

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE



POLICY:	Gout	P&T DATE:	3/11/2025
THERAPEUTIC CLASS:	Rheumatologic Disorders	REVIEW HISTORY:	3/24, 3/23, 5/22, 2/21, 2/20,
LOB AFFECTED:	MCL	(MONTH/YEAR)	2/19, 2/18, 2/17, 11/15, 5/11, 5/09

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the Health Plan of San Joaquin/Mountain Valley Health Plan (Health Plan) Pharmacy and Therapeutic Advisory Committee.

Effective 1/1/2022, the Pharmacy Benefit is regulated by Medi-Cal Rx. Please visit <https://medicalrx.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 3/2025)

CPT Code	Generic Name (Brand Name)	Available Strengths	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
Anti-Gout Agent				
--	Colchicine (Colcrys)	Tablet: 0.6mg	Yes	No
Nonsteroidal Anti-Inflammatory Drugs (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	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 Health Plan Pharmacy & Therapeutics (P&T) Advisory Committee. For agents that do not have established prior authorization criteria, Health Plan will make the determination based on Medical Necessity criteria as described in Health Plan 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 glucose-6-phosphate-dehydrogenase deficiency (G6PD) deficiency (eg, African, Mediterranean [including Southern European and Middle Eastern], and Southern Asian ancestry) should be screened prior to initiation of therapy.

REFERENCES

1. Khanna D, FitzGerald JD, Khanna PP, et al. 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): 1447-1461.
2. Khanna D, Khanna PP, FitzGerald JD, et al. 2012 American College of Rheumatology Guidelines for Management of Gout. Part 2: Therapy and Antiinflammatory Prophylaxis of Acute Gouty Arthritis. *Arthritis Care Res (Hoboken)*. 2012 Oct; 64(10): 1447-1461.
3. Duzallo [package insert]. Ironwood Pharmaceuticals Inc, Cambridge, MA; September 2017. http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125293s089lbl.pdf. Accessed February 12, 2017.
4. Zurampic [package insert]. Astra Zeneca Pharmaceuticals LP, Wilmington, DE; December 2015. http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/207988lbl.pdf. Accessed February 13, 2017.
5. Shekelle PG, Newberry SJ, FitzGerald JD, Motala A, O'Hanlon CE, Tariq A, et al. Management of Gout: A Systematic Review in Support of an American College of Physicians Clinical Practice Guideline. *Ann Intern Med*. 2017;166:37-51.
6. Richette P, Doherty M, Pascual E, et al. 2016 updated EULAR evidence-based recommendations for the management of gout. *Annals of the Rheumatic Diseases* 2017;76:29-42.
7. Sundy JS, Becker MA, Baraf HS, Barkhuizen A, Moreland LW, Huang W, Waltrip RW 2nd, Maroli AN, Horowitz Z; Pegloticase Phase 2 Study Investigators Reduction of plasma urate levels following treatment with multiple doses of pegloticase (polyethylene glycol-conjugated uricase) in patients with treatment-failure gout: results of a phase II randomized study. *Arthritis and Rheumatism* 2008 Sep;58(9):2882-91.
8. Sundy JS, Baraf HSB, Yood RA, Edwards NL, Gutierrez-Urena SR, Treadwell EL, Vázquez-Mellado J, White WB, Lipsky PE, Horowitz Z, Huang W, Maroli AN, Waltrip RW, Hamburger SA, Becker MA. Efficacy and Tolerability of Pegloticase for the Treatment of Chronic Gout in Patients Refractory to Conventional Treatment Two Randomized Controlled Trials. *JAMA*. 2011;306(7):711-720.
9. Saag, K. G., Fitz-Patrick, D., Kopicko, J., Fung, M., Bhakta, N., Adler, S., Storgard, C., Baumgartner, S. and Becker, M. A. (2017), Lesinurad Combined With Allopurinol: A Randomized, Double-Blind, Placebo-Controlled Study in Gout Patients With an Inadequate Response to Standard-of-Care Allopurinol (a US-Based Study). *Arthritis & Rheumatology*, 69: 203-212.
10. Bardin T, Keenan RT, Khanna PP, et al. Lesinurad in combination with allopurinol: a 3 randomized, double-blind, placebo-controlled study in patients with gout with inadequate response to standard of care (the multinational CLEAR

2 study). *Annals of the Rheumatic Diseases* Published Online First: 07 November 2016. Doi: 10.1136/annrheumdis-2016-209213.

11. Dalbeth N, Jones G, Terkeltaub R, *et al.* SAT0329 Lesinurad, A Novel Selective Uric Acid Reabsorption Inhibitor, in Combination with Febuxostat, in Patients with Tophaceous Gout: the Crystal Phase III Clinical Trial. *Annals of the Rheumatic Diseases* 2015;**74**:778.
12. Federal Drug Administration. Uloric (febuxostat): Drug Safety Communication-FDA to Evaluate Increased Risk of Heart-related Death. 11/15/2017
13. Colcrys [package insert]. Takeda Pharmaceuticals America, Inc., Deerfield, IL; December 2015.
14. FitzGerald, JD, *et al.* 2020 American College of Rheumatology Guidelines for Management of Gout. *Arthritis Care Res (Hoboken)*. 2020 June; 72(6): 744-760.
15. Krystexxa (pegloticase) [package insert]. Lake Forest, IL: Horizon Pharma USA, Inc.; 2016.
16. NICE Guideline: Gout: Diagnosis and management. National Institute for Health and Care Excellence. June 9, 2022. Accessed December 24, 2024. <https://www.nice.org.uk/guidance/ng219/chapter/Recommendations#long-term-management-of-gout>.

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
Update to Policy	HPSJ Coverage Policy – Rheumatologic Disorders – Gout 2024-03.docx	3/2024	Matthew Garrett, PharmD
Update to Policy	HPSJ Coverage Policy – Rheumatologic Disorders – Gout 2025-03.docx	3/2025	Matthew Garrett, PharmD

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