

# Patient Enrollment Form Guide

The Patient Enrollment Form (PEF) must be completely filled out in order to get your patients started on KRYSTEXXA 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 KRYSTEXXA:



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

### Three ways to submit the Patient Enrollment Form:

- DocuSign®: [goutenroll.com/hcp](https://goutenroll.com/hcp)
- Email: [GoutABYS@amgen.com](mailto:GoutABYS@amgen.com)
- Fax: 1-877-633-9522

## INDICATION

KRYSTEXXA® (pegloticase) is indicated for the treatment of chronic gout in adult patients who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors at the maximum medically appropriate dose or for whom these drugs are contraindicated.

Limitations of Use: KRYSTEXXA is not recommended for the treatment of asymptomatic hyperuricemia.

## IMPORTANT SAFETY INFORMATION

### WARNING: ANAPHYLAXIS AND INFUSION REACTIONS, G6PD DEFICIENCY ASSOCIATED HEMOLYSIS AND METHEMOGLOBINEMIA

- **Anaphylaxis and infusion reactions have been reported to occur during and after administration of KRYSTEXXA.**
- **Anaphylaxis may occur with any infusion, including a first infusion, and generally manifests within 2 hours of the infusion. Delayed hypersensitivity reactions have also been reported.**
- **KRYSTEXXA should be administered in healthcare settings and by healthcare providers prepared to manage anaphylaxis and infusion reactions.**
- **Premedicate with antihistamines and corticosteroids and closely monitor for anaphylaxis for an appropriate period after administration of KRYSTEXXA.**
- **Monitor serum uric acid levels prior to each infusion and discontinue treatment if levels increase to above 6 mg/dL, particularly when 2 consecutive levels above 6 mg/dL are observed.**
- **Screen patients at risk for glucose-6-phosphate dehydrogenase (G6PD) deficiency prior to starting KRYSTEXXA. Hemolysis and methemoglobinemia have been reported with KRYSTEXXA in patients with G6PD deficiency. KRYSTEXXA is contraindicated in patients with G6PD deficiency.**

**If you have any questions while completing the form, please contact Amgen By Your Side at 1-877-633-9521.**

**Please see Important Safety Information on last page and [Full Prescribing Information](#), including Boxed Warning.**

## PATIENT ENROLLMENT FORM

Once complete, submit pages 1-4 by fax 1-877-633-9522 or email [GoutLABYS@amgen.com](mailto:GoutLABYS@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 1-877-633-9521.

**1 PATIENT INFORMATION**

Stephen Patient  
 First name\* Last name\*  
 Gender:  Male  Female  
 Date of birth\*: 05 / 16 / 1957 (MM/DD/YYYY)  
 Email address\*: stephenpatient@email.com Primary language: English  
 555-123-1234 Primary Home phone\*: 555-321-4321 Primary  
 Mobile phone\*  
 123 Main Street Address\*  
 Lake Forest IL 60045  
 City\* State\* Zip code\*  
 Jane Spouse 555-234-5678  
 Alternate contact name Alternate contact phone

**2 DIAGNOSIS**  
 Required for benefits investigation  
 Primary diagnosis code\*: MIA\_00X1 — Chronic gout  
 See full list of codes at [ChronicGoutCodes.com](http://ChronicGoutCodes.com).  
 Additional disease manifestation codes: N/A  
 Medications tried/previous therapy\*: N/A

**3 CO-ADMINISTRATION MEDICATION**  
 Is there an immunomodulator prescribed?  Yes  No  
 If yes, please indicate:  methotrexate  Other

**4 INSURANCE INFORMATION**  
 Please include front and back copies of insurance card[s] with this form

Insurance provider 1 Insurance provider 2  
 Primary insurance\* Secondary insurance  
 1234567 9876543  
 Policy #\* Policy #\*  
 Stephen Patient Jane Spouse  
 Policyholder's first and last name\* Policyholder's first and last name\*  
 800-123-4567 888-123-4567  
 Insurance company phone\* Insurance company phone  
 000001 000002  
 Group #\* Group #\*  
 Policyholder's 05 / 16 / 1957 Policyholder's 01 / 01 / 1960  
 Date of birth\*: (MM/DD/YYYY) Date of birth\*: (MM/DD/YYYY)  
 Sunshine Healthcare Healthcare for You  
 IPA/Medical group name IPA/Medical group name  
 Reverification request  Patient is uninsured to my knowledge.

**5 PRESCRIBER INFORMATION**

John Prescriber  
 First name\* Last name\*  
 123 Medical Way  
 Address\*  
 Deerfield IL 60016  
 City\* State\* Zip code\*  
 000000000 00-0000000 12121212  
 NPI #\* State license #\* Tax ID #\*  
 Memorial Hospital  
 Clinic/hospital affiliation  
 Jenny Assistant 555-123-0987  
 Office contact name\* Office contact phone\*  
 johnprescriber@email.com 555-123-4567  
 Email address\* Fax number\*  
 Prescriber specialty\*: Rheumatologist  
 Preferred communication:  Phone  Email

**6 CO-MANAGING/REFERRING HCP**  
 Complete if patient was sent to you by another healthcare provider. They will be part of the patient's care team.

