

# Treatment Initiation Brochure

Your step-by-step guide to getting your patients treated with KRYSTEXXA

## WHAT'S INCLUDED:



### Process for New Patients

Walking you through every step of your patient's journey with KRYSTEXXA treatment, including prior authorization, screening, billing codes, lab work, and infusion information



### Amgen By Your Side Overview

A patient support program that provides nonmedical support to help patients as they start and continue on treatment as prescribed.



Not actual size.

## 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.

Please see Important Safety Information on pages 10-12 and see [Full Prescribing Information](#), including Boxed Warning.

**KRYSTEXXA**<sup>®</sup>  
pegloticase

# Amgen By Your Side

## A PATIENT SUPPORT PROGRAM

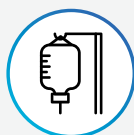
Amgen By Your Side is a support program for patients prescribed KRSTEXXA. After your patient has enrolled, they will be paired with a dedicated support partner, called a Patient Access Liaison (PAL). Their PAL can be a partner, providing nonmedical education to help them navigate their unique treatment experience—including information on insurance, financial assistance options, important appointment-related information, and other patient support services.



Financial Assistance\*



Patient Support



Infusion Logistics Assistance



Insurance Benefits Investigation

Start the enrollment process for Amgen By Your Side on behalf of your patient at [AmgenByYourSideEnrollment.com](https://AmgenByYourSideEnrollment.com)

### CHOOSE 1 OF THE 3 METHODS BELOW 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



Scan the QR code or visit [amgenbyyourside.com](https://amgenbyyourside.com) for a guide to help you complete the form accurately for submission.

### QUESTIONS?

Contact Amgen By Your Side at **1-877-633-9521**

\*For eligible patients.

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# Discover the Amgen Commercial Co-Pay Program

Eligible patients with commercial insurance may pay as little as \$0 out-of-pocket<sup>†</sup> for the cost of the medication and the infusion administration through the Amgen Commercial Co-Pay Program.

## SEE BELOW FOR ADDITIONAL FINANCIAL ASSISTANCE OPTIONS

PATIENT SITUATION	MEDICAL COST ASSISTANCE
<b>Commercially insured</b>	The Amgen Commercial Co-Pay Program <sup>†</sup> helps eligible patients on KRYSTEXXA with deductibles, coinsurance, and co-pays associated with medication and IV infusions. <b>Eligible patients will receive a digital co-pay card.</b>
<b>Uninsured</b>	Contact Amgen By Your Side. Our team is committed to exploring all options for your patient.
<b>Insured, but not eligible for the co-pay program</b>	If additional financial assistance is needed, independent foundation support may be available. Please contact Amgen By Your Side. <sup>‡</sup>

<sup>†</sup>Eligibility criteria and program maximums apply. See [KRYSTEXXACoverage.com](https://www.krystexxa.com/coverage) for full terms and conditions. Patients who are residents of Massachusetts or Rhode Island are not eligible for administration support.

<sup>‡</sup>Please note that independent foundations establish, administer, and implement the funds, which are separate and apart from Amgen.

IV, intravenous.

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## STEP 1: COVERAGE

Initiate your patient's enrollment in

# Amgen By Your Side by submitting the Patient Enrollment Form (PEF)

**Your patient must complete enrollment to access our patient-focused services and resources.**

Patient will work with a Patient Access Liaison (PAL), who provides enrollment support and can educate on Prior Authorization process, where needed.

Once your patient is enrolled in the program, you will receive a comprehensive summary of benefits from Amgen By Your Side.

### Patient is covered by approved product label

- Date of birth (adult patients only)
- Lab results: glucose-6-phosphate dehydrogenase (G6PD) (normal activity only)
- Appropriate chronic gout diagnosis code. Code for chronic gout due to renal impairment should only be used as a secondary diagnosis code

