

Gout Agents

WA.PHAR.40 Gout Agents

Effective Date: March 1, 2021

Note: New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit:

https://pharmacy.envelopehealth.com/content/dam/centene/envelope-pharmacy-solutions/pdfs/PDL/FORMULARY-CoordinatedCare_Washington.pdf

Background:

Gout is a crystalline arthropathy predominantly observed in patients 30 to 50 years old and is more common in men than in women. Gout is caused by either an over-production or an under-excretion of uric acid. This results in deposits of monosodium urate crystals in joints and soft tissue. The disease is often, but not always, associated with increased blood uric acid levels.

Symptoms of gout include recurrent inflammatory arthritis; the development of tophi, and uric acid urolithiasis. Acute gout most commonly affects the first metatarsal joint of the foot, but other joints may be affected, such as the small joints of the hands, wrists, and elbows.

Medical necessity

Drug	Medical Necessity
Febuxostat (Uloric) Pegloticase (Krystraxa)	Febuxostat and pegloticase may be considered medically necessary when used for the treatment of symptomatic hyperuricemia associated with gout.

Clinical policy:

Clinical Criteria	
Febuxostat (Uloric)	Febuxostat, may be covered when ALL of the following are met: <ol style="list-style-type: none"> 1. Diagnosis of symptomatic hyperuricemia associated with gout confirmed by ONE of the following: <ol style="list-style-type: none"> a. Measurement of blood uric acid levels b. Measurement of erythrocyte sedimentation rate c. Polarized light microscopy for identification of crystal in synovial fluids obtained from joints or bursas (as well as material aspirated from tophaceous deposits, if any) d. Magnetic resonance imaging for gouty tophus 2. Is NOT used for the treatment of asymptomatic hyperuricemia

	<ol style="list-style-type: none"> 3. Greater than or equal to (\geq) 3 gout flares in the previous 18 months that were inadequately controlled by colchicine, corticosteroids, or non-steroidal anti-inflammatory drugs (NSAIDs), or at least 1 gout tophus or gouty arthritis 4. Trial and failure (normalize serum uric acid to less than 6 mg/dL) for at least 3 months, contraindication or intolerance to allopurinol at maximum tolerated dose 5. Medications known to precipitate gout attacks have been discontinued/changed when possible 6. Client will NOT be receiving treatment with azathioprine or mercaptopurine 7. An assessment of cardiovascular risk factors to determine the benefits and risks associated with beginning febuxostat for the patient. Patient has been counseled about the cardiovascular risks associated with febuxostat <p>If ALL criteria are met, the request will be approved for 12 months</p> <p>If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be approved by a clinical reviewer on a case-by-case basis up to the initial authorization duration.</p> <p>Criteria (Reauthorization)</p> <p>Febuxostat may be reauthorized when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. Confirmation of a positive clinical response defined as an improvement in blood uric acid levels, erythrocyte sedimentation rate, polarized light microscopy, magnetic resonance imaging, or reduction in gout flares 2. Prescriber submits an assessment of cardiovascular risk factors <p>If ALL criteria are met, the request will be approved for 12 months</p> <p>If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be approved by a clinical reviewer on a case-by-case basis up to the reauthorization duration.</p>
<p>Pegloticase (Krystexxa)</p>	<p>Krystexxa may be covered when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. Diagnosis of symptomatic hyperuricemia associated with gout confirmed by ONE of the following: <ol style="list-style-type: none"> a. Measurement of blood uric acid levels b. Measurement of erythrocyte sedimentation rate c. Polarized light microscopy for identification of crystal in synovial fluids obtained from joints or bursas (as well as material aspirated from tophaceous deposits, if any) d. Magnetic resonance imaging for gouty tophus

	<ol style="list-style-type: none"> 2. Greater than or equal to (\geq) 3 gout flares in the previous 18 months that were inadequately controlled by colchicine, corticosteroids or non-steroidal anti-inflammatory drugs (NSAIDs), or the patient has at least 1 gout tophus or gouty arthritis 3. Trial and failure (normalize serum uric acid to less than 6 mg/dL) for at least 3 months, contraindication or intolerance to allopurinol AND Uloric at maximum tolerated dose 4. Medications known to precipitate gout attacks have been discontinued/changed when possible 5. Client does not have history of G6PD deficiency 6. Client will not take oral urate-lowering medications while on Krystexxa therapy <p>If ALL criteria are met, the request will be approved for 12 months</p> <p>If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be approved by a clinical reviewer on a case-by-case basis up to the initial authorization duration.</p>
	Criteria (Reauthorization)
	<p>Pegloticase may be reauthorized when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. Confirmation of positive clinical response defined as an improvement in blood uric acid levels, erythrocyte sedimentation rate, polarized light microscopy, magnetic resonance imaging, or reduction in gout flares. <p>If ALL criteria are met, the request will be approved for 12 months</p> <p>If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be approved by a clinical reviewer on a case-by-case basis up to the reauthorization duration.</p>

