Medical Policy:

Krystexxa® (pegloticase) intravenous infusion

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.225	February 7, 2024	2016

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Krystexxa, a PEGylated uric acid specific enzyme, is indicated for treatment of chronic gout refractory to conventional therapy, in adult patients. Krystexxa has a Boxed Warning due to concerns for hemolysis and methemoglobinemia, in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency.

Length of Authorization

Initial-6 months

Continuation-12 months

Dosing Limits [Medical Benefit]

Approve 8 mg as an intravenous infusion every 2 weeks. (16 billable units every 28 days)

Guideline

1. **Gout, Chronic.** Approve for the duration noted below if the patient meets ONE of the following conditions (A or B):

A. Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, and iii):
   i. Patient has at least one tophus OR a history of 2 previous flares in the past year (prior to the current flare); **AND**
   ii. Patient meets one of the following conditions (a or b):
      a. Patient had an inadequate response, defined as serum uric acid level that remained > 6 mg/dL following a 3-month trial of a xanthine oxidase inhibitor ; **OR**
         Note: Examples of xanthine oxidase inhibitor include allopurinol and febuxostat.
      b. Patient has a contraindication or has had an intolerance to a trial of allopurinol, as determined by the prescriber; **AND**
   iii. Patient meets one of the following conditions (a or b):
      a. Patient had an inadequate response, defined as serum uric acid level that remained > 6 mg/dL following a 3-month trial of a uricosuric agent; **OR**
         Note: Examples of uricosuric agents include probenecid, fenofibrate, and losartan.
      b. According to the prescriber, the patient has renal insufficiency (e.g., decreased glomerular filtration rate); **AND**
   iv. Krystexxa will be used in combination with ONE of the following (a, b, or c):
      a. Methotrexate; **OR**
      b. Leflunomide; **OR**
      c. Azathioprine; **AND**
   v. Krystexxa will not be used in combination with another uric acid lowering drug.
      Note: Examples of uric acid lower drugs include allopurinol, febuxostat, or probenecid.
   vi. Krystexxa is prescribed by or in consultation with a rheumatologist or a nephrologist.

B. Patient is Currently Receiving Krystexxa. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
   i. Patient is continuing therapy with Krystexxa to maintain response/remission; **AND**
   ii. Patient has responded to therapy with evidence of serum uric acid level < 6 mg/dL with continued Krystexxa treatments; **AND**
   iii. Krystexxa is being used in combination with ONE of the following (a, b, or c):
      a. Methotrexate; **OR**
      b. Leflunomide; **OR**
      c. Azathioprine; **AND**
   iv. Krystexxa is not being used in combination with another uric acid lowering drug.
      Note: Examples of uric lower drugs include allopurinol, febuxostat, or probenecid.
   iv. Krystexxa is prescribed by or in consultation with a rheumatologist or a nephrologist.

Applicable Procedure Codes

Code	Description
J2507	Injection, pegloticase, 1 mg

Applicable NDCs

Code	Description
75987-0080-10	Krystexxa 8mg/mL

ICD-10 Diagnoses

Code	Description
M1A.9XX1	Chronic Gout, unspecified

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/7/2024	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	4/4/2023	Transfer form CCUM Template to Medical CoBranded Template Retired MG.MM.PH.225
EmblemHealth & ConnectiCare	11/9/2022	Gout, Chronic: Initial Therapy. The requirement for current symptoms of gout was changed to require at least one tophus OR a history of 2 previous flares in the past year (prior to the current flare). Criterion requiring a 3-month trial of at least one of allopurinol, Uloric, or a uricosuric agent was changed to separate criteria to require a 3-month trial of both a xanthine oxidase inhibitor and a uricosuric agent. Notes were added to both criterion to give examples of each. Initial Therapy and Continuation of Therapy. Criteria were added to require: Krystexxa will be used in combination with either methotrexate, leflunomide, or azathioprine; and Krystexxa will not be used with another uric acid lowering drug with a Note providing examples. Nephrolithiasis and/or Gouty Nephropathy: The condition and criteria were removed from the Other Uses with Supportive Evidence section of the policy.
EmblemHealth & ConnectiCare	5/4/2022	Annual Revision: No criteria changes
EmblemHealth & ConnectiCare	5/12/2021	Annual Revision: Gout, Chronic: For the exception applying to a patient with a contraindication or an intolerance to a trial of allopurinol, wording was updated to more generally allow this determination by the prescriber (criteria previously specified this was according to the prescribing physician). To align more with product labeling, Dosing was changed from administration “no sooner than every 2 weeks” to “every 2 weeks”. Nephrolithiasis and/or Gouty Nephropathy: For the exception applying to a patient with a contraindication or an intolerance to a trial of allopurinol, wording was updated to more generally allow this determination by the prescriber (criteria previously specified this was according to the prescribing physician). To align more with product labeling, Dosing was changed from administration “no sooner than every 2 weeks” to “every 2 weeks”.

References

1. Krystexxa™ intravenous infusion [prescribing information]. Lake Forest, IL: Horizon Therapeutics; May 2021.