Effective Date: 12.21.2022

Nevada Health Solutions LLC

NHS MEDICAL POLICY

Krystexxa (pegloticase)
Medicine 2022-004

Mechanism of Action: Oxidizes uric acid to something else (allantoin) thereby lowering uric acid.

A. May be indicated when ALL the following are met:

1	Diagnosis: Chronic, symptomatic Gout in adult patient's refractory to conventional therapy
2	Prescribed by or in consultation with rheumatologist or nephrologist
3	Individuals is 18 years of age or older AND
4	Individual has 1 or more of the following: A. History of at least gout flares in the previous 12 months B. One or more tophus present OR C. History of gouty arthropathy, defined clinically or radiographically as joint damage due to gout AND
5	Documentation is provided that individual has confirmed baseline serum uric acid of 6 mg/dl or greater prior to initiating
6	Documentation is provided that the individual has failed to respond to, is intolerant of, or has a medical contraindication to 1 or more of the following conventional therapies: A. A xanthine oxidase inhibitor (allopurinol or febuxosat) at maximum medically appropriate dose OR B. Combination therapy of 1 xanthine oxidase inhibitor given with a uricosuric agent (for example, probenecid)
7	Krystexxa (pegloticase) may **not** be approved for the following: A. Individual has asymptomatic hyperuricemia or B. Individual has a known glucose 6 dehydrogenase (G6PD) deficiency or C. May not be approved when the above criteria are not met and for all other indications
8	Initial Approval length – 12 months. Reauthorization required based on clinical presentation.

B. Continuation requests for Krystexxa (pegloticase) may be approved if the following criteria is met:

1	This is confirmation of clinically significant improvement in clinical signs and symptoms of disease (including but not limited to reduction in serum uric acid level, gout flare reduction, tophus resolution, reduction in joint pain)

C. Medication Guidelines

Drug	Dosing Regimen	Dose Limit/Maximum Dose
allopurinol (Aloprim® / Zyloprim®)	Gout: (mild) 100 to 300 mg/day PO as a single or divided dose (2-3 times daily) Gout: (moderate to severe) 400 to 600 mg/day PO as a single or divided dose (2-3 times daily)	800 mg /day
colchicine (Colcrys®)	Gout flare - Treatment 1.2 mg PO at the first sign of flare followed by 0.6 mg one hour later. Gout flare - Prophylaxis 0.6 mg PO QD to BID	Treatment – 1.8 mg over 1 hour Prophylaxis – 1.2 mg/day Maximum dose in patients with risk factors for colchicine toxicity (e.g., elderly, renal or hepatic impairment, weight < 50 kg): Severe renal impairment (< 30 ml/min CrCl) and hepatic impairment: do not repeat course more than once every 2 weeks
febuxostat (Uloric®)	Hyperuricemia – Chronic Management: 40 mg PO QD; may be increased to 80 mg PO QD if serum uric acid levels are not less than 6 mg/dL after 2 weeks.	Specific maximum dosage information is not available; doses of up to 120 mg PO daily have been used in clinical trials
probenecid (Benuryl®)	Hyperuricemia – Initial: 250 mg PO BID for 1 week Hyperuricemia – Prophylaxis: 500 mg PO BID; if symptoms persist or 24-hour urate excretion is below 700mg,	2000 mg/day

	may incrementally increase by 500 mg every 4 weeks as tolerated or otherwise contraindicated.	
Krystexxa®	8 mg IV over 2 hours every 2 weeks Before receiving each Krystexxa dose, patients should be pre-medicated with an oral antihistamine, IV corticosteroid, and acetaminophen. Patients should also receive prophylaxis for gout flares with an NSAID and/or colchicine starting 1 week prior to initiating therapy unless not tolerated or otherwise contraindicated. Serum uric acid levels should be monitored before each infusion. Krystexxa should be diluted and only be administered by intravenous infusion over no less than 120 minutes via gravity feed, syringe-type pump, or infusion pump. Krystexxa should be administered in a healthcare setting by healthcare providers prepared to manage anaphylaxis.	

PROPRIETARY POLICY

SOURCES

Anthem Blue Cross Blue Shield (2022, June 20) Retrieved from Clinical Criteria Page: https://www.anthem.com/ms/pharmacyinformation/Krystexxa.pdf

Fernando Perez-Ruiz MD, P. (2022, August 03) Pharmacologic urate-lowering therapy and treatment of tophi in patients with gout. Retrieved from UpToDate: https://www.uptodate.com/contents/pharmacologic-urate-lowering-therapy-andtreatment-of-tophi-in-patients with gout?search=Krystexxa&source=searchTitlr=2-10&usage_type=default&display_rank=1

Lexicomp. (n.d) Pegloticase Drug Information. Retrieved from UpToDate: https//www.uptodate.com/contents/pegloticase-drug information?search=Krystexxa&source=panel_search_results&selectedTitle=1-10&usage_type=panel&p_tab=drug_general&display_rank=1.

CODE REFERENCE (This may not be a comprehensive list of codes to apply to this policy.)

J2507

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
12/20/2023	Annual review and approval by UM/QM Committee
12/23/2024	Annual review and approval by UM/QM Committee
09/30/2025	Annual review and approval by UM/QM Committee
09/29/2026	Annual review and approval by UM/QM Committee