### PLANS MAY REQUIRE ADDITIONAL NOTES ON INSUFFICIENT EFFECTIVENESS OR TOLERABILITY

<b>Dates, dosage, and duration of treatment with urate-lowering therapies</b> (allopurinol, febuxostat, or uricosuric agent) <ul style="list-style-type: none"><li>• Include any medication side effects, if applicable</li></ul>	<b>Lab results: serum uric acid (sUA)</b> levels throughout previous treatment(s) <ul style="list-style-type: none"><li>• ACR guidelines</li></ul>	<b># of gout flares</b> in the last 18 months and/or <b># of visible tophi</b> <ul style="list-style-type: none"><li>• Provide relevant imaging results</li></ul>
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**ACR guidelines** recommend pegloticase in patients who have failed to reach sUA target levels on oral urate-lowering therapies at maximum medically appropriate doses and continue to have frequent gout flares ( $\geq 2$  flares/year) and/or nonresolving tophi.<sup>1</sup>

ACR, American College of Rheumatology.

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## CODING AT A GLANCE

To assist in obtaining insurance coverage, refer to this table of insurance and billing codes.

Please note, these codes are subject to change. To ensure you have the most up-to-date codes, please visit [KRYSTEXXACodes.com](https://www.krystexxa.com/codes).

Drugs and biologics	NDC	10-digit	<b>75987-058-01:</b> <sup>2</sup> 8-mg/50-mL solution of pegloticase in a single-dose KRYSTEXXA Ready-to-Use vial <b>1 dose = 8mg</b>
	HCPCS		<p><b>J2507:</b> Injection, pegloticase, 1 mg (x8) <b>8 mg dose does not vary</b></p> <p><b>J2919:</b> Injection, methylprednisolone sodium succinate, 5 mg  <b>J1700:</b> Injection, hydrocortisone acetate, up to 25 mg  <b>J1710:</b> Injection, hydrocortisone sodium phosphate, up to 50 mg  <b>J1720:</b> Injection, hydrocortisone sodium succinate, up to 100 mg</p>
Professional services	CPT		<b>96365:</b> IV infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug), initial, up to 1 hour
			<b>+96366:</b> IV infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug), each additional hour
			<b>+96367:</b> IV infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (list separately in addition to code for primary procedure)
			<b>96413:</b> Chemotherapy administration, IV infusion technique; up to 1 hour, single or initial substance/drug
	Laboratory CPT		<p><b>82955:</b> G6PD (enzyme) level*  <b>82960:</b> G6PD (enzyme) screening test*  <b>84550:</b> Uric acid; blood (sUA)  <b>84550-QW:</b> Uric acid; blood (sUA); CLIA-waived test</p> <p><small>*G6PD deficiency is an abnormally low level of glucose-6-phosphate dehydrogenase. Patients of African, Mediterranean, and Southern Asian ancestry have a higher risk of deficiency.<sup>2</sup></small></p>
Hospital services and supplies	Revenue codes		<p><b>0250:</b> Pharmacy, general  <b>0260:</b> IV therapy, general  <b>0261:</b> IV therapy, infusion pump  <b>0636:</b> Pharmacy, drugs requiring detailed coding</p>

**Consult individual payers on any coding and documentation requirements**

This coding information may assist you as you complete payor forms. Correct coding is the responsibility of the provider submitting the claim for the item or service. Please check with the payor to verify codes and special billing requirements. Amgen does not make any representation or guarantee concerning reimbursement or coverage for any service or item.

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## STEP 2: PREINFUSION

Identify your patient’s infusion location  
(office, hospital, infusion center, or at home)

**KRYSTEXXA® (pegloticase) should be administered in a healthcare setting by professionals trained to manage serious allergic reactions.<sup>2</sup>**

**Potential use of home infusion must be determined by healthcare professionals’ assessment of individual patient needs.**

### 1 ORDER LAB WORK

Confirm screening results for G6PD deficiency prior to first infusion

**KRYSTEXXA is contraindicated in patients with G6PD deficiency<sup>2,3</sup>**

Patients with G6PD deficiency may experience life-threatening hemolytic reactions and methemoglobinemia.

It is important to test patients for G6PD deficiency prior to initiating treatment because they often appear asymptomatic and will likely not be aware of this deficiency.

