Pharmacy Medical Necessity Guidelines:
Lupkynis™ (voclosporin)

Effective: March 10, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION (FDA)-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.

COVERAGE GUIDELINES

The plan may authorize coverage of **Lupkynis (voclosporin)** 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 Member 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 corticosteroids

AND

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

LIMITATIONS

None

CODES

None

REFERENCES

1. Lupkynis (voclosporin) [prescribing information]. Victoria, BC: Aurinia Pharmaceuticals Inc.; April 2024.
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 HISTORY

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

- June 13, 2023: Updated provider requirements to be allow for "in consultation with a rheumatologist or nephrologist." Administrative update to clarify wording for Benlysta prerequisite in criterion #6 (effective July 1, 2023).
- April 9, 2024: No changes
- March 11, 2025: No changes (eff 3/11/25)
- March 10, 2026: No changes.

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.

Provider Services