MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY:	Gout	**P&T DATE:**	3/21/2023
THERAPEUTIC CLASS:	Rheumatologic Disorders	**REVIEW HISTORY:** (MONTH/YEAR)	5/22, 2/21, 2/20, 2/19, 2/18, 2/17, 11/15, 5/11, 5/09
LOB AFFECTED:	MCL		

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.

Effective 1/1/2022, the Pharmacy Benefit is regulated by Medi-Cal Rx. Please visit https://medi-calrx.dhcs.ca.gov/home/ for portal access, formulary details, pharmacy network information, and updates to the pharmacy benefit. All medical claims require that an NDC is also submitted with the claim. If a physician administered medication has a specific assigned CPT code, that code must be billed with the correlating NDC. If there is not a specific CPT code available for a physician administered medication, the use of unclassified CPT codes is appropriate when billed with the correlating NDC.

OVERVIEW

Gout is a disorder derived from an excess amount of uric acid in the body that typically presents as acute episodic arthritis but can manifest as chronic arthritis as well. Although there is advanced understanding of how to treat gout, there are still significant shortfalls in gout management due to shortfalls in patient education and adherence. The American College of Rheumatology has developed recommendations for the overall management and treatment of not only active gout flares, but also for prophylaxis of gouty attacks. This review will examine the management guidelines of gout, the currently available agents for gout management, and their coverage criteria.

The purpose of this coverage policy is to review the available agents (Table 1) and distinguish where the medications may be billed to. For agents listed for coverage under the medical benefit, this coverage is specific to outpatient coverage only (excludes emergency room and inpatient coverage).

Table 1: Available Agents for the Management of Gout *(Current as of 2/2023)*

CPT Code	Generic Name (Brand Name)	Available Strengths	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
Anti-Gout Agent				
--	Colchicine (Colcrys)	*Tablet:* 0.6mg	Yes	No
NSAIDS				
--	Celecoxib (Celebrex)	*Capsule:* 50mg, 100mg, 200mg, 400mg	Yes	No
--	Indomethacin (Indocin)	*Capsule IR:* 25mg, 50mg	Yes	No
		Capsule ER: 75mg		
		Suppository: 50mg		
		Suspension: 25mg/5mL		
--	Sulindac (Clinoril)	*Tablet:* 150mg, 200mg	Yes	No
--	Naproxen (Naprosyn)	*Tablet IR:* 250mg, 375mg, 500mg, 550mg	Yes	No

		Tablet DR: 500mg *Suspension:* 125mg/5mL		
Oral Corticosteroids				
--	Dexamethasone (DexPak)	*Tablet:* 0.5mg, 0.75mg, 1mg, 1.5mg, 2mg, 4mg, 6mg *Solution:* 0.5mg/5mL	Yes	No
--	Prednisone (Deltasone)	*Tablet:* 1mg, 2.5mg, 5mg, 10mg, 20mg, 50mg *Solution*: 5mg/5mL	Yes	No
--	Prednisolone (Millipred)	*Tablet*: 5mg *Solution/Syrup*: 5mg/5mL, 15mg/5mL	Yes	No
--	Methylprednisolone (Medrol)	*Tablet:* 2mg, 4mg, 8mg, 16mg, 32mg	Yes	No
Uricosuric Agent				
--	Probenecid	*Tablet:* 500mg	Yes	No
Uric Acid Transporter 1 Inhibitor				
--	Lesinurad (Zurampic)	Tablets: 200mg	Discontinued	No
Xanthine Oxidase Inhibitors				
--	Allopurinol (Zyloprim)	100mg, 300mg	Yes	No
--	Febuxostat (Uloric)	40mg, 80 mg	Yes	No
Urate-Oxidase (Recombinant) Enzyme				
J2507 INJECTION, PEGLOTICASE, 1 MG	Pegloticase (Krystexxa)	8mg/mL	Yes	Yes (PA)
Combinations				
--	Colchicine/Probenecid	0.5mg/500mg	Yes	No
--	Lesinurad/Allopurinol (Duzallo)	200mg/300mg, 200mg/200mg	Discontinued	No

PA=prior authorization

Clinical Justification:

Urate lowering therapy (ULT) is a primary focus in the management of gout. Although both Allopurinol and Febuxostat are recommended as first line pharmacologic ULT, Febuxostat has not been shown to be more cost effective than Allopurinol. However, due to the possibility of a severe allergic reaction to Allopurinol in certain subsets of patients, Febuxostat is available for patients with positive HLA-B*5801 alleles. In cases where monotherapy with a xanthine oxidase inhibitor is insufficient to reaching the serum urate target, the addition of a uricosuric agent is appropriate. During initiation of prophylaxis with ULT, colchicine may be used at 0.6mg twice daily dosing for up to 6 months while agents such as allopurinol are titrated to optimal doses.