HOW TO INTERPRET SCREENING RESULTS		
SCREENING CLASSIFICATION	INTERPRETATION	RECOMMENDATION
<b>Normal</b> quantitative value or <b>Negative</b> qualitative result for deficiency	Patient does not have G6PD deficiency*	Can proceed to treatment with KRYSTEXXA as indicated
<b>Low</b> quantitative value or <b>Positive</b> qualitative result for deficiency	Patient may have G6PD deficiency	<b>Do not administer KRYSTEXXA to patients with G6PD deficiency</b> If you have questions regarding screening for G6PD deficiency, please call Medical Information at 1-866-479-6742

### 2 MEASURE sUA:<sup>2,4</sup>

Baseline sUA is typically required and patient sUA levels must be measured before each subsequent treatment.

### 3 ADMINISTER OTHER MEDICATIONS<sup>2,5,6</sup>

- Initiate methotrexate with oral folic acid at least 4 weeks prior to initiating and throughout treatment with KRYSTEXXA
- Stop urate-lowering therapies 1 week prior to first infusion
- Begin gout flare prophylaxis with non-steroidal anti-inflammatory drug (NSAID) or colchicine at least 1 week before starting KRYSTEXXA

\*Acute hemolysis, which may be the result of the patient’s medications, can produce inaccurate results. Additionally, if a patient has received a blood transfusion, the transfusion could alter the test results. For either of these situations, postpone testing or consider retesting in 2 to 3 months.<sup>3,7</sup>

G6PD, glucose-6-phosphate dehydrogenase.

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### STEP 3: INFUSION

Ready-to-Use (RTU) vial—with the same KRYSTEXXA you've come to rely on<sup>2,†</sup>

**Perform preinfusion sUA test, preferably within 48 hours prior to each infusion** (with exception of the first infusion)<sup>2,4</sup>

- sUA level is a predictive biomarker for infusion reactions risk and product efficacy

**The RTU vial—no IV bags, no saline dilution, and it's ready for infusion via an infusion pump<sup>2</sup>**

1. Parenteral drug products should be **inspected visually** for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use vial if either is present.
2. Allow the RTU vial to **reach room temperature** at 20°C to 25°C (68°F to 77°F). KRYSTEXXA in a vial should never be subjected to artificial heating (eg, hot water, microwave). Unopened vial may be stored for up to 4 hours at room temperature.
3. Use appropriate aseptic technique. Insert a vented intravenous set through the septum of the vial. **Once the stopper is punctured, use immediately.**
4. To administer, **invert and hang the vial** utilizing the built-in hanger label affixed to the bottom of the vial.
5. **Administer as an intravenous infusion over no less than 120 minutes using an infusion pump.** After the entire contents of the vial have been administered, flush the intravenous line with sodium chloride injection to ensure delivery of the required dose.
  - To administer the RTU vial over 120 minutes, the appropriate infusion rate is 25 mL per hour

**Reminder: Account for infusion pump variance.  
Check settings and confirm infusion completes in no less than 120 minutes.**

**Remind your patients<sup>2,5</sup>**

- Of upcoming infusion appointments and sUA tests
- Gout flare prophylaxis is recommended for at least 6 months
- The need to continue methotrexate and folic acid regimen throughout the duration of treatment:
  - 15 mg oral methotrexate weekly with 1 mg oral folic acid daily
- Best results were seen at **6-12 months** for KRYSTEXXA with methotrexate<sup>‡</sup>



<sup>†</sup>Available through Amgen authorized specialty distribution partners.

<sup>‡</sup>Optimal treatment duration has not been established.<sup>2</sup>

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# Important contact information

See everything the Amgen By Your Side support program has to offer for you and your patients.

**AMGEN BY  
YOUR SIDE  
PHONE**

1-877-633-9521

**AMGEN BY  
YOUR SIDE  
FAX**

1-877-633-9522

**ADVERSE EVENT  
REPORTING AND MEDICAL  
INFORMATION**

1-866-479-6742

Contact the numbers below to get your patients connected with a KRYSTEXXA distributor.

