers: By using this co-pay program, you acknowledge and confirm that the prescription will not be reimbursed in whole or in part by any government-funded program (such as, without limitation, Medicare, Medicaid, VA, DOD, TRICARE) and the patient and prescription meet the eligibility criteria set forth in the terms and conditions. You are responsible for reporting the receipt of the co-pay program benefits as required by an insurer, payor, or applicable law or regulation.

Patients: By enrolling in this co-pay program, you acknowledge and confirm that you and the prescription meet the eligibility requirements set forth in the terms and conditions, including that the prescription will not be reimbursed in whole or in part by any government-funded program (such as, without limitation, Medicare, Medicaid, VA, DOD, TRICARE). You may not seek any claims to government payors or other payors or insurers for this prescription. You may not seek reimbursement from any health savings, flexible savings, or other healthcare reimbursement account for any amounts received from the co-pay program. You are responsible for reporting the receipt of the co-pay program benefits as required by an insurer, payor, or applicable law or regulation.



Simplify access to PROCYSBI for your patients with Amgen By Your Side

Initiate your patient's enrollment in Amgen By Your Side by submitting the Patient Enrollment Form.

Options available at: amgenbyside.com/procysbi/hcp



Questions?

Contact the Amgen By Your Side team

Phone:

1-855-888-4004



Please see Indications and Important Safety Information on page 8 and [Full Prescribing 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 [Full Prescribing Information](#).