KRYSTEXXA pegloticase

SERVICE REQUEST FORM

Please fax completed form with a copy of the front and back of the patient's insurance card.

Fax: 1-877-633-9522 • Phone: 1-877-633-9521 • Monday–Friday, 8:00 AM–8:00 PM ET

KRYSTEXXA*Connect*

Welcome to KRYSTEXXA*Connect*!

To get started, fill out Section 1, followed by the other sections as needed.

1 **Patient Services:** This section is required and includes the option to have a dedicated Patient Access Manager (PAM) provide financial and medical support, including co-pay assistance, to your patient throughout treatment.

2 **Benefits Investigation:** To have KRYSTEXXA*Connect* conduct a benefits investigation for your patient, **please also complete this section.**

3 **Insurance Authorization Support:** Complete this section and send clinical documentation to receive insurance authorization support (recommended for buy and bill, prior authorization, and predetermination support, including pre/post infusion denials). **Please also complete page 2.**

1 ☑ Patient Services

PATIENT INFORMATION (Please provide physical address; no PO boxes.)

Name (First, MI, Last): _____

Address: _____

City: _____ State: _____ ZIP: _____

Phone: _____ Email: _____

Gender: ☐ Male ☐ Female Primary Language: _____

Date of Birth: _____ Height: _____ Weight: _____

Alternate Contact: _____ Relationship: _____

Phone: _____ Email: _____

Patient:

SIGNATURE: _____ Date: _____

(Only required if requesting co-pay assistance or uninsured)

☐ UNINSURED: Patient is ineligible for any health insurance, including Medicare and Medicaid, or has been denied by third-party payer. Please evaluate them for Patient Assistance Program. (Proof of income is required.)

Primary Insurance (Please include a copy of front and back of insurance card.)

Plan Name: _____ Phone: _____

ID Number: _____ Group Number: _____

Secondary Insurance

Plan Name: _____ Phone: _____

ID Number: _____ Group Number: _____

Please read Patient Authorization on page 3.

PHYSICIAN INFORMATION

Name (First, MI, Last): _____

Practice Name: Metro Infusion Center

Address: _____

City: _____ State: _____ ZIP: _____

Phone: _____ Fax: _____

Referring Physician: _____

Specialty: Infectious Disease

Office Contact: Katie Keller Office Phone: 630-590-2831

Email: ivissues@innovativeventures.com

License #: _____ NPI #: _____

Tax ID #: 36966745

Specialty: _____

Physician:

SIGNATURE: _____ Date: _____

(Required)

☐ Opt out of Patient Services

Please read Physician Authorization on page 3.

2 Benefits Investigation (Please fill in the following information.)

SITE OF CARE

☐ Yes ■ No **Need assistance identifying facility per payer guidance?**

→ If no, please continue to the following questions.

Preferred Facility: _____

☐ Yes ■ No Is this facility a hospital outpatient facility?

NPI #: _____ (if in-office) Tax ID #: 36-3966745 (if site of care)

Medication Acquisition Route: ■ Buy and Bill ☐ Specialty Pharmacy

■ Yes ☐ No Does the facility accept Mastercard®?

☐ Send summary of benefits to the SOC if different from Physician Information above:

Contact Name: _____

Phone: _____ Fax: _____

DIAGNOSIS AND CONTRAINDICATIONS

Primary Diagnosis: ☐ M1A. ☐☐☐☐ – Chronic Gout*

*Use Chronic Gout ICD-10 Codes Wheel in Reimbursement Kit or see the full list of the most current codes at ChronicGoutCodes.com

☐ Yes ☐ No Does the patient have a diagnosis of asymptomatic hyperuricemia† or a deficiency in G6PD?

→ If yes, patient is not a candidate for KRYSTEXXA.

†Asymptomatic hyperuricemia is defined as elevated uric acid level (>6.8 mg/dL) in patients who have never exhibited signs or symptoms of gout (eg, gout flare, tophi)

G6PD=glucose-6-phosphate dehydrogenase.

HORIZON PHARMA

Please see Important Safety Information on page 4 and click for Full Prescribing Information, including Boxed Warning, and Medication Guide.

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KRYSTEXXAConnect

For Patient: _____ **DOB:** _____

3 Insurance Authorization Support (Please fill in the following information.)

SELECT SERVICE(S):

☐ **Prior Authorization (PA) or Predetermination**
A predetermination is recommended if your practice is planning to buy and bill KRYSTEXXA.

☐ **Reconsideration or Appeal**

DOSE: 8 mg every 2 weeks, NDC: 75987-0080-10 J Code: J2507

Is this for initiation or continuation of therapy?

