Beacon Infusion
Healthcare Services

Headquarters Location:
1075 Stephenson Ave, Suite D-2, Oceanport, NJ 07757
Telephone: (833) 223-2266 Fax: (732) 329-2322

KRYSTEXXA MEDICATION ORDER

Please complete all attached pages.

The two Horizon By Your Side forms should be submitted to Horizon Therapeutics via fax at 877-633-9522.

The last page, the Beacon Infusion order, should be accompanied by the required chart notes and lab results and submitted to Beacon Infusion via fax at 732-329-2322.

The forms should be as complete as possible. This will significantly ease the authorization process. Once the case is transferred to us by Horizon Therapeutics, we will be in touch with your office regarding next steps.

Thank you!

Patient Enrollment Form

Once complete, submit by fax **1-877-633-9522** or email **GoutHBYS@horizontherapeutics.com**

HORIZON BY your side

KRYSTEXXA® pegloticase

Complete all required fields, including prescriber's signature and date, to initiate patient enrollment process.

For support and/or assistance obtaining patient signature, call Horizon By Your Side at 1-877-633-9521.

(*Indicates a required field)

Patient Information

First name* _____ **Last name*** _____

Sex*: ☐ Male ☐ Female **Date of birth*:** _____ (MM/DD/YYYY)

Primary language _____ Email address _____

Primary Telephone* _____ Consent to leave voice message at patient and/or alternate contact telephone? ☐ Yes ☐ No

☐ Home ☐ Cell Consent to send text message? ☐ Yes ☐ No

Address* _____

City* _____ **State*** _____ **ZIP Code*** _____

Alternate contact name _____ Alternate contact telephone _____

Diagnosis and Contraindications (Required for benefits investigation)

Primary diagnosis*: **M1A.** _____ — **Chronic Gout**

(Use coding wheel or see full list of codes at ChronicGoutCodes.com.)

KRYSTEXXA is contraindicated in patients with G6PD deficiency (glucose-6-phosphate dehydrogenase).

Date of Chronic Gout Diagnosis: _____ (MM/DD/YYYY)

Additional disease manifestation codes: _____

Insurance Information (Please include front and back copy of insurance card(s) along with this form)

Primary insurance* _____ Secondary insurance _____

Policy #* _____ Policy # _____

Policyholder's first and last name* _____ Policyholder's first and last name _____

Insurance company telephone* _____ Insurance company telephone _____

Group #* _____ Group # _____

Policyholder's DOB*: _____ (MM/DD/YYYY) Policyholder's DOB: _____ (MM/DD/YYYY)

IPA/Medical group name _____ IPA/Medical group telephone _____

☐ Reverification request

☐ Patient is uninsured to my knowledge

Patient Authorization (Please see authorization language on page 2)

X _____ **Date:** _____ (MM/DD/YYYY)

Patient signature
Please read page 2

_____ **DOB:** _____ (MM/DD/YYYY)

Printed full name

Please see Important Safety Information on page 2 and see Full Prescribing Information, including Boxed Warning, at KRYSTEXXAhcp.com.

Prescriber Information

First name* _____ **Last name*** _____

Address* _____

City* _____ **State*** _____ **ZIP Code*** _____

NPI #* _____ **Tax ID #*** _____ **State license #*** _____

Clinic/hospital affiliation _____

Office contact name _____

Office contact telephone* _____ **Fax*** _____

Email address* _____

Preferred communication: ☐ Telephone ☐ Email **Prescriber specialty*:** _____

Is there a Co-Managing Prescriber?* ☐ Yes ☐ No If yes, please populate with their information:

☐ Rheumatologist: _____ ☐ Nephrologist: _____

☐ Other specialty (please specify): _____

Address/City/State/Zip* _____

Infusion Facility

Do you have a preferred infusion facility?* ☐ Yes ☒ No If yes, please fill out the preferred infusion facility information below. If no, Horizon By Your Side will help identify a facility in close proximity to your patient.

