

# KRYSTEXXA (pegloticase) Ready-to-Use (RTU) Vial PATIENT ENROLLMENT FORM



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

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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.

## PATIENT INFORMATION

First name\* Last name\*  
Gender: Male Female Date of birth\*: \_\_\_/\_\_\_/\_\_\_  
(MM/DD/YYYY)  
Email address\* Primary language  
Primary Home phone\* Primary  
Mobile phone\* Home phone\*  
Address\*  
City\* State\* Zip code\*  
Alternate contact name Alternate contact phone

## DIAGNOSIS

Required for benefits investigation

Primary diagnosis code\*: MIA. \_\_\_\_\_ – Chronic gout  
See full list of codes at [ChronicGoutCodes.com](http://ChronicGoutCodes.com).  
Additional disease manifestation codes: \_\_\_\_\_  
Medications tried/previous therapy\*: \_\_\_\_\_

## CO-ADMINISTRATION MEDICATION

Is there an immunomodulator prescribed?  Yes  No  
If yes, please indicate: methotrexate Other

## INSURANCE INFORMATION

Please include front and back copies of insurance card[s] with this form

Primary insurance\* Secondary insurance  
Policy #\* Policy #  
Policyholder's first and last name\* Policyholder's first and last name  
Insurance company phone\* Insurance company phone  
Group #\* Group #  
Policyholder's Date of birth\*: \_\_\_/\_\_\_/\_\_\_ (MM/DD/YYYY) Policyholder's Date of birth: \_\_\_/\_\_\_/\_\_\_ (MM/DD/YYYY)  
IPA/Medical group name IPA/Medical group name  
Reverification request Patient is uninsured to my knowledge.

## PRESCRIBER INFORMATION

First name\* Last name\*  
Address\*  
City\* State\* Zip code\*  
NPI #\* State license #\* Tax ID #\*  
Clinic/hospital affiliation  
Office contact name\* Office contact phone\*  
Email address\* Fax number\*  
Prescriber specialty\*: \_\_\_\_\_  
Preferred communication: Phone Email

## 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.

First name Last name  
Specialty Phone  
Address  
City State Zip code

## PREFERRED INFUSION FACILITY

If none, Amgen By Your Side can provide options.

The infusion facility is the same as the prescribing office  
Facility name Address  
City State Zip code  
Phone Fax number  
Facility NPI # Tax ID #

Complete signatures and prescription information on next page

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.

\_\_\_\_\_  
Patient name\*

\_\_\_\_\_  
Name of Legal Representative (if needed)



\_\_\_\_\_  
Signature of Patient (or Legal Representative)\*

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Date\* (MM/DD/YYYY)\*

**PRESCRIPTION (Required)**

\_\_\_\_\_  
Patient first name\*

\_\_\_\_\_  
Patient last name\*

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

Dose: KRYSTEXXA® (pegloticase) injection, 8 mg/50 mL, for intravenous infusion every two weeks for no less than 120 minutes

Vial quantity\*: \_\_\_\_\_ Refills\*: \_\_\_\_\_ Allergies\*: \_\_\_\_\_ 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:** Do not administer KRYSTEXXA as an intravenous push or bolus. KRYSTEXXA should only be administered by intravenous infusion. An infusion pump may be used for the Ready-to-Use vial.

**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.**



\_\_\_\_\_  
Prescriber signature (Dispense as written)\*

\_\_\_\_\_  
Prescriber signature (substitutions allowed)

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Date\* (MM/DD/YYYY)

Written or e-signature only; stamps not acceptable.

**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/50 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, 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 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.

## Uses and Disclosure of Protected Health Information

I authorize Amgen and its data processors (collectively, “Amgen”) to collect, use, and disclose my protected health information for the following purposes:

- To operate, administer, enroll me in, and/or continue my participation in the Amgen By Your Side program or any other Amgen-affiliated patient support services and activities related to my condition or treatment (for example, co-pay card programs, reimbursement assistance programs, drug coverage verification, patient access liaison services, adherence program and disease management support);
- To contact, with my permission, my doctor and the rest of my health care team and share with them my health information that may be useful for my care;
- To improve, develop, and evaluate Amgen’s products, services, materials and programs related to my condition or treatment.

