

STANDARD KRYSTEXXA® (pegloticase injection) PLAN OF TREATMENT

NOTE: Patient may be ineligible to receive KRYSTEXXA® if patient has a diagnosis of G6PD or has new or worsening symptoms of CHF.

1. Patient Name: _____ Height (inches): _____ Weight (lbs): _____

2. Allergies: _____

3. Diagnosis: * Please complete the 2nd and 3rd digits to complete the ICD-10 code for billing

M1A. ____ 0 Chronic gout, without tophi M1A. ____ 1 Chronic gout, with tophi

M10. ____ Idiopathic gout Other ICD-10 Code: _____ Diagnosis description: _____

4. Pre-medications to be administered 30 minutes prior to infusion:

**Product Information suggests that all patients are premedicated with IV corticosteroid and antihistamine prior to infusion as per selected by referring physician below.*

Acetaminophen: 325 mg PO 500 mg PO 650 mg PO or 1000 mg PO

Diphenhydramine: 50 mg IVP 25 mg IVP 25 mg PO 50 mg PO / **Fexofenadine:** 60 mg PO 180 mg PO

Methylprednisolone IVP: 125 mg IVP 62.5 mg IVP 40 mg IVP or ____ mg IVP

Famotidine: 20 mg PO, 40 mg PO, 20 mg IVP, 40 mg IVP / **Other:** Cetirizine 10 mg, Loratadine 10 mg

Other: _____

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Drug/Frequency:

KRYSTEXXA® (pegloticase injection) 8 mg in 250 ml Sodium Chloride 0.9% IV over 2 hours via pump every 2 weeks, followed by (1) hour post infusion monitoring after each dose

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

Special orders: _____

If adverse drug reaction occurs, utilize the ADVERSE DRUG REACTION GUIDELINES

5. Physician's Signature: _____ / _____ Date: _____

No Stamp Signatures

(Dispense as written)

(Substitution permitted)

Printed Physician's Name with Credentials: _____ NPI: _____

6. Fax updated supporting clinical MD notes with each order renewal or change in orders

Infusion order forms and Adverse Drug Reaction Guidelines are available at www.palmettoinfusion.com



MRN: _____

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

DOB: _____

Guidelines for Prescribing KRYSTEXXA® (pegloticase injection)

(Required documentation with all initial referrals)

Patient Name: _____

Referral Date: _____

_____ Include signed and completed **Plan of Treatment**. (MD must complete sections 1-6)
 (Infusion order forms & Standard Adverse Reactions orders are available at www.palmettoinfusion.com under Agency/MD tab)

_____ Include patient demographic information and insurance information. (Copy of insurance cards if available)

_____ **Supporting clinical MD notes to include any past tried and/or failed therapies to include xanthine oxidase inhibitors, intolerance, outcomes or contraindications to conventional therapy. Include any lab results and/or tests to support diagnosis.**

- KRYSTEXXA® (pegloticase) is a PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients that are refractory to conventional therapy. Limitations of Use: not recommended for the treatment of asymptomatic hyperuricemia.

_____ Other as requested: _____

Pre-Screening:

_____ **Baseline Serum Uric Acid Level**

_____ **G6PD Serum Level** (Treatment is contraindicated in Glucose – 6 – phosphate dehydrogenase deficient patients)

_____ **Please specify or circle if patient is ordered any prophylaxis gout flare protocol including: Colcrys® (colchicine), oral NSAIDs, and/or corticosteroid treatment.**

_____ (Product information suggested initiating 1 week prior to start of therapy and for 6 months, unless medically contraindicated)

**** Warnings/Precautions:**

- **Anaphylaxis and Infusion Reactions:** 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. Patients should be pre-medicated with antihistamines and corticosteroids. Patients should be closely monitored for an appropriate period of time for anaphylaxis after administration. Monitor patients closely for signs and symptoms of infusion reactions. In the event of an infusion reaction, the infusion should be slowed, or stopped and restarted at a slower rate. If a severe infusion reaction occurs, discontinue infusion and institute treatment as needed. The risk of an infusion reaction is higher in patients who have lost therapeutic response.
- **Gout Flares:** An increase in gout flares is frequently observed upon initiation of anti-hyperuricemic therapy. If a gout flare occurs during treatment, KRYSTEXXA® need not be discontinued. **Gout flare prophylaxis (i.e., non-steroidal anti-inflammatory drugs [NSAID] or colchicine upon initiation of treatment) is recommended for at least the first 6 months of therapy 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 clinical trials experienced exacerbation. Exercise caution when using KRYSTEXXA in patients who have congestive heart failure and monitor patients closely following infusion.
- **Pregnancy Category C.** • See full prescribing information.

Palmetto Infusion Services will complete insurance verification and submit all required clinical documentation to the patient's insurance company for eligibility. Our office will notify you if any further information is required.

We will review financial responsibility with the patient and refer them to any available Co-pay assistance as required. Thank you for the referral.

Please fax all information to 1-866-872-8920 or call 1-800-809-1265 for assistance.