POLICY Document for KRYSTEXXA (pegloticase)

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, lower cost site of care and overall, clinically appropriate use. This document provides specific information to each of the three sections of the overall policy.

Section 1: Site of Care

- Policy information specific to site of care (outpatient, hospital outpatient, home infusion)

Section 2: Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

Section 1: Site of Care

Site of Care Criteria
Krystexxa

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Krystexxa	pegloticase	intravenous

Criteria For Approval For Administration In Outpatient Hospital Setting

This policy provides coverage for administration of Krystexxa in an outpatient hospital setting for up to 57 days when a member is new to therapy or is reinitiating therapy after not being on therapy for at least 6 months.

This policy provides coverage for administration of Krystexxa in an outpatient hospital setting for a longer course of treatment when ANY of the following criteria are met:

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- The member has experienced an adverse reaction to the drug that did not respond to conventional interventions (eg, acetaminophen, steroids, diphenhydramine, fluids, other pre-medications or slowing of infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion.
- The member has developed laboratory confirmed anti-pegloticase antibodies which increases the risk for infusion related reactions
- The member is medically unstable (eg respiratory, cardiovascular, or renal conditions).
- The member has severe venous access issues that require the use of special interventions only available in the outpatient hospital setting.
- The member has significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver.
- Alternative infusion sites (pharmacy, physician office, ambulatory care, etc.) are greater than 30 miles from the member's home.
- The member is less than 14 years of age.

For situations where administration of Krystexxa does not meet the criteria for outpatient hospital infusion, coverage for Krystexxa is provided when administered in alternative sites such as physician office or ambulatory care.

Required Documentation

The following information is necessary to initiate the site of care prior authorization review (where applicable):

- Medical records supporting the member has experienced an adverse reaction that did not respond to conventional interventions or a severe adverse event during or immediately after an infusion
- Medical records supporting the member has developed anti-pegloticase antibodies
- Medical records supporting the member is medically unstable
- Medical records supporting the member has severe venous access issues that requires specialized interventions only available in the outpatient hospital setting
- Medical records supporting the member has behavioral issues and/or physical or cognitive impairment and no access to a caregiver
- Records supporting alternative infusion sites are greater than 30 miles from the member's home.
- Medical records supporting the member is new to therapy

Section 2: Clinical Criteria

CAREFIRST: KRYSTEXXA

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Client Requested: The intent of the criteria is to ensure that patients follow selection elements as established by CareFirst.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

A. Initial criteria: Authorization of 6 months may be granted for members with a diagnosis of chronic gout when ALL of the following criteria are met:
   1. Member is 18 years of age or older.
   2. Krystexxa will NOT be used concomitantly with oral urate-lowering therapies.
   3. The member has at least 2 gout flares per year that were inadequately controlled by colchicine or NSAIDs or at least 1 gout tophus or gouty arthritis.
   4. Member has had an inadequate response to or a clinical reason for not completing at least a three-month trial (see Appendix) with the following medications at the medically appropriate maximum doses:
      i. Allopurinol or febuxostat
      ii. Probenecid (alone or in combination with allopurinol or febuxostat)

B. Continuation criteria: Authorization of 12 months may be granted for continued treatment in all members (including new members) requesting reauthorization for chronic gout when ALL of the following criteria are met:
   1. Member has taken Krystexxa for less than 18 months
   2. Member meets ALL initial authorization criteria
   3. Member has NOT had two consecutive uric acid levels above 6 mg/dL since starting treatment with Krystexxa
   4. Member is experiencing benefit from therapy (e.g., serum uric acid levels < 6 mg/dL, reduction of tophi, reduction of symptoms and/or flares). Documentation (e.g., chart notes, lab test results) of a response to therapy (e.g., serum uric acid levels < 6 mg/dL, reduction of tophi, reduction of symptoms and/or flares) must be submitted.

C. Appendix: Clinical reasons for not completing a three-month trial with allopurinol, febuxostat, and probenecid (examples, not all inclusive):
   1. Member experienced a severe allergic reaction to the medication
   2. Member experienced toxicity with the medication
   3. Member could not tolerate the medication
   4. Member's current medication regimen has a significant drug interaction
   5. Member has severe renal dysfunction (allopurinol)
   6. Member has known blood dyscrasias or uric acid kidney stones (probenecid)
   7. Member has renal insufficiency (i.e., glomerular filtration rate 30 mL/minute or less) (probenecid)
   8. Member has end stage renal impairment (febuxostat)
   9. Member has a history of CVD or a new CV event (febuxostat)

All other indications are considered experimental/investigational and not medically necessary.

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REFERENCES

SECTION 1

1. Krystexxa [package insert]. Dublin, Ireland: Horizon Therapeutics; November 2022.
2. Calabrese LH, Kavanaugh A, Yeo AE, Lipsky PE. Frequency, distribution and immunologic nature of infusion reactions in subjects receiving pegloticase for chronic refractory gout. Arthritis Res Ther. 2017 Aug 17;19(1):191.

SECTION 2

1. Krystexxa [package insert]. Dublin, Ireland: Horizon Therapeutics; November 2022.
2. Calabrese LH, Kavanaugh A, Yeo AE, Lipsky PE. Frequency, distribution and immunologic nature of infusion reactions in subjects receiving pegloticase for chronic refractory gout. *Arthritis Res Ther*. 2017 Aug 17;19(1):191.

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