In order for Amgen to provide me with the services and/or programs described above, Amgen needs to collect and use my personal information, including my protected health information. I understand that my protected health information may include any information, in electronic or physical form, in the possession of or derived from a health care provider, health care plan, pharmacy, pharmaceutical company, laboratory and/or their contractor (each, a “Health Care Provider”). This may include select information from or about my medical history and general health, my health care plan benefits, payment limits or restrictions covered by my health care plan policy, and/or my adherence to my treatment.

I authorize my Health Care Providers to disclose my protected health information to Amgen, and between themselves, as necessary, but only for the purposes stated above in this Authorization. I understand that certain of my Health Care Providers (such as pharmacies and specialty pharmacies) may receive remuneration from Amgen in exchange for disclosing my protected health information and/or for using my information to contact me with communications about Amgen products which have been prescribed to me (for example, medication reminder programs and other patient support services).

## Expiration, Right to Obtain a Copy, and Right to Cancel

I understand that by signing this form, I authorize my Health Care Providers or others who might hold my health information to disclose it to Amgen. I also understand I am authorizing my personal information, including my protected health information, to be used for the purposes described above. I understand and agree that by signing below, I am authorizing those who rely on this Authorization to disclose my protected health information for the earlier of five (5) years or until my participation in the Amgen By Your Side program ends through my cancellation, unless a shorter time period is required by state law.

I understand that I can obtain a copy of this Authorization or cancel this Authorization at any time by calling Amgen at 1-844-469-4297 or by writing to Amgen By Your Side, 1 Horizon Way, Deerfield, IL 60015. If I cancel this Authorization, I will no longer qualify for the services described. I also understand that if a Health Care Provider is disclosing my protected health information to Amgen in reliance on this Authorization on an on-going basis, my cancellation with Amgen will be effective with respect to any such Health Care Providers as soon as they receive notice of my cancellation.

## AUTHORIZATION FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION, CONTINUED

Please read and provide signature in Patient Consent and Authorization section on page 2

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### No Effect on Treatment

I understand I do not have to sign this Authorization and that my enrollment in any of the services and/or programs described above is entirely voluntary. I understand that Amgen, as well as Health Care Providers, cannot require me, as a condition of having access to medications, prescription drugs, treatment or other care, to sign this Authorization. Federal Law (including HIPAA) requires a signed authorization in order for Amgen to collect my protected health information from my Health Care Providers. I understand I cannot participate in the listed services and/or programs without signing this Authorization or an equivalent authorization with my Health Care Providers.

### Information Received from Health Care Providers

I understand that once my protected health information has been disclosed to Amgen, federal privacy laws may no longer apply and may no longer protect it from further disclosure, and that Amgen may disclose my protected health information to its data processors, contractors, and business partners for its business purposes. Amgen agrees, however, to protect my protected health information by only using and disclosing it as stated in the Authorization or as otherwise allowed or required by law.

## U.S. STATE LAW CONSENT TO PROCESS HEALTH DATA FOR AMGEN BY YOUR SIDE

Please read and provide response in Patient Consent and Authorization section on page 2

I consent to Amgen processing my Health Data for the following purposes:

- To enroll me and manage my participation in the Amgen By Your Side program, which includes activities related to my condition or treatment (for example, co-pay card programs, payer medication coverage verification, patient access liaison support, disease management support), and to manage Amgen's products, services, and programs related to my condition or treatment.

### Amgen uses the following when it administers the Amgen By Your Side program:

- Health Data – my name (and the name of my caregiver if applicable), gender, date of birth, contact information and information relating to my health condition or treatment.

I understand that my consent to processing is required for me to participate in the Amgen By Your Side program. I also understand that Amgen will not sell my Health Data to third parties, but Amgen may disclose my Health Data to Amgen's data processors, contractors, and business partners for Amgen's business purposes related to the Amgen By Your Side program. I understand that Amgen may use my Health Data to contact me by mail, email, telephone, or text for the above purposes. Mobile Terms & Conditions can be found at [AmgenByYourSide.com/mobile-terms-and-conditions](http://AmgenByYourSide.com/mobile-terms-and-conditions). I also understand that if I do not consent to the use of my Health Data for the above purposes, I will not be able to participate in the Amgen By Your Side program. Finally, I understand that I may withdraw my consent to processing my Health Data for the above purposes at any time using one of the methods listed in the Additional Disclosures section below and that if I withdraw my consent, I will no longer be able to participate in the Amgen By Your Side program.