## KRYSTEXXA authorized specialty distributors

ASD Healthcare   <a href="http://asdhealthcare.com">asdhealthcare.com</a> .....	1-800-746-6273
Besse® Medical   <a href="http://besse.com">besse.com</a> .....	1-800-543-2111
BioCareSD®   <a href="http://biocaresd.com">biocaresd.com</a> .....	1-800-304-3064
Cardinal Health™   <a href="http://cardinalhealth.com">cardinalhealth.com</a> .....	1-800-926-3161
Cardinal Specialty   <a href="http://cardinalhealth.com">cardinalhealth.com</a> .....	1-866-677-4844
CuraScript SD®   <a href="http://curascriptsd.com">curascriptsd.com</a> .....	1-877-599-7748
McKesson Plasma   <a href="http://mckesson.com">mckesson.com</a> .....	1-877-625-2566
McKesson Specialty Health   <a href="http://mcs.mckesson.com">mcs.mckesson.com</a> .....	1-855-477-9800
Metro Medical   <a href="http://metromedicalorder.com">metromedicalorder.com</a> .....	1-800-768-2002
Oncology Supply®   <a href="http://oncologysupply.com">oncologysupply.com</a> .....	1-800-633-7555

KRYSTEXXA Ready-to-Use vial National Drug Code number:<sup>2</sup> **75987-058-01**

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## 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. Life threatening hemolytic reactions and methemoglobinemia have been reported with KRYSTEXXA in patients with G6PD deficiency. KRYSTEXXA is contraindicated in patients with G6PD deficiency.

### 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

### Anaphylaxis

In a 52-week controlled trial of KRYSTEXXA co-administered with methotrexate (MTX) compared to KRYSTEXXA alone, one patient treated with KRYSTEXXA co-administered with MTX (1%) experienced anaphylaxis during the first infusion and no patients experienced anaphylaxis treated with KRYSTEXXA alone. Patients were pre-treated with infusion reaction prophylaxis and KRYSTEXXA was discontinued following 2 consecutive serum uric acid levels above 6 mg/dL to reduce the risk of anaphylaxis and infusion reactions. These risks are higher in patients whose uric acid level increases to above 6 mg/dL, particularly when 2 consecutive levels above 6 mg/dL are observed.

During pre-marketing clinical trials with KRYSTEXXA alone, KRYSTEXXA was not discontinued following 2 consecutive serum uric acid levels above 6 mg/dL. Anaphylaxis was reported with 6.5% (8/123) of patients treated with KRYSTEXXA every 2 weeks and 4.8% (6/126) for the every 4-week dosing regimen. There were no cases of anaphylaxis in patients receiving placebo. Anaphylaxis generally occurred within 2 hours after treatment.

Diagnostic criteria of anaphylaxis were skin or mucosal tissue involvement, and, either airway compromise, and/or reduced blood pressure with or without associated symptoms, and a temporal relationship to KRYSTEXXA or placebo injection with no other identifiable cause. Manifestations included wheezing, peri-oral or lingual edema, or hemodynamic instability, with or without rash or urticaria, nausea or vomiting. Cases occurred in patients being pre-treated with one or more doses of an oral antihistamine, an intravenous corticosteroid and/or acetaminophen, which may have resulted in an underestimate of anaphylaxis frequency reported.

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

## IMPORTANT SAFETY INFORMATION (continued)

Patients should be informed of the symptoms and signs of anaphylaxis and instructed to seek immediate medical care should anaphylaxis occur after discharge from the healthcare setting.

It is recommended that before starting KRYSTEXXA patients discontinue oral urate-lowering medications and not institute therapy with oral urate-lowering agents while taking KRYSTEXXA.

### Infusion Reactions

In the 52-week trial, infusion reactions were reported in 4% of patients in the KRYSTEXXA co-administered with MTX group compared to 31% of patients treated with KRYSTEXXA alone. In both treatment groups, the majority of infusion reactions occurred at the first or second KRYSTEXXA infusion and during the time of infusion.

During pre-marketing 24-week controlled clinical trials with KRYSTEXXA alone, infusion reactions were reported in 26% of patients treated with KRYSTEXXA 8 mg every 2 weeks, and 41% of patients treated with KRYSTEXXA 8 mg every 4 weeks, compared to 5% of patients treated with placebo. These infusion reactions occurred in patients being pre-treated with an oral antihistamine, intravenous corticosteroid and/or acetaminophen, which may have resulted in an underestimate of infusion reaction frequency reported.