☐ **Initiation:**

Date of 1st Infusion: ____/____/____ (mm/dd/yyyy) Duration of Treatment: _____

☐ **Continuation:**

Original Start Date: ____/____/____ (mm/dd/yyyy) Last Infusion Date: ____/____/____ (mm/dd/yyyy)

CURRENT SYMPTOMS

What is the patient's most recent sUA level and date obtained?

_____ mg/dL, date obtained: ____/____/____ (mm/dd/yyyy)

☐ Yes ☐ No Is there evidence of a tophus?
→ **If yes**, how many: _____

☐ Yes ☐ No Is there evidence of gouty arthritis? (tender and swollen or lesioned joints)
→ **If yes**, how many joints are impacted? _____

☐ Yes ☐ No Has the patient experienced functional impairment?
→ **If yes**, please describe: _____

☐ Yes ☐ No Has the patient experienced 3 or more flares in the past 18 months?
→ **If no,** how many flares has the patient experienced in the past 18 months? _____
→ **If yes,** please provide most recent dates: ____/____/____ (mm/dd/yyyy), ____/____/____ (mm/dd/yyyy), ____/____/____ (mm/dd/yyyy)

☐ Yes ☐ No Does patient have kidney dysfunction?
→ **If yes**, GFR: _____ Serum creatinine: _____

☐ Yes ☐ No Has the patient undertaken appropriate lifestyle modifications?
→ **If yes**, please check all that apply:

- ☐ Discontinuing or changing medications that are known to precipitate gout attacks
- ☐ Implementing diet changes (consume low-purine diet, reduce refined carbohydrates, limit meats, increase vegetables and fruit)
- ☐ Decreasing alcohol consumption
- ☐ Limiting drinks rich in fructose
- ☐ Unknown
- ☐ Other: _____

sUA=serum uric acid.

ORAL URATE LOWERING TREATMENT HISTORY

Treatment	Patient at Max Medically Appropriate Dose	Max Dose	Start Date	End Date	sUA at End of Treatment	Explain Outcome or Specify Contraindication	Patient Is Contraindicated
Allopurinol							☐
Febuxostat							☐
Probenecid/ Lesinurad/ _____ (circle or write in uricosuric)							☐

☐ Yes ☐ No Will oral urate-lowering treatments be discontinued before starting KRYSTEXXA?
Patients should discontinue oral urate-lowering treatments before starting KRYSTEXXA.

I verify that the patient and healthcare provider information on this enrollment form was completed by me or at my direction and that the information contained herein is complete and accurate to the best of my knowledge.

Physician:

SIGNATURE: _____ Date: _____
(Required)

Please read Physician Authorization on page 3.

HORIZON PHARMA

Please see Important Safety Information on page 4 and click for Full Prescribing Information, including Boxed Warning, and Medication Guide.

PATIENT AUTHORIZATION (Please read and provide signature in Patient Information section on page 1.)

I hereby authorize my healthcare providers, my health insurance carriers, and my pharmacies to use and disclose my individually identifiable health information, including my medical records, insurance coverage information, and my name, address and telephone number to Horizon Pharma USA, Inc. and its affiliates and their respective agents and representatives (collectively, "Horizon"), including third parties authorized by Horizon to administer drug support and to dispense drugs (collectively, "KRYSTEXXA*Connect*™") for the following purposes: (1) to establish eligibility for benefits; (2) to communicate with my healthcare providers and me about my treatment or condition and related products; (3) to facilitate the provision of products, supplies, or services by a third party including, but not limited to, specialty pharmacies; (4) to register me in any applicable product registration program required for my treatment; (5) to enroll me in eligible patient support programs offered by KRYSTEXXA*Connect*™ and/or Horizon, including nursing or patient access support services (government-reimbursed programs may not be eligible for all support services offered; please contact KRYSTEXXA*Connect*™ for determination); and (6) to send me marketing information related to my treatment or condition (or related products or services in which I might be interested) and to contact me occasionally to obtain my feedback (for market research purposes only) about my treatment, my condition, or my experience with Horizon and/or KRYSTEXXA*Connect*™ otherwise as required or permitted by law. I understand the pharmacies may receive a fee from Horizon in exchange for (1) providing me with certain materials and information described above, and (2) using or disclosing certain health information pursuant to this Authorization.

I understand that Horizon, as well as my healthcare providers, cannot require me, as a condition of having access to medications, prescription drugs, treatment, or other care, to sign this Authorization. I understand that I am entitled to a copy of this Authorization. I understand that information disclosed pursuant to this Authorization in some cases may be redisclosed by the recipient and no longer protected by HIPAA or other privacy laws. But Horizon has agreed to use and disclose my information only for purposes of operating the program.