Dosage and quantity limits

Drug	Dose and Quantity Limits
febuxostat (Uloric)	<ul style="list-style-type: none"> • Symptomatic hyperuricemia associated with gout: MAX 80 mg per day; #30 tablets for 30-day supply
pegloticase (Krystexxa)	<ul style="list-style-type: none"> • 8 mg (1 mL) infusion every 2 weeks; 26 infusions per year

Coding:

HCPCS Code	Description
J2507	Injection, pegloticase, 1 mg

References

1. Uloric [package insert]. Takeda Pharmaceuticals NA; Chicago, Illinois; 2009.

2. Matsuo H, Yamamoto K, Nakaoka H, et al. Genome-wide association study of clinically defined gout identifies multiple risk loci and its association with clinical subtypes. *Ann Rheum Dis*. 2016;75(4):652-659.
3. Dalbeth N, Stamp LK, Merriman TR. The genetics of gout: Towards personalised medicine? *BMC Med*. 2017;15(1):108.
4. Cleophas MC, Joosten LA, Stamp LK, et al. ABCG2 polymorphisms in gout: Insights into disease susceptibility and treatment approaches. *Pharmgenomics Pers Med*. 2017;10:129-142.
5. Becker MA. Clinical manifestations and diagnosis of gout. UpToDate [online serial] Waltham, MA: UpToDate; reviewed July 2017a.
6. Becker MA. Treatment of acute gout. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed July 2017b.
7. Qaseem A, McLean RM, Starkey M, Forciea MA1; Clinical Guidelines Committee of the American College of Physicians. Diagnosis of acute gout: A clinical practice guideline From the American College of Physicians. *Ann Intern Med*. 2017a;166(1):52-57.
8. Qaseem A, Harris RP, Forciea MA; Clinical Guidelines Committee of the American College of Physicians. Management of acute and recurrent gout: A clinical practice guideline from the American College of Physicians. *Ann Intern Med*. 2017b;166(1):58-68.
9. Son CN, Song Y, Kim SH, et al. Digital tomosynthesis as a new diagnostic tool for assessing of chronic gout arthritic feet and ankles: comparison of plain radiography and computed tomography. *Clin Rheumatol*. 2017 Jun 8
10. Becker, M. Clinical manifestations and diagnosis of gout. In: UpToDate, Basow, DS (Ed). UpToDate, Waltham, MA, 2010.
11. Food and Drug Administration; Center for Drug Evaluation and Research; Medical Review for BLA 125293, Krystexxa (Pegloticase) August 20, 2010. [cited 01/25/2017]; Available from: <http://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/125293s0000TOC.cfm>
12. Krystexxa [package insert]. Glendale, WI: Crealta Pharmaceuticals, Inc.; September 2016.
13. Sundy JS, Baraf HS, Yood RA, et. al. Efficacy and tolerability of pegloticase for the treatment of chronic gout in patients refractory to conventional treatment: two randomized controlled trials. *JAMA*. 2011 Aug 17;306(7):711-20. PubMed PMID: 21846852.
14. Khanna D, Fitzgerald JD, Khanna PP, et al.; American College of Rheumatology. 2012 American College of Rheumatology guidelines for management of gout. Part 1: systematic nonpharmacologic and pharmacologic therapeutic approaches to hyperuricemia. *Arthritis Care Res (Hoboken)*. 2012 Oct;64(10):1431-46. doi: 10.1002/acr.21772. PubMed PMID: 23024028.
15. Spina M, Nagy Z, Ribera JM, et al: FLORENCE: a randomized, double-blind, phase III pivotal study of febuxostat versus allopurinol for the prevention of tumor lysis syndrome (TLS) in patients with hematologic malignancies at intermediate to high TLS risk. *Ann Oncol* 2015; 26(10):2155-2161.
16. Tamura K, Kawai Y, Kiguchi T, et al: Efficacy and safety of febuxostat for prevention of tumor lysis syndrome in patients with malignant tumors receiving chemotherapy: a phase III, randomized, multi-center trial comparing febuxostat and allopurinol. *Int J Clin Oncol* 2016; 21(5):996-1003.
17. Gloperba [prescribing information]. Ferndale Laboratories, Inc.; Ferndale, MI; 2019.

History

Date	Action and Summary of Changes
03/02/2021	Removed colchicine from policy
11/30/2020	Added link to AHPDL publication
11/12/2020	Added language in clinical policy section for cases which do not meet policy criteria
08/19/2020	Approved by DUR Board
07/21/2020	Moved dosing lines in criteria to dosing limits section below; added examples of cardiovascular disease in Uloric criteria;
05/06/2020	Added colchicine (Gloperba)

10/01/2019	Removed lesinurad (Zurampic) and lesinurad-allopurinol (Duzallo) due to product discontinuation by manufacturer
05/31/2019	Updated febuxostat (Uloric) criteria to reflect new black box warning; updated pegloticase reauthorization criteria; updated background section
02/21/2018	New Policy