SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Krystexxa® (pegloticase) **(J2507) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Recommended Dosage: IV: 8 mg every 2 weeks as monotherapy (if methotrexate is contraindicated or not clinically appropriate) or co-administered with weekly oral methotrexate and folic acid or folinic acid supplementation; begin methotrexate and folic acid/folinic acid at least 4 weeks prior to starting pegloticase. Note: Discontinue pegloticase if pre-infusion serum uric acid levels initially decrease but subsequent pre-infusion levels rebound to > 6 mg/dL, especially if 2 consecutive levels of > 6 mg/dL are observed.

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- ❑ Prescriber is a rheumatologist or nephrologist
- ❑ Member has baseline serum uric acid level ≥ 8 mg/dL **(must submit labs from within the last 30 days)**
- ❑ Member has undertaken lifestyle modifications to lower uric acid levels (e.g., weight loss for obese individuals or avoidance/limitation of alcohol consumption, limited dietary intake of meats or fish high in purine content)
- ❑ Member has symptomatic hyperuricemia with the presence of at least **ONE** of the following **(must submit documentation)**:
  - ❑ ≥ 1 non-resolving subcutaneous tophi
  - ❑ 2 or more gout flares per year that were inadequately controlled by colchicine, nonsteroidal anti-inflammatory drugs (NSAIDS), or oral or injectable corticosteroids
  - ❑ Radiographic damage of any modality that is attributable to gout
- ❑ Member must have a 3-month trial and failure (failure defined as serum uric acid not being reduced to < 6 mg/dL) with **ONE** of the following medications used within the last 6 months **(verified by pharmacy paid claims)**:
  - ❑ allopurinol (maximally dosed at 400-800 mg/day)
  - ❑ febuxostat
- ❑ Provider attests Krystexxa will **NOT** be prescribed for members with asymptomatic hyperuricemia or Glucose-6-phosphate dehydrogenase (G6PD) deficiency
- ❑ Medication must be used in combination with methotrexate unless clinically significant contraindication or therapy intolerance exists **(must submit documentation of contraindication or intolerance)**
- ❑ Provider attests antihistamines and corticosteroids will be administered prior to infusion of Krystexxa®
- ❑ Provider must note requested dosage regimen: _____

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Prescriber is a rheumatologist or nephrologist
- ❑ Member has experienced a positive clinical response to therapy (i.e., reduction of gout flares, reduction of tophi, reduction of joint pain) **(must submit documentation of clinical response to therapy)**

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- ❑ Member has experienced an absence of unacceptable toxicity from the drug (e.g., anaphylaxis, hypersensitivity or infusion reactions, exacerbation of congestive heart failure)
- ❑ Medication must be used in combination with methotrexate unless clinically significant contraindication or therapy intolerance exists **(must submit documentation of contraindication or intolerance)**
- ❑ Provider must submit documentation that serum uric acid level is < 6 mg/dL prior to scheduled infusion **(must submit 2 recent serum uric acid level test results, one of which was completed within the last 30 days)**
- ❑ Medication will be discontinued if serum uric acid levels increase to above 6 mg/dL on 2 consecutive lab tests

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.

***Approved by Pharmacy and Therapeutics Committee:** ~~3/17/2011; 9/15/2022;~~ **11/16/2023**
REVISED/UPDATED/REFORMATTED: ~~9/19/2011; 10/4/2011; 3/1/2012; 4/19/2012; 10/9/2012; 4/9/2014; 8/20/2014; 10/31/2014; 4/3/2015; 5/23/2015; 12/30/2015; 1/29/2016; 8/18/2016; 9/22/2016; 12/11/2016; 7/24/2017; 5/24/2018; 3/17/2019; 4/30/2019; 7/7/2019; 7/18/2019; 9/24/2019; 6/30/2021; 10/4/2022; 11/9/2023;~~ **12/11/2023**