



Effective Date: 06/2013
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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

A. CHRONIC GOUT

1. Documented diagnosis 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

Drug and Biologic Coverage Criteria

- AND
- Documentation of baseline serum uric acid level >6mg/dL
- AND
- Documentation of a therapeutic trial and clinical failure of TWO of the following for maintenance treatment of gout, at a maximum tolerated dose or an adequate therapeutic dose for 3 months: allopurinol [Maximum Doses: Alopurinol® 600 mg/day; Zylorprim® 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 \leq 6 mg/dL after reaching the maximum tolerated dose or an adequate therapeutic dose****
- AND
- Prescriber attests that member will NOT concurrently be receiving other urate lowering therapies such as allopurinol, febuxostat, probenecid, lesinurad, etc.
- AND
- Prescriber attests that member has been screened for higher risk for glucose 6 phosphate dehydrogenase (G6PD) deficiency and found negative for G6PD before starting Krystexxa.

CONTINUATION OF THERAPY:

A. CHRONIC GOUT

- 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 (documentation required)
- AND
- Documentation of no intolerable adverse effects or drug toxicity
- AND
- Documented positive response to Krystexxa® (pegloticase) treatment, including, but not limited to: reduction in serum uric acid levels compared to baseline or reductions in gout flares
- AND
- Prescriber attests 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 member s 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.

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a rheumatologist or nephrologist (submit consultation notes if applicable)

AGE RESTRICTIONS:

18 years of age or older

QUANTITY:

Quantity limitation: maximum of twelve (12) infusions for 6 months; maximum of twenty-six (26) infusions for 12 months. [Krystexxa 8mg IV every two (2) weeks. Dose not to exceed one 8mg infusion 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 \(molinamarketplace.com\)](https://www.molinamarketplace.com/specialty-medication-administration-site-of-care-coverage-criteria)

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Intravenous

DRUG CLASS:

Gout Agents

FDA-APPROVED USES:

Gout: For the treatment of long-term gout in adult member's refractory to conventional therapy.

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 the Krystexxa (pegloticase) that are not an FDA-approved indication are considered experimental/investigational and is not a covered benefit. The following list may not be all-inclusive and is subject to change based on research and medical literature

OTHER SPECIAL CONSIDERATIONS:

None

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

HCPDS CODE	DESCRIPTION
J2507	Injection, pegloticase, 1 mg

AVAILABLE DOSAGE FORMS:

Krystexxa SOLN 8MG/ML (1ml vial)

REFERENCES

1. Krystexxa [package insert]. . Deerfield, IL: Horizon Therapeutics; March 2021.
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. Rothschild BM. Gout and Psuedogout. Medscape.
4. Sivera F, Andres M, Carmona L et al. Recommendations for the Diagnosis and Management of Gout. Ann Rheum Dis 2014; 73(2):328-335.
5. 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.