Palmetto INFUSION®

Phone: 1-800-809-1265 Fax: 1-866-872-8920

Referral Status:		MRN:
☐ New referral	☐ Order change	☐ Order Renewal
Patient preferred clinic:		

Krystexxa® (pegloticase) Standard Plan of Treatment

PATIENT DEMOGRAPHICS:

Date of Referral:				Patient's Phone:			
Patient Name:				Address:			
Date of Birth:				City, State, Zip:			
Height in inches:	Weight:	LB or	KG	Gender:	Allergies:	☐ See list	☐ NKDA

DIAGNOSIS: (PLEASE COMPLETE 2ND AND 3RD DIGITS TO COMPLETE ICD 10 FOR BILLING)

- ☐ M1A._____ - Chronic gout, without tophi
- ☐ M1A._____ - Chronic gout, with tophi
- ☐ M10._____ - Idiopathic gout
- ☐ _____- Other:_____

REQUESTED DOCUMENTATION:		PREVIOUS ADMINISTRATION: HAS THIS PATIENT TAKEN THIS MEDICATION BEFORE?	
1	Insurance information	IF NO:	IF YES:
2	Most recent History & Physical	PLEASE STATE REQUIRED WASHOUT FROM PREVIOUS THERAPY:	LAST INFUSION DATE:
3	Full medication list		NEXT INFUSION DATE:
4	Tried and failed therapies		**IF ORDER CHANGE:**
5	Baseline serum uric acid level		☐ **Continue current order until insurance approved**
6	G6PD serum level		
7	Specify if patient is prescribed prophylaxis for gout flare:	8	Specify if patient is prescribed methotrexate or other immunomodulation therapy:

MEDICATION ORDERS:

NOTE: Patient may be ineligible to receive Krystexxa® if patient has a diagnosis of G6PD or has new or worsening symptoms of CHF. If appropriate, it is reccomended that Krystexxa® be coadministered with methotrexate and Folic Acid.

PREMEDICATION TO BE ADMINISTERED 30 MINUTES PRIOR TO ADMNISTRATION AS SELECTED

Manufacturing guidelines suggest the administration of IV corticosteroids and antihistamine prior to administration of Krystexxa®.

IV	Diphenhydramine	☐ 25mg	☐ 50mg						
	Methylprednisolone	☐ 40mg	☐ 125mg	☐ Other:					
	Famotidine	☐ 20mg	☐ 40 mg						
	Other:	☐							
PO	Acetaminophen	☐ 325mg	☐ 500mg	☐ 650mg	☐ 1000mg				
	Famotidine	☐ 20mg	☐ 40mg						
	Diphenhydramine	☐ 25mg	☐ 50mg						
	Fexofenadine	☐ 60mg	☐ 180mg						
	Cetirizine	☐ 10mg							
	Loratadine	☐ 10mg							
	Other:	☐							

MEDICATION/DOSE:

☑ Krystexxa® (pegloticase) 8 mg in 250ml NS IV to infuse over 2 hours

Monitor patient for one (1) hour post infusion completion.

LAB PARAMETERS: (Pharmacist to perform clinical lab monitoring)

Serum uric acid level preferred 48 hours prior to each infusion. Hold infusion if 2 consecutive levels are above 6 mg/dL or unknown.

Please ensure all lab work is faxed to Palmetto Infusion Services

FREQUENCY:

- ☐ Dosing every 2 weeks
- ☐ Other: _____

SPECIAL/LAB ORDERS:

☐ _____

If 2 doses (4 weeks) of therapy are missed, then referring provider must give written clearance to resume therapy or treatment will be discontinued.

☑ Refills x 12 months unless noted otherwise here:

LINE USE/CARE ORDERS:

- ☑ Start PIV/Access CVC
- ☑ Flush device per facility standard flushing procedure

ADVERSE REACTION & ANAPHYLAXIS ORDERS:

Administer acute infusion and anaphylaxis medications per Palmetto Infusion standing adverse reaction orders, which can be found at our website or scan here.

PRESCRIBER INFORMATION:

PROVIDER NAME:	PHONE:
ADDRESS:	FAX:
CITY, STATE, ZIP:	NPI:

PRESCRIBER SIGNATURE: (No stamp signatures)		DATE:
Dispense as written/Brand medically necessary	Substitution permitted	

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

Patient Information (*Indicates a required field)

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 _____

Insurance Information (*Indicates a required field) (Please include front and back copies of insurance card[s] with this form)

Primary insurance* _____ Secondary insurance, if applicable _____

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

Infusion Facility (*Indicates a required field)

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

Facility name* _____

Facility address* _____

City* _____ **State*** _____ **ZIP code*** _____

Telephone* _____ **Fax*** _____

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

Patient Authorization (Required – please see authorization language on page 2)

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

Patient signature
Please read page 2

_____

Printed full name

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

Prescriber Information (*Indicates a required field)

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*:** _____

Referring healthcare provider: Was this patient referred to you by another HCP? ○ Yes ○ No If yes, please populate:

Name: _____ Specialty: _____

City: _____ State: _____

ZIP code: _____ Telephone: _____

Diagnosis (Required for benefits investigation) (*Indicates a required field)

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

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

Additional disease manifestation codes: _____

Co-administration Medication

Is there an immunomodulator prescribed? ○ Yes ○ No If yes, please indicate below:

○ methotrexate ○ Other

Prescription Information (Required for specialty pharmacy benefit) (*Indicates a required field)

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

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: 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 preinfusion 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 (Required – please see certification language on page 2)

X _____ _____

Prescriber signature / Dispense as written* Substitutions allowed

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 referring office 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.

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. Hemolysis 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

Gout Flares: An increase in gout flares is frequently observed upon initiation of anti-hyperuricemic therapy, including KRYSTEXXA. 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 formally studied in patients with congestive heart failure, but some patients in the pre-marketing placebo-controlled clinical trials experienced exacerbation. Exercise caution in patients who have congestive heart failure and monitor patients closely following infusion.

ADVERSE REACTIONS

The most commonly reported adverse reactions (≥5%) are:

KRYSTEXXA co-administration with methotrexate trial:
KRYSTEXXA with methotrexate: gout flares, arthralgia, COVID-19, nausea, and fatigue; KRYSTEXXA alone: gout flares, arthralgia, COVID-19, nausea, fatigue, infusion reaction, pain in extremity, hypertension, and vomiting.

KRYSTEXXA pre-marketing placebo-controlled trials:
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