Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Lupkynis™ (voclosporin)

Effective: March 10, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Lupkynis (voclosporin) is a calcineurin-inhibitor immunosuppressant indicated in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis.

Safety and efficacy of Lupkynis (voclosporin)have not been established in combination with cyclophosphamide. Use of Lupkynis (voclosporin) is not recommended in this situation.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Lupkynis for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of systemic lupus erythematosus

AND

2. Documentation of presence of lupus nephritis confirmed by urine/blood tests or kidney biopsy

AND

3. Prescribed by or in consultation with a rheumatologist or nephrologist

AND

4. The patient is at least 18 years of age or older

AND

5. Documentation of **one (1)** of the following:
    a. Use in combination with mycophenolate and a systemic corticosteroid
    b. Clinical inappropriateness of mycophenolate and systemic corticosteroid

AND

6. Documentation of **one (1)** of the following:
    a. Inadequate response to Benlysta
    b. Clinical inappropriateness of Benlysta

Limitations

1. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. Lupkynis (voclosporin) [prescribing information]. Victoria, BC: Aurinia Pharmaceuticals Inc.; October 2025.
2. Bertsias GK, Ioannidis JP, Aringer M, et al. EULAR recommendations for the management of systemic lupus erythematosus with neuropsychiatric manifestations: report of a task force of the EULAR standing committee for clinical affairs. *Ann Rheum Dis*. 2010 Dec;69(12):2074-82.
3. Bertsias GK, Ioannidis JP, Boletis J, et al. EULAR points to consider for conducting clinical trials in systemic lupus erythematosus: literature based evidence for the selection of endpoints. *Ann Rheum Dis*. 2009; 68(4):477-83.

4. Bertsias G, Ioannidis JP, Boletis J et al. EULAR recommendations for the management of systemic lupus erythematosus. Report of a task force of the EULAR Standing Committee for international clinical studies including therapeutics. *Ann Rheum Dis*. 2008; 67(2):195-205.
5. Fanouriakis A, et al. EULAR recommendations for the management of systemic lupus erythematosus: 2023 update. Ann Rheum Dis 2024;83:15–29.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

- June 13, 2023: No changes
- April 9, 2024: No changes
- March 11, 2025: No changes (eff 3/11/25)
- March 10, 2026: Administrative update to remove CareLink from Medical Necessity Guideline template.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.