James Smith  
 First name Last name  
 Primary Care 555-876-4321  
 Specialty Phone  
 123 Medical Way  
 Address  
 Deerfield IL 60015  
 City State Zip code

**7 PREFERRED INFUSION FACILITY**  
 If none, Amgen By Your Side can provide options.  
 The infusion facility is the same as the prescribing office  
 Infusion Center 123 Facility Drive  
 Facility name Address  
 Chicago IL 60601  
 City State Zip code  
 555-123-1111 555-123-1112  
 Phone Fax number  
 0000000009 00-0000000807  
 Facility NPI # Tax ID #

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

### 2 Diagnosis

Confirm the diagnosis code (required to conduct a benefits investigation)

- Add additional disease manifestation codes, if applicable

### 3 Co-Administration Medication

Confirm if an immunomodulator was prescribed and, if so, indicate methotrexate or other

### 4 Insurance Information

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

(Continued)

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

If the patient does not have any insurance check the "Patient is uninsured to my knowledge" box

### 5 Prescriber Information

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

### 6 Co-Managing/Referring HCP

Complete the referring healthcare provider section if there is another HCP involved in the patient's treatment- Fill in the name of the HCP as well as their specialty and address

### 7 Preferred Infusion Facility

If you have a preference for the infusion facility where your patient will receive KRYSTEXXA, complete this section.

- If you are infusing in the office of the prescriber, check the box in this section
- If you do not have a preference, Amgen By Your Side will provide options based on the patient's insurance and proximity to the patient

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

**Please see Important Safety Information on last page and Full Prescribing Information, including Boxed Warning.**

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**PATIENT CONSENT AND AUTHORIZATION (Required - please see language on pages 3-4.)**

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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.

Stephen Patient

Patient name\*

Name of Legal Representative (if needed)



Stephen Patient

Signature of Patient (or Legal Representative)\*

01 / 07 / 2025

Date\* (MM/DD/YYYY)

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**PRESCRIPTION (Required)**

Stephen

Patient first name\*

Patient

Patient last name\*

05 / 16 / 1957

Date of Birth\* (MM/DD/YYYY)

Dose: KRYSTEXXA\* (pegloticase) injection, 8 mg/mL, for intravenous infusion every two weeks

Vial quantity\*: 2 Refills\*: 6 Allergies\*: Sulfa or  No known drug allergies (NKDA)

Authorize administration supplies as needed

**Contraindications:**

- Patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency
- Patients with a history of serious hypersensitivity reactions, including anaphylaxis, to KRYSTEXXA or any of its components

**Administration:** The KRYSTEXXA admixture should only be administered by intravenous infusion over no less than 120 minutes via gravity feed, syringe-type pump, or infusion pump. Do not administer as an intravenous push or bolus. Please refer to the KRYSTEXXA Full Prescribing Information on preinfusion medications and how to reconstitute and dilute KRYSTEXXA for intravenous (IV) infusion.

**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.



John Prescriber

Prescriber signature (Dispense as written)\*

Written or e-signature only; stamps not acceptable.

Prescriber signature (substitutions allowed)

01 / 07 / 2025

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 KRYSTEXXA (pegloticase), for injection, 8mg/mL, for intravenous infusion 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 KRYSTEXXA, 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](http://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](http://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 applicable 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 KRYSTEXXA or any other Amgen product or service, for any other person; (b) my decision to prescribe KRYSTEXXA 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. On behalf of the patient, Amgen expects the prescriber to coordinate with Amgen By Your Side to provide, to the best of the prescriber's ability, in-network infusion services and work with Amgen By Your Side to effectively communicate both in-network and out-of-network choices and the corresponding financial obligations of the patient connected to each choice. Should the prescriber knowingly perform out-of-network services without the knowledge and consent of the patient, the prescriber cannot balance bill the patient for the out-of-network services.

**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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**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

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**Prescription and Prescriber Signature**

Complete the prescription section

- Include patient name and date of birth within prescription section along with prescription information
- Prescriber signature is required for processing the Patient Enrollment Form

**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.**

## 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, the infusion process, and getting started on KRYSTEXXA
- 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 1-877-633-9522 or emailed to [GoutABYS@amgen.com](mailto:GoutABYS@amgen.com). Incomplete forms may delay enrollment.**

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### CONTRAINDICATIONS:

- In patients with G6PD deficiency.
- In patients with history of serious hypersensitivity reactions, including anaphylaxis, to KRYSTEXXA or any of its components.

### WARNINGS AND PRECAUTIONS

**Gout Flares:** An increase in gout flares is frequently observed upon initiation of anti-hyperuricemic therapy, including KRYSTEXXA. Gout flare prophylaxis with a non-steroidal anti-inflammatory drug (NSAID) or colchicine is recommended starting at least 1 week before initiation of KRYSTEXXA therapy and lasting at least 6 months, unless medically contraindicated or not tolerated.

**Congestive Heart Failure:** KRYSTEXXA has not been formally studied in patients with congestive heart failure, but some patients in the pre-marketing placebo-controlled clinical trials experienced exacerbation. Exercise caution in patients who have congestive heart failure and monitor patients closely following infusion.

### ADVERSE REACTIONS

The most commonly reported adverse reactions ( $\geq 5\%$ ) are:

#### **KRYSTEXXA co-administration with methotrexate trial:**

KRYSTEXXA with methotrexate: gout flares, arthralgia, COVID-19, nausea, and fatigue; KRYSTEXXA alone: gout flares, arthralgia, COVID-19, nausea, fatigue, infusion reaction, pain in extremity, hypertension, and vomiting.

#### **KRYSTEXXA pre-marketing placebo-controlled trials:**

gout flares, infusion reactions, nausea, contusion or ecchymosis, nasopharyngitis, constipation, chest pain, anaphylaxis, and vomiting.

**Please see [Full Prescribing Information](#), including Boxed Warning.**