MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY:	Gout	**P&T DATE:**	3/10/2026
THERAPEUTIC CLASS:	Rheumatologic Disorders	**REVIEW HISTORY:** (MONTH/YEAR)	3/25, 3/24, 3/23, 5/22, 2/21, 2/20, 2/19, 2/18, 2/17, 11/15, 5/11, 5/09
LOB AFFECTED:	Medi-Cal/Medicare		

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://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.

Any biosimilars pending litigations or not officially available in the US Market for consumer use is not an available treatment option or covered on the medical benefit. Biosimilars that are FDA approved and available in the US Market for consumer use will follow the reference brand name criteria as available per our PH05 - Prior Authorizations processes. Certain biosimilars may be subject to alternative criteria based on the preferences of Health Plan.

This coverage policy is updated on an annual basis. For more recent or up-to-date criteria, reference the Medi-Cal Provider Manual and/or the Medicare National Coverage Determination/Local Coverage Determination (NCD/LCD) for specific criteria. If the Medi-Cal Provider Manual and/or the Medicare NCD/LCD do not have medical necessity criteria, please refer to the "Evaluation Criteria" section in this policy for specific criteria. It is also important to reference the Medicare Benefit Manuals - Chapter 15 and Chapter 16 - when determining benefit coverage and criteria for review of physician administered drugs on the Medicare benefit.

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.

For agents listed for coverage under the medical benefit, this coverage is specific to outpatient coverage only (excludes emergency room and inpatient coverage).

Guidelines used in the creation of this policy include the following (please review the references section for all the relevant literature used):

- 2020 American College of Rheumatology Guideline for the Management of Gout
- 2016 updated EULAR evidence-based recommendations for the management of gout

MEDI-CAL 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

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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.
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17. Ilaris (canakinumab) [package insert]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation, Inc.; 2024.

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

Review of Policy	HPSJ Coverage Policy – Rheumatologic Disorders – Gout 2026-03.docx	3/2026	Matthew Garrett, PharmD

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