Original Effective Date: 06/2013
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Last P&T Approval/Version: 01/31/2024
Next Review Due By: 10/2024
Policy Number: C2729- A

Krystexxa (pegloticase)

PRODUCTS AFFECTED

Krystexxa (pegloticase)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Chronic Gout

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. CHRONIC GOUT:
1. Documented diagnosis of gout
   AND

2. Documentation of ONE of the following:
   (a) At least 2 gout flares in the previous 12 months
   OR
   (b) A history of at least 1 gouty tophus
   OR
   (c) Chronic gouty arthropathy
   AND
3. Documentation of baseline serum uric acid level >6mg/dL [DOCUMENTATION REQUIRED]
   AND
4. Documentation of trial and failure, serious side effects or contraindication to TWO of the following for maintenance treatment of gout, at a maximum tolerated dose or an adequate therapeutic dose for 3 months: allopurinol (maximum dose 800 mg/day) OR a probenecid containing medication (e.g., probenecid or probenecid-colchicine) OR febuxostat
   ****Clinical failure is defined as the inability to maintain serum uric acid (SUA) level ≤ 6 mg/dL after reaching the maximum tolerated dose or an adequate therapeutic dose****
   AND
5. Prescriber attests that member will NOT concurrently be receiving other urate lowering therapies such as allopurinol, febuxostat, probenecid, etc.
   AND
6. Prescriber attests that member has been screened for higher risk for glucose 6 phosphate dehydrogenase (G6PD) deficiency
   AND
7. Prescriber attests that member will be pre-medicated with antihistamines and corticosteroids and closely monitored for anaphylaxis for an appropriate period of time after administration of Krystexxa.
   NOTE: 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.
   AND
8. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Krystexxa (pegloticase) include: patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency, patients with history of serious hypersensitivity reactions, including anaphylaxis, to Krystexxa or any of its components]

CONTINUATION OF THERAPY:

A. CHRONIC GOUT:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documented positive response to Krystexxa (pegloticase) treatment, including, but not limited to: reduction in serum uric acid levels compared to baseline or reduction in gout flares [DOCUMENTATION REQUIRED]
   AND
4. Prescriber attests, or clinical reviewer has found, that the member has not had 2 consecutive uric acid levels >6 mg/dL while on therapy
   NOTE: Members with documented serum uric acid concentrations (prior to their next infusion) of greater than 6 mg/dl on more than one occasion during treatment must discontinue treatment with pegloticase. The risk of infusion reaction is higher in members whose uric acid level increases to above 6 mg/dL, particularly when 2 consecutive levels above 6 mg/dL are observed. Monitor

serum uric acid levels prior to infusions and consider discontinuing treatment if levels increase to above 6 mg/dL despite treatment.
AND

5. Prescriber attests that member is NOT concurrently receiving other urate lowering therapies such as allopurinol, febuxostat, probenecid, etc.
AND
6. Prescriber attests that member will be pre-medicated with antihistamines and corticosteroids and closely monitored for anaphylaxis for an appropriate period of time after administration of Krystexxa.
NOTE: Anaphylaxis may occur with any infusion, and generally manifests within 2 hours of the infusion. However, delayed type hypersensitivity reactions have also been reported.

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of therapy: 12 months

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a rheumatologist or nephrologist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
18 years of age or older

QUANTITY:
8mg every 2 weeks

PLACE OF ADMINISTRATION:
The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-hospital facility-based location as per the Molina Health Care Site of Care program.

Note: Site of Care Utilization Management Policy applies for Krystexxa (pegloticase). For information on site of care, see Specialty Medication Administration Site of Care Coverage Criteria (molinamarketplace.com)

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous

DRUG CLASS:
Gout Agents

FDA-APPROVED USES:
Indicated for the treatment of chronic gout in adult patients refractory to conventional therapy.
Limitations of Use: Krystexxa is not recommended for the treatment of asymptomatic hyperuricemia

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Pegloticase (Krystexxa™) has been indicated for the treatment of chronic gout in adult members refractory to conventional therapy. Pegloticase (Krystexxa™) is a PEGylated uric acid-specific enzyme that reduces serum uric acid levels by catalyzing the oxidation of uric acid to allantoin. Pegloticase is a PEGylated uric acid-specific enzyme that consists of recombinant modified mammalian urate oxidase produced by a genetically modified strain of Escherichia coli (Krystexxa prescribing information, 2010). It is approved for the treatment of chronic gout in adult member s' refractory to conventional therapy.
Krystexxa is not recommended for the treatment of asymptomatic hyperuricemia

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Krystexxa (pegloticase) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Krystexxa (pegloticase) include: Patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency, patients with history of serious hypersensitivity reactions, including anaphylaxis, to Krystexxa or any of its components.

OTHER SPECIAL CONSIDERATIONS:

Krystexxa (pegloticase) has a black box warning for anaphylaxis and infusion reactions, G6PD deficiency associated hemolysis and methemoglobinemia.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J2507	Injection, pegloticase,1 mg

AVAILABLE DOSAGE FORMS:

Krystexxa SOLN 8MG/ML single-dose vial

REFERENCES

1. Krystexxa [package insert]. Deerfield, IL: Horizon Therapeutics USA Inc; November 2022.
2. Khanna, D., et al. 2012 American College of Rheumatology Guideline Management of Gout part 1. Arthritis Care & Research: Vol 64, No 10, October 2012, pp 1431-1446.
3. Sivera F, Andres M, Carmona L et al. Recommendations for the Diagnosis and Management of Gout. Ann Rheum Dis 2014; 73(2):328-335.
4. Qaseem Amir, et al. Management of Acute and Recurrent Gout: A Clinical Practice Guideline from the American College of Physicians. Ann Intern Med. Doi: 10.7326/M16-0570. November 2016.
5. FitzGerald, J., Dalbeth, N., Mikuls, T., Brignardello-Petersen, R., Guyatt, G., & Abeles, A. et al. (2020). 2020 American College of Rheumatology Guideline for the Management of Gout. Arthritis Care & Research, 72(6), 744-760. doi: 10.1002/acr.24180

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Quantity	Q1 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Quantity FDA-Approved Uses	Q4 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Prescriber Requirements FDA-Approved Uses Contraindications/Exclusions/Discontinuation Other Special Considerations References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file