Manifestations of these reactions included urticaria (10.6%), dyspnea (7.1%), chest discomfort (9.5%), chest pain (9.5%), erythema (9.5%), and pruritus (9.5%). These manifestations overlap with the symptoms of anaphylaxis, but in a given patient did not occur together to satisfy the clinical criteria for diagnosing anaphylaxis. Infusion reactions occurred at any time during a course of treatment with ~3% occurring with the first infusion, and ~91% occurred during the time of infusion.

KRYSTEXXA should be infused slowly over no less than 120 minutes. In the event of an infusion reaction, the infusion should be slowed, or stopped and restarted at a slower rate.

### Gout Flares

In the 52-week trial of KRYSTEXXA co-administered with MTX vs KRYSTEXXA alone, patients were administered gout flare prophylaxis, resulting in 66% and 69% of patients with any flare for the first 3 months, respectively. In the KRYSTEXXA co-administered with MTX group, the percentages of patients with any flare for the subsequent 3 month increments of treatment were 27%, 8%, and 9% during Months 6, 9, and 12, respectively; in the group treated with KRYSTEXXA alone, 14%, 9%, and 21% during Months 6, 9, and 12, respectively.

During the 24-week pre-marketing, controlled trials, with KRYSTEXXA alone the frequencies of gout flares were high in all treatment groups, but more so with KRYSTEXXA treatment during the first 3 months, and decreased in the subsequent 3 months. The percentages of patients with any flare for the first 3 months were 74%, 81%, and 51%, for KRYSTEXXA 8 mg every 2 weeks, KRYSTEXXA 8 mg every 4 weeks, and placebo, respectively. The percentages of patients with any flare for the subsequent 3 months were 41%, 57%, and 67%, for KRYSTEXXA 8 mg every 2 weeks, KRYSTEXXA 8 mg every 4 weeks, and placebo, respectively. Patients received gout flare prophylaxis with colchicine and/or NSAIDs starting at least one week before receiving KRYSTEXXA. Gout flares may occur after initiation of KRYSTEXXA. An increase in gout flares is frequently observed upon initiation of anti-hyperuricemic therapy, due to changing serum uric acid levels resulting in mobilization of urate from tissue deposits. Gout flare prophylaxis with a 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. KRYSTEXXA does not need to be discontinued because of a gout flare. The gout flare should be managed concurrently as appropriate for the individual patient.

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

## IMPORTANT SAFETY INFORMATION (continued)

### Congestive Heart Failure (CHF)

KRYSTEXXA has not been formally studied in patients with CHF, but some patients in the pre-marketing placebo-controlled clinical trials experienced exacerbation. Two cases of CHF exacerbation occurred during the trials in patients receiving treatment with KRYSTEXXA 8 mg every 2 weeks. No cases were reported in placebo-treated patients. Four subjects had exacerbations of pre-existing CHF while receiving KRYSTEXXA 8 mg every 2 weeks during the OLE study. Exercise caution in patients who have congestive heart failure and monitor patients closely following infusion.

### Re-treatment with KRYSTEXXA

No controlled trial data are available on re-treatment after stopping treatment for longer than 4 weeks. Due to the immunogenicity of KRYSTEXXA, patients receiving re-treatment may be at increased risk of anaphylaxis and infusion reactions. Therefore, patients receiving re-treatment after a drug-free interval should be monitored carefully.

### ADVERSE REACTIONS

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

#### Co-administration with MTX:

Gout flares, arthralgia, COVID-19, nausea, and fatigue.

#### KRYSTEXXA alone:

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

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

**References:** 1. FitzGerald JD, et al. *Arthritis Care Res (Hoboken)*. 2020;72:744-760. 2. KRYSTEXXA (pegloticase) [prescribing information] Amgen. 3. Belfield KD, et al. *Am J Health Syst Pharm*. 2018;75:e69-e76. 4. Keenan RT, et al. *Rheumatol Ther*. 2019;6:299-304. 5. Botson JK, et al. *Arthritis Rheumatol*. 2023;75(2):293-304. 6. Baraf HSB, et al. *J Clin Rheumatol*. 2014;20:427-432. 7. Minucci A, et al. *IUBMB Life*. 2009;61:27-34.

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