Washington State Health Care Authority

Gout Agents

Medical policy no. 68.00.00-1 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://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx

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 (Krystexxa)	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: 1. Diagnosis of symptomatic hyperuricemia associated with gout confirmed by **ONE** of the following: 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

	3. Greater than or equal to (≥) 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 If **ALL** criteria are met, the request will be approved for 12 months 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.
	Criteria (Reauthorization) Febuxostat may be reauthorized when **ALL** of the following are met: 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 If **ALL** criteria are met, the request will be approved for 12 months 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.
Pegloticase (Krystexxa)	Krystexxa may be covered when ALL of the following are met: 1. Diagnosis of symptomatic hyperuricemia associated with gout confirmed by **ONE** of the following: 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.* Greater than or equal to (≥) 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 If **ALL** criteria are met, the request will be approved for 12 months 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.
	Criteria (Reauthorization) Pegloticase may be reauthorized when **ALL** of the following are met: 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. If **ALL** criteria are met, the request will be approved for 12 months 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.

Dosage and quantity limits

Drug	Dose and Quantity Limits
febuxostat (Uloric)	• Symptomatic hyperuricemia associated with gout: MAX 80 mg per day; #30 tablets for 30-day supply
pegloticase (Krystexxa)	• 8 mg (1 mL) infusion every 2 weeks; 26 infusions per year

Coding:

HCPCS Code	*Description*
J2507	Injection, pegloticase, 1 mg

References

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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