Washington State Health Care Authority

Gout Agents

Medical policy no. 68.00.00-1 Effective Date: TBD

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.*

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*
Colchicine (Gloperba) Febuxostat (Uloric) Pegloticase (Krystexxa)	Febuxostat and pegloticase may be considered medically necessary when used for the treatment of symptomatic hyperuricemia associated with gout. Colchicine oral solution may be considered medically necessary when used for prophylaxis of gout flares.

Clinical policy:

Clinical Criteria	
Colchicine (Gloperba)	Colchicine oral solution may be covered when ALL of the following are met: 1. Prescribed for prophylaxis of gout flares 2. Client is 18 years of age or older 3. Unable to tolerate a colchicine tablets or capsules due to ONE of the following: a. Dysphagia b. Oral/motor difficulties 4. Client does NOT have both hepatic and renal impairment 5. Colchicine is not prescribed for clients taking CYP3A4 **AND** P-glycoprotein inhibitors and who have renal **OR** hepatic impairment If ALL criteria are met, the request will be approved for 12 months

	Criteria (Reauthorization)
	Colchicine may be reauthorized if ALL of the initial authorization criteria are met. If **ALL** criteria are met, the request will be approved for 12 months.
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. No history of cardiovascular disease (e.g. non-fatal myocardial infarctions (MI), and non-fatal strokes) 8. An assessment of cardiovascular risk factors to determine the benefits and risks associated with beginning febuxostat for the patient 9. Counsel patients about the cardiovascular risks with febuxostat, and advise them to seek medical attention if they experience symptoms such as chest pain, shortness of breath, rapid or irregular heartbeat, numbness or weakness on one side of their body, dizziness, trouble talking, or sudden severe headache If **ALL** criteria are met, the request will be approved for 12 months
	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

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	3. Patient has an absence of cardiovascular disease (e.g. non-fatal myocardial infarctions (MI), and non-fatal strokes) If **ALL** criteria are met, the request will be approved for 12 months
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
	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

Dosage and quantity limits

Drug	Dose and Quantity Limits
colchicine	• 2.4 mg per day; #120 capsules per 30-day supply
colchicine (Gloperba)	• 10 ml per day; #300 ml per 30-day supply
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

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Coding:

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

References

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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
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

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Please provide the information below, please print your answer, attach supporting documentation, sign, date, and return to our office as soon as possible to expedite this request. **Without this information, we may deny the request in seven (7) working days.**

Date of request:	Reference #:	MAS:	
Patient	Date of birth	ProviderOne ID	
Pharmacy name	Pharmacy NPI	Telephone number	Fax number
Prescriber	Prescriber NPI	Telephone number	Fax number
Medication and strength	Directions for use	Qty/Days supply	

1. Is this request for a continuation of existing therapy? ☐ Yes ☐ No
   If yes, is there documentation showing a positive clinical response? ☐ Yes ☐ No

2. Please indicate patient's diagnosis:
   - ☐ Symptomatic hyperuricemia associated with gout
   - ☐ Prophylaxis of gout flares
   - ☐ Other. Specify: _____

For colchicine oral solution, answer the following:

3. Is patient unable to tolerate colchicine tablets or capsules due to one of the following?
   ☐ Dysphagia ☐ Oral/motor difficulties ☐ Other. Specify: _____

4. Does patient have any of the following? (check all that apply)
   ☐ Hepatic impairment ☐ Renal impairment ☐ None

5. Is patient taking any of the following? (check all that apply)
   ☐ CYP3A4 inhibitors ☐ P-glycoprotein inhibitors

For febuxostat and pegloticase, answer the following:

6. Has patient's diagnosis been confirmed by one of the following:
   - ☐ Measurement of blood uric acid levels
   - ☐ Measurement of erythrocyte sedimentation rate
   - ☐ Polarized light microscopy for identification of crystal in synovial fluids obtained from joints or bursas
   - ☐ Magnetic resonance imaging for gouty tophus

7. Has patient had any of the following in the last 18 months?
   - ☐ At least 3 gout flares that were inadequately controlled by colchicine, corticosteroids, or non-steroidal anti-inflammatory drugs (NSAIDs)
   - ☐ At least 1 gout tophus or gouty arthritis

8. Have medications known to precipitate gout attacks been discontinued/changed? ☐ Yes ☐ No
   If no, explain: _____

For pegloticase (Krystexxa), answer the following:

9. Does patient have a history of failure (normalize serum uric acid to less than 6 mg/dL) to at least 3 months at maximum tolerated dose, contraindication or intolerance to allopurinol AND febuxostat? ☐ Yes ☐ No

10. Does the patient have history of G6PD deficiency? ☐ Yes ☐ No

11. Will the patient take an oral urate-lowering medication while on Krystexxa? ☐ Yes ☐ No

For febuxostat (Uloric), answer the following:

BLACK BOX WARNING:

- **Gout patients with established cardiovascular (CV) disease treated with febuxostat had a higher rate of CV death compared to those treated with allopurinol in a CV outcome study.**
- **Consider the risks and benefits of febuxostat when deciding to prescribe or continue patients on febuxostat. Febuxostat should only be used in patients who have inadequate response to a maximally titrated dose of allopurinol, who are intolerant to allopurinol, or for whom treatment with allopurinol is not advisable.**

12. Does patient have a history of failure (normalize serum uric acid to less than 6 mg/dL) to at least 3 months at maximum tolerated dose, contraindication or intolerance to allopurinol? ☐ Yes ☐ No

13. Will the patient be taking azathioprine or mercaptopurine? ☐ Yes ☐ No

14. Does patient have a history of cardiovascular disease (e.g. non-fatal myocardial infarctions (MI), and non-fatal strokes)?
☐ Yes ☐ No

15. Has prescriber assessed cardiovascular risk factors to determine the benefits and risk associated with febuxostat?
☐ Yes ☐ No

16. Has prescriber counseled patient about the cardiovascular risks with febuxostat, and advised them to seek medical attention if they experience symptoms such as chest pain, shortness of breath, rapid or irregular heartbeat, numbness or weakness on one side of their body, dizziness, trouble talking, or sudden severe headache?
☐ Yes ☐ No

CHART NOTES ARE REQUIRED WITH THIS REQUEST

Prescriber signature	Prescriber specialty	Date