

pegloticase (Krystexxa)

HCPCS: J2507 Injection, pegloticase, 1 mg (Krystexxa)

LOB:	MCAL
Duration of Approval:	Six months
Quantity Limit:	Per FDA Approved/Compendia Supported Dosing
MCG Available:	Yes
DHCS Drug Policy:	No

Requires Prior Authorization (PA)

Krystexxa (pegloticase) injection

PA CRITERIA FOR APPROVAL:**New Therapy**

1. The member has a diagnosis for an FDA-approved indication (refer to package insert under References) OR a compendia-supported (Drugdex or AHFS) indication **AND**
2. The medication was prescribed by a rheumatologist or nephrologist **AND**
3. Documentation of a baseline serum uric acid level of >7 mg/dL **AND**
4. Documentation of symptomatic gout defined by ONE or more of the following:
 - a. ≥ Two gout flares in the prior 12 months that were inadequately controlled by colchicine (Colcrys), non-steroidal anti-inflammatory drugs (e.g., indomethacin, sulindac or naproxen) or corticosteroids (e.g., prednisone, prednisolone or methylprednisolone)
 - b. ≥ One gout tophus confirmed by photographs/images of affected joints
 - c. Gouty arthropathy or arthritis confirmed by radiographic imaging results (such as X-rays, MRI, polarized light microscopy)

AND

5. The member does not have Glucose-6-phosphate dehydrogenase (G6PD) deficiency as indicated by ONE of the following:
 - a. The member is at high risk for G6PD deficiency (e.g., of Mediterranean or African ancestry) and has been screened and confirmed negative for G6PD deficiency
 - b. The member is not high risk for G6PD deficiency

AND

6. The member has a history of failure (defined as a failure to reduce serum uric acid to <6 mg/dL), contraindications (refer to Appendix for comorbidities) or reasons for intolerance for not using up to maximum dosage (such as severe allergic reactions or toxicity) of the following for ≥ three months:
 - a. Allopurinol (up to 800 mg/day) or febuxostat (Uloric up to 80 mg/day)
 - b. Probenecid (alone or in combination with allopurinol or febuxostat)

AND

7. Member is not receiving other urate-lowering therapies (i.e., allopurinol, febuxostat or probenecid)

Continuation of Therapy

1. The member has a diagnosis for an FDA-approved indication (refer to package insert under References) OR a compendia-supported (Drugdex or AHFS) indication **AND**
2. Documentation of serum uric acid level of <6 mg/dL after ≥three months of continuous Krystexxa therapy **AND**
3. Documentation of clinical improvement (e.g., reduction in flares, reduction of tophi, reduction in joint pain) **AND**
4. Member is not receiving other urate-lowering therapies (i.e., allopurinol, febuxostat or probenecid)

(Note: Per Krystexxa prescribing information [PI], discontinuation should be considered once therapeutic goals have been reached [best results seen after six to 12 months of treatment]. **Please request for the treatment duration and reasons for continuation if member has received at least 12 months of therapy.**)

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Appendix**For members with comorbidities, refer to the table for recommended dosing and treatments (not all inclusive):**

Clinical Reasons	Notes
Renal insufficiency/ESRD	Allopurinol: Allopurinol ≤ 100 mg/day can be used in CKD stage ≥ 3. Allopurinol is recommended over probenecid in moderate-to-severe CKD (stage ≥ 3). Febuxostat: Febuxostat ≤ 40 mg/day can be used in CKD stage ≥ 3. Febuxostat is recommended over probenecid in moderate-to-severe CKD (stage ≥ 3). Probenecid: Low-dose probenecid 500 mg (qd or bid) can be used. However, Allopurinol or febuxostat are recommended over probenecid in moderate-to-severe CKD (stage ≥ 3). Probenecid may not be effective in estimated glomerular filtration rate (eGFR) ≤ 30 mL/minute.
Cardiovascular disease	Febuxostat: Not contraindicated. Per PI, a higher rate of cardiovascular thromboembolic events was observed in patients treated with Febuxostat. Monitoring for signs and symptoms of myocardial infarction (MI) and stroke is recommended. Krystexxa: Exacerbation of congestive heart failure.
Hepatic disease	Febuxostat: Should not be used if the member has alanine aminotransferase (ALT) or aspartate aminotransferase (AST) $> 3\times$ the upper limit of normal (ULN) and serum total bilirubin $> 2\times$ ULN in the clinical context of potential liver injury (e.g., fatigue, anorexia, right upper quadrant pain, dark urine, jaundice). Febuxostat has not been studied in patients with severe hepatic impairment (Child-Pugh Class C). Probenecid: Hepatic necrosis reported.
Uric acid kidney stones	Probenecid: Is contraindicated
Combo therapy	Probenecid with methotrexate (MTX): Increases plasma concentrations of MTX. In animal studies, increased MTX toxicity has been reported. If probenecid is given with MTX, the dosage of MTX should be reduced and serum levels may need to be monitored. Probenecid with Salicylates: Is contraindicated Febuxostat with azathioprine or mercaptopurine: Is contraindicated

OTHER INFORMATION:

HCPCS	Description	Brand name
J2507	Injection, pegloticase, 1 mg	Krystexxa

REFERENCES:

1. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout. [pmc.ncbi.nlm.nih.gov/articles/PMC10563586/pdf/nihms-1930632.pdf](https://pubmed.ncbi.nlm.nih.gov/articles/PMC10563586/pdf/nihms-1930632.pdf)
2. Krystexxa Prescribing Information: www.hzndocs.com/KRYSTEXXA-Prescribing-Information.pdf. 08/2025.

P&T APPROVAL HISTORY:

May 2017 P&T Drug Review

UMC REVIEW:

4/2026