☐ The infusion facility is the same as the prescribing office

Beacon Infusion Healthcare Services
Facility name*

Whichever site is most convenient for the patient. Please see www.beaconinfusion.com.
Facility address*

City* _____ **State*** _____ **ZIP Code*** _____

833-223-2266
Telephone*

732-329-2322
Fax*

Facility NPI #* _____ **Facility tax ID #*** _____

Prescription Information (Required for specialty pharmacy benefit)

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

Vial Quantity*: _____ **Refills*:** _____

Allergies*: _____ or ☐ No known drug allergies (NKDA)

☐ Authorize administration supplies as needed

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 preinfusions 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.

Prescriber Certification (Please see certification language on page 2)

X _____ _____ Substitutions allowed

Prescriber signature / Dispense as written*

Written or e-signature only; stamps not acceptable.

Date*: _____ (MM/DD/YYYY)

☐ **I certify that the above therapy is medically necessary for the treatment of documented uncontrolled gout.***

The above signature grants permission to share records with the co-management team and infusion facility.

Prescriber Certification

Please read and provide signature in Prescriber Certification section on page 1

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) injection, 8 mg/mL, for intravenous infusion in accordance with the labeled use of the product. I understand that Horizon Therapeutics USA, Inc. and its affiliates and their respective employees or agents (collectively, "Horizon") will use this information to administer the Horizon By Your Side program (the "Program"), which provides a wide array of patient-focused services, including providing logistical and non-medical treatment support for KRYSTEXXA, as prescribed, and educating about the insurance process. By my signature, I also certify that (1) my patient or his/her personal representative has provided a signed HIPAA authorization that allows me to share protected health information with Horizon for purposes of the Program and (2) I have obtained the patient's authorization to release such information as may be required for AllCare Plus Pharmacy (or another party acting on behalf of Horizon) to assess insurance coverage for KRYSTEXXA and assistance in initiating or continuing KRYSTEXXA as prescribed. 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 Horizon 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 Horizon 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. Horizon makes no representation or guarantee concerning coverage or reimbursement for any item or service. On behalf of the patient, Horizon expects the prescriber to coordinate with Horizon By Your Side to provide, to the best of the prescriber's ability, in-network infusion services and work with Horizon 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: 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.

By filling out and signing this form, the enrollment process in Horizon By Your Side has initiated; however, your patient must sign a Patient Authorization to complete enrollment in Horizon 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, Horizon will contact the patient to determine whether the patient is interested in signing a separate Patient Authorization.

Patient Consent for Patient Information, Enrolling in Services, and Accessing Financial Support (referred to as "Patient Authorization")

Please read and provide signature in Patient Authorization 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 Therapeutics 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, "Horizon By Your Side") 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 Horizon By Your Side and/or Horizon, including nursing or patient access support services (government-reimbursed programs may not be eligible for all support services offered; please contact Horizon By Your Side for determination); and (6) to send me marketing information or offer me products and services related to my treatment or condition (or other 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 Horizon By Your Side otherwise as required or permitted by law. Further, I appoint the Program, on my behalf, to proceed with Program services and to convey this prescription to the dispensing pharmacy, to the extent permitted under state 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 Horizon By Your Side, 1 Horizon Way, Deerfield, IL 60015, 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 remaining on this treatment or (b) 10 years from the date signed above. A photocopy of this Authorization will be treated in the same manner as the original.

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.

For additional information on KRYSTEXXA, please see Full Prescribing Information, including Boxed Warning, at KRYSTEXXAhcp.com.

HORIZON

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KRYSTEXXA MEDICATION ORDER

Patient's Name (Last, First, Middle) _____ **DOB:** _____

■ Diagnosis

Please provide diagnosis and code to the highest possible level of specificity.

☐ M1A._____ Chronic gout: _____

■ Details Needed for Authorization

Please send documentation, chart notes and results which support these answers.