I understand that I may cancel this Authorization at any time by mailing a signed letter requesting such cancellation to KRYSTEXXA*Connect*™, P.O. Box 5667, Louisville, KY 40255-0667, but that this cancellation will not apply to any information used or disclosed by my healthcare providers and/or health insurance carriers based on this Authorization before they are notified that I have cancelled it. Unless required by state law, this Authorization is valid for whichever is greater: (a) the duration of remaining on this treatment or (b) 10 years from the date signed below. A photocopy of this Authorization will be treated in the same manner as the original.

PHYSICIAN AUTHORIZATION (Please read and provide signature in Physician Information section on page 1.)

By filling out this form, your Chronic Gout patient is automatically enrolled into the Patient Access Manager Program.

My signature on page 1 certifies that the person named on this form is my patient and medications received from Horizon Pharma plc for any program are only for the use of the patient named on this form. I certify that the described therapy is medically necessary and my patient is being administered KRYSTEXXA® (pegloticase) Injection, 8 mg/mL, for Intravenous Infusion in accordance with the labeled use of the product. I further certify that I have received the necessary authorization to release the referenced medical and/or other patient information relating to KRYSTEXXA therapy for the purpose of seeking KRYSTEXXA therapy and/or assisting in initiating or continuing KRYSTEXXA therapy. This medication will not be offered for sale, trade, or barter. I further acknowledge that I have obtained the patient's authorization to release the above information and such other information as may be required for RxC Acquisition Company d/b/a RxCrossroads, acting on behalf of Horizon Pharma plc, to assist in obtaining coverage for KRYSTEXXA and to assist in initiating or continuing therapy. By signing, I also acknowledge that Horizon Pharma plc has the right to contact me or the patient regarding information related to reimbursement. I understand that Horizon Pharma plc has the right to revise, change, or terminate this program at any time.

I acknowledge that I shall not seek reimbursement for any medication that is returned for credit or dispensed through the Patient Assistance Program from Medicare, Medicaid, or any government program, or any public or private third-party insurer. Finally, to the best of my knowledge, my patient meets Horizon Pharma plc's criteria for the services requested.

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATIONS AND USAGE

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.

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

IMPORTANT SAFETY INFORMATION

WARNING: ANAPHYLAXIS AND INFUSION REACTIONS
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. However, delayed-type hypersensitivity reactions have also been reported. KRYSTEXXA should be administered in healthcare settings and by healthcare providers prepared to manage anaphylaxis and infusion reactions. Patients should be premedicated with antihistamines and corticosteroids. Patients should be closely monitored for an appropriate period of time for anaphylaxis after administration of KRYSTEXXA. Monitor serum uric acid levels prior to infusions and consider discontinuing treatment if levels increase to above 6 mg/dL, particularly when 2 consecutive levels above 6 mg/dL are observed.

The risk of anaphylaxis and infusion reactions is higher in patients who have lost therapeutic response.

Concomitant use of KRYSTEXXA and oral urate-lowering agents may blunt the rise of sUA levels. Patients should discontinue oral urate-lowering agents and not institute therapy with oral urate-lowering agents while taking KRYSTEXXA.

In the event of anaphylaxis or infusion reaction, the infusion should be slowed, or stopped and restarted at a slower rate.

Inform patients of the symptoms and signs of anaphylaxis, and instruct them to seek immediate medical care should anaphylaxis occur after discharge from the healthcare setting.

CONTRAINDICATIONS: G6PD DEFICIENCY ASSOCIATED HEMOLYSIS AND METHEMOGLOBINEMIA
Screen patients for G6PD deficiency prior to starting KRYSTEXXA. Hemolysis and methemoglobinemia have been reported with KRYSTEXXA in patients with G6PD deficiency. Do not administer KRYSTEXXA to these patients.

GOUT FLARES
An increase in gout flares is frequently observed upon initiation of anti-hyperuricemic therapy, including treatment with KRYSTEXXA. If a gout flare occurs during treatment, KRYSTEXXA need not be discontinued. 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 studied in patients with congestive heart failure, but some patients in the clinical trials experienced exacerbation. Exercise caution when using KRYSTEXXA in patients who have congestive heart failure and monitor patients closely following infusion.

ADVERSE REACTIONS
The most commonly reported adverse reactions in clinical trials with KRYSTEXXA are gout flares, infusion reactions, nausea, contusion or ecchymosis, nasopharyngitis, constipation, chest pain, anaphylaxis and vomiting.

Please click for Full Prescribing Information, including Boxed Warning, and Medication Guide.