Palmetto Infusion Services COMPLIANCE

MRN:_____

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

DOB:_____

STANDARD KRYSTEXXA® (pegloticase injection) PLAN OF TREATMENT

(Re) Certification Period From_____to _____

NOTE: Patient ***may be ineligible*** to receive KRYSTEXXA® if receiving antibiotics for active infectious process, active fever and/or suspected infection, new or worsening symptoms of CHF, and/or surgery.

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:

Standard premedication of Acetaminophen 650mg PO, Diphenhydramine 25mg IVP, and Methylprednisolone 125mg IVP will be administered prior to infusion unless otherwise noted or selected below:

Alternate option to standard premedication: **a)** Acetaminophen: ☐ 325 mg PO ☐ 500 mg PO or ☐ 1000 mg PO
b) Diphenhydramine: ☐ 25 mg PO ☐ 50mg PO or ☐ 50mg IVP **c)** Methylprednisolone IVP: ☐ 40mg ☐ 62.5mg ☐ _____mg IV
d) Alternate oral antihistamine to diphenhydramine: ☐ Cetirizine 10 mg, ☐ Loratadine 10 mg, Fexofenadine ☐ 60mg ☐ 180mg
e) Famotidine: ☐ 20mg PO, ☐ 40mg PO, ☐ 20mg IVP, ☐ 40mg IVP **f)** Other: _____

Orders: Obtain weight each visit. Instruct patient/caregiver on medications and signs/symptoms of adverse reaction. Assess patient for response to therapy. Utilize existing central line for administration or initiate a peripheral IV with each infusion as needed. Sodium Chloride 0.9% flush 3-10 ml before, after, and as needed during the infusion. Follow infusion with Heparin 100 units/ml 1 – 5 ml per line type or to peripheral IV as required for multiple day treatments. Pump, tubing, 0.22-micron filter, and supplies needed to complete prescribed therapy. Pharmacist to perform clinical drug monitoring. **Extended one (1) hour post infusion monitoring after each treatment.** ***If adverse drug reaction occurs, utilize the ADVERSE DRUG REACTION GUIDELINES.***

Drug/Frequency:

KRYSTEXXA 8mg in 250 ml Sodium Chloride 0.9% IV over 2 hours via pump every 2 weeks

Other: 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: _____

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 available at www.palmettoinfusion.com

Revised 4/26/18

Palmetto Infusion Services COMPLIANCE

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.