In regard to treating or preventing acute gouty arthritis attacks, recommended first line agents include colchicine, NSAIDS, or glucocorticoids. The dosing of colchicine during an acute gouty attack is a maximum of 1.8 mg over 1 hour, followed by 0.6 mg QD to BID until the attack has resolved.

Regarding other ULT agents, Zurampic (Lesinurad) and Duzallo (Lesinurad/Allopurinol) have been discontinued in the U.S. while Krystexxa (Pegloticase) is indicated for use in patient's refractory to conventional therapy such as xanthine oxidase inhibitors and uricosurics. The benefits of using Kystexxa only outweigh the safety risks and cost in patients with severe disease (patients who have frequent gout flares or nonresolving subcutaneous tophi).

EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for agents with medical benefit restrictions. This coverage criteria has been reviewed and approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For agents that do not have established prior authorization criteria, HPSJ will make the determination based on Medical Necessity criteria as described in HPSJ Medical Review Guidelines (UM06).

Urate-Oxidase (Recombinant) Enzyme

Pegloticase (Krystexxa)

- ❒ **Coverage Criteria:** Krystexxa (pegloticase) is reserved for patients with all of the following:
  - Patient has one of the following:
    i. At least 2 gout flares per year that were inadequately controlled by colchicine, NSAIDs, or corticosteroids; OR
    ii. At least 1 non-resolving gout tophus.
  - Documented contraindication, intolerance, or treatment failure (inability to reduce serum uric acid to < 6 mg/dL, frequent gout flares, or nonresolving tophi) to three months of either of the following:
    i. Allopurinol at 800mg/day. If unable to tolerate allopurinol at maximum dosing, febuxostat at 80mg/day is required; OR
    ii. Maximum medically appropriate xanthine oxidase inhibitor AND uricosuric agent.
  - Must be prescribed by rheumatology, nephrology, or podiatry.
- ❒ **Limits:** N/A
- ❒ **Required Information for Approval:** Prescription history or medical authorization history showing at least 1) a three-month trial of allopurinol 800mg/day or febuxostat 80mg/day or 2) a three-month trial of maximum medically-appropriate xanthine oxidase inhibitor and uricosuric agent except if intolerable or contraindicated.
- ❒ **Notes:** Providers should not use concurrent oral antihyperuricemic agents. Patients at increased risk for G6PD deficiency (eg, African, Mediterranean [including Southern European and Middle Eastern], and Southern Asian ancestry) should be screened prior to initiation of therapy.

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REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Uloric – Febuxostat v3 5-13-09.docx	5/2009	Allen Shek PharmD BCPS
Update to Policy	Formulary Realignment 5-11.xlsx	5/2011	Allen Shek PharmD BCPS
Update to Policy	HPSJ Coverage Policy – Rheumatologic Disorders – Gout 2015-11.docx	11/2015	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Rheumatologic Disorders – Gout 2017-02.docx	2/2017	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Rheumatologic Disorders – Gout 2018-02.docx	2/2018	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Rheumatologic Disorders – Gout 2019-02.docx	2/2019	Matthew Garrett, PharmD
Update to Policy	HPSJ Coverage Policy – Rheumatologic Disorders – Gout 2020-02.docx	2/2020	Matthew Garrett, PharmD
Update to Policy	HPSJ Coverage Policy – Rheumatologic Disorders – Gout 2021-02.docx	2/2021	Matthew Garrett, PharmD
Update to Policy	HPSJ Coverage Policy – Rheumatologic Disorders – Gout 2022-05.docx	5/2022	Matthew Garrett, PharmD
Update to Policy	HPSJ Coverage Policy – Rheumatologic Disorders – Gout 2023-03.docx	3/2023	Matthew Garrett, PharmD

Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy