KRYSTEXXA pegloticase

SERVICE REQUEST FORM

KRYSTEXXA*Connect*

Please fax the completed form with a copy of the front and back of the patient's insurance card to 1-877-633-9522.

(Physician signature required. Patient signature required only if requesting co-pay assistance, Patient Access Manager, or PAP.)

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

Please check service(s) you are requesting

☐ Benefit Investigation ☐ Prior Authorization Support ☐ Patient Assistance Program (PAP) (complete section 2) ☐ Patient Access Manager Enrollment

1. PATIENT INFORMATION Please provide physical address; no P.O. boxes.

Name (First, MI, Last): _____

Address: _____

City: _____ State: _____ ZIP: _____

Phone: _____

Gender: ☐ Male ☐ Female Primary Language: _____

Date of Birth: _____ SSN: _____

Caregiver Name: _____

Phone: _____ Email: _____

Patient:

SIGNATURE: _____ Date: _____

(Optional)

☐ UNINSURED: Ineligible for any health insurance (including Medicare, Medicaid, or has been denied by a third-party payer)

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 section 8 ("Patient Authorization") on page 2.

2. PATIENT ASSISTANCE PROGRAM (Optional)

Number of People in Household: _____ Annual Household Income: $_____

Please submit proof of total household income. Accepted forms include most recently filed Federal Tax Forms (eg, Form 1040), including supporting documents (W-2 or Social Security income [SSA 1099]). If you do not have proof of income, please call 1-877-633-9521 to request an Income Statement.

3. PRESCRIBER INFORMATION

Prescriber Name: _____ Specialty: _____

Practice Name: _____ Office Contact: _____ Office Phone: _____

Address: _____ Email: _____

City: _____ State: _____ ZIP: _____ License #: _____ NPI #: _____

Phone: _____ Fax: _____ Tax ID #: _____

4. INFUSION FACILITY INFORMATION

Facility Name: _____

NPI #: _____ Tax ID #: _____

Anticipated Date of First Infusion: _____

Medication Acquisition Route: ☐ Buy and Bill ☐ Specialty Pharmacy: _____

Does the office accept Mastercard®? ☐ Yes ☐ No

5. PRIOR AUTHORIZATION ASSISTANCE Please provide chart notes or other clinical information for PA support.

Does the individual have documented symptomatic gout? ☐ Yes ☐ No

Baseline Serum Uric Acid Level: _____ mg/dL

Does the patient have a failure, contraindication, or intolerance to the following treatment options? (Check all that apply)

☐ allopurinol ☐ probenecid ☐ febuxostat ☐ colchicine ☐ NSAIDs

Gout medications previously tried and failed, with reason for discontinuation:
(Provide the information below or include chart notes containing the required information.)

Medication, dose	Reason	Start Date	End Date
1			
2			
3			

6. DIAGNOSIS AND THERAPY INFORMATION

Primary Diagnosis: ☐ M1A.xxx0 – Chronic Gout without tophi
☐ M1A.xxx1 – Chronic Gout with tophi
☐ Other

☐ Patient cannot take xanthine oxidase inhibitors due to contraindication or hypersensitivity reaction

☐ Patient's current oral treatment with xanthine oxidase inhibitors has failed to normalize serum uric acid and signs and symptoms are inadequately controlled despite receiving maximum medically appropriate dose of oral urate-lowering therapy (ULT)

7. PRESCRIBER AUTHORIZATION

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

My signature below 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.

☐ Check here if you choose not to enroll this patient into the Patient Access Manager Program

Please see KRYSTEXXA Indications and Important Safety Information on page 2.

Healthcare Provider:

SIGNATURE: _____ Date: _____

(Required)

HORIZON PHARMA

8. PATIENT AUTHORIZATION

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 certain employees at Horizon Orphan LLC and its 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 healthcare providers and me about my medical care; (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 certain 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 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 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 law, this Authorization is valid for whichever is greater: (a) the duration of remaining on this treatment or (b) ten (10) years from the date signed below. A photocopy of this Authorization will be treated in the same manner as the original.

Please read Patient Authorization above and sign in section 1 ("Patient Information") on page 1.

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 see Prescribing Information, including Boxed Warning, and Medication Guide.