### Additional Disclosures

I understand that participation in the Amgen By Your Side program is an optional service at no cost to me. The consent above in no way affects my right to obtain any medications and I do not have to provide consent to be able to receive any medications. To obtain a copy of the consent above or to withdraw my consent to collection, processing, and/or disclosure of my Health Data for any of the above purposes to which I have consented, I can contact Amgen by visiting [www.amgen.com/DataSubjectRights](http://www.amgen.com/DataSubjectRights) or calling 1-844-469-4297. For more information about Amgen's privacy practices, Amgen's Privacy Statement can be found at <http://www.amgen.com/privacy>

**PATIENT INFORMATION**

Patient Name: \_\_\_\_\_ Sex: \_\_\_\_\_ DOB: \_\_\_\_\_  
Address: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_  
Phone: \_\_\_\_\_ Alt. Phone: \_\_\_\_\_ Height: \_\_\_\_\_ Weight: \_\_\_\_\_ kg  
Allergies: \_\_\_\_\_  No Known Drug Allergies  
Emergency Contact: \_\_\_\_\_ Emergency Contact Phone: \_\_\_\_\_  
Alternate Contact: \_\_\_\_\_ Alternate Contact Phone: \_\_\_\_\_  
Patient Status:  New to therapy  Continuing therapy  Therapy change Last Infusion Date (if applicable): \_\_\_\_\_  
Is the patient pregnant, nursing or planning a pregnancy?  Yes  No Does the patient need interpreter services?  Yes  No

**PRESCRIBER INFORMATION**

Ref. Coordinator Name: \_\_\_\_\_ Ref. Coordinator Phone: \_\_\_\_\_  
Ref. Coordinator Email: \_\_\_\_\_ Practice Name: \_\_\_\_\_  
Prescriber's Name: \_\_\_\_\_ NPI: \_\_\_\_\_ Tax ID: \_\_\_\_\_  
Address: \_\_\_\_\_ City: \_\_\_\_\_  
State: \_\_\_\_\_ Zip Code: \_\_\_\_\_ Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

**PREFERRED PURE INFUSION LOCATION**

City, State: \_\_\_\_\_

**DIAGNOSIS (ICD-10 Codes)**

M1A.9XX0 Chronic gout without tophus (tophi)  M1A.9XX1 Chronic gout with tophus (tophi)  
 Other: \_\_\_\_\_

**MEDICATION ORDER**

Krystexxa® (pegloticase)  8mg IV every 2 weeks

*Duration: 1 year of treatment unless indicated otherwise*

**PRE-MEDICATIONS**

acetaminophen (Tylenol)  500 mg PO  650 mg PO  1000 mg PO  
 diphenhydramine (Benadryl)  25 mg  50 mg  PO  IV  
 cetirizine (Zyrtec)  10 mg PO OR  loratadine (Claritin)  10 mg PO  
 methylprednisolone (Solu-Medrol)  40 mg IV  125 mg IV OR  hydrocortisone (Solu-Cortef)  100 mg IV  
 Other: \_\_\_\_\_  No pre-medications  All pre-medications are PRN

**LAB ORDERS**

Required pre-treatment labs to be completed prior to infusion/injection. If lab results are unavailable or outside required timeframes, Pure may obtain required labs.

Other: \_\_\_\_\_

*If patient has port, please complete port order form.*

**REQUIRED DOCUMENTATION (submit copies of the following with this order form)**

Insurance card (front & back)  Current Medications  History/Progress Notes to Support Diagnosis  
 G6PD and Uric Acid within 72 hours of each dose

**PATIENT INFORMATION**

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Patient Name: \_\_\_\_\_ DOB: \_\_\_\_\_

**INFUSION REACTION PROTOCOL**

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 [Pure Infusion Reaction Protocol](#) Other Reaction Protocol (please send with order)\_\_\_\_\_  
Prescriber's Signature\_\_\_\_\_  
Date\_\_\_\_\_  
Time