COMMUNITY HEALTH CHOICE

Krystexxa (Pegloticase)

Effective Date: 11/1/2025
Medical Care Management Committee Approval: 8/21/2025

Contents

Coverage Policy

This Medical Review Guideline (Guideline) is provided for informational purposes only and does not constitute medical advice. It is intended solely for the use of Community Health Choice, Inc. (Community) clinical staff as a guideline for use in determining medical necessity of requested procedures, medications and therapy. This Guideline does not address eligibility or benefit coverage. Other Policies and Coverage Determination Guidelines may apply. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Medical Review Guideline. If there is a discrepancy between this Guideline and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern. Community reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

This policy applies to the following Krystexxa (Pegloticase) product:

HCPCS Code	Description	Maximum Dosage per Administration
J2507	Injection, pegloticase, 1mg	8 mg

Diagnosis-Specific Criteria

Krystexxa **(**pegloticase**)** will be considered medically necessary and approved for 6 months duration for members meeting ALL of the following criteria:

1. Age 18 years or older
2. Diagnosis of symptomatic gout as evidenced by either:
    a. Presence of at least one tophus; OR
    b. At least 2 gout flares within the past 12 months prior to current active flare
3. Prescribed by or in consultation with a rheumatologist or nephrologist
4. Documented intolerance, contraindication or inadequate response (documented uric acid > 6mg/dL after at least 3 months on therapy) to BOTH of the following:
    a. Xanthine oxidase inhibitor: Allopurinol, Febuxostat (must have tried BOTH at max dose)
    b. Uricosuric agent: Probenecid, Fenofibrate, Losartan (trial of at least one in combination with

a xanthine oxidase inhibitor)

5. Krystexxa will be used in combination with Methotrexate or documentation of contraindication to methotrexate
6. Evidence of currently elevated uric acid >6mg/dL (documentation required)

Continuation Criteria; approval of 6 months

1. Previously approved by Community Health Choice or another health plan (as evidenced by documentation of a paid claim within 3 months prior to authorization request), OR meeting all initial request criteria above.
2. Documentation of beneficial response to therapy as evidenced by either:
    a. Uric acid <6 mg/dL ; OR
    b. Documented resolution of 1+ tophi
3. Krystexxa will be used in combination with Methotrexate unless documented contraindication

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive.

HCPCS Code	Description
J2507	Injection, pegloticase, 1mg

Diagnosis Code	Description
M1A.00X0 - M1A.09X1	Idiopathic chronic gout
M1A.10X0 - M1A.19X1	Lead-induced chronic gout
M1A.20X0 - M1A.29X1	Drug-induced chronic gout
M1A.30X0 - M1A.39X1	Chronic gout due to renal impairment
M1A.40X0 - M1A.49X1	Other secondary chronic gout
M1A.9XX0 - M1A.9XX1	Chronic gout, unspecified

Policy Revision History

Status	Effective Date	Description
Baseline	10/1/25	Initial version of pegloticase diagnosis specific policy