

## **Clinical Policy: Voclosporin (Lupkynis)**

Reference Number: CP.PHAR.504

Effective Date: 01.22.21

Last Review Date: 05.26

Line of Business: Commercial, HIM/ICHRA, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

Voclosporin (Lupkynis<sup>™</