- Is the patient refractory to conventional therapy? _____
- Has the patient failed to normalize serum uric acid? _____
- Are the patient's symptoms inadequately controlled with xanthine oxidase inhibitors (allopurinol, febuxostat, etc.)? _____
- Is the patient's combination therapy of uricosuric agent (probenecid) and xanthine oxidase inhibitor at the maximum medically appropriate dose, or, alternatively, is probenecid contraindicated in this patient? _____
- Has the patient had at least 3 gout flares in the past 18 months which were inadequately controlled by colchicine and/or NSAIDS or steroids? _____
- Does the patient have at least 1 gout tophus or chronic gouty arthritis? _____
- Is the patient's baseline serum uric acid level >8 mg/dL? _____
- Will the patient concurrently receive other urate lowering therapies such as allopurinol, febuxostat, probenecid, lesinurad, etc? _____
- Is the prescriber a specialist in the area of the patient's diagnosis (rheumatologist, nephrologist, etc)? _____ If yes, which specialty? _____
- Has the patient been tested for, and found to be negative for, G6PD deficiency? _____ If yes, please send the laboratory results.
- If the patient is currently prescribed any immunomodulator therapy such as methotrexate, mycophenolate, leflunomide, azathioprine, or cyclosporine, which medication and what is the dosage? _____

Important note: Your office is responsible for ordering serum uric acid level testing of the patient 48-72 hours before each Krystexxa infusion. It is imperative that these results are faxed to us immediately so that there is no delay in the delivery of the medication. Administration when sUA rises to >6mg/dL will require a peer-to-peer conversation with our Chief Medical Officer.

■ Premedication Order

Oral medications to be taken by the patient at least 60 minutes prior to start of infusion treatment. May be taken at home:

☐ Acetaminophen _____mg ☐ Diphenhydramine _____mg ☐ Cetirizine 10mg

IV medications to be administered prior to start of the infusion treatment:

☐ Diphenhydramine _____mg ☐ Solu-Medrol _____mg ☐ Solu-Cortef _____mg

■ Medication Order

Patient's height in feet/inches: _____ Patient's weight in pounds: _____

☐ Krystexxa (pegloticase) 8mg IV in 250mg normal saline every 2 weeks for _____ months.

Before therapy confirm patient is not G6PD deficient, has discontinued taking urate-lowering therapies (ie. allopurinol, febuxostat), that no more than 2 treatments have taken place since we last received serum uric acid levels, and that those levels are below 6mg/dL (initial pre-treatment levels may be higher, but not once therapy has commenced). Medication to be handled per manufacturer directions. Allow to come to room temperature without warming, dilute dose in 250ml of 0.9% sodium chloride IV bag and mix with gentle inversion, do not shake. Infusion administered at a rate of 125 ml/h or slower. Post infusion flush with normal saline. Check vitals and monitor for signs and symptoms of an infusion reaction at start, throughout infusion, and after completion. Patient to be monitored for at least one hour after the completion of the infusion.

■ Rescue Management in case of Reaction

These include fever, chills, rigors, headache, rash, itching, swelling, edema, nausea, vomiting, abdominal pain, hypotension, and respiratory distress.

- Stop medication infusion and start normal saline infusion at 50 ml/hr. Call ordering provider to report reaction.
- Follow standing reaction orders, including diphenhydramine, methylprednisolone, albuterol and oxygen as needed.
- For severe reactions, administer Epi-pen or equivalent and call 911. Repeat if severe symptoms persist.

■ Ordering Provider Authorization

Provider's Signature: _____ Name: _____ Date: _____

Address: _____

Phone: _____ Fax: _____ NPI #: _____ License: _____

Best Contact Person in Office: _____ Direct Phone Line to Contact Person:

STANDARD DOCUMENTATION TO INCLUDE:

- Patient demographics and insurance, including card scans (both medical and pharmacy benefit cards, both sides).
- Most recent chart notes and, if available, last history and physical. All relevant scans, tests and laboratory results.
- If new medication for patient, chart notes which include decision to begin treatment. If not, provide last treatment date.

Fax this order and supporting documentation to (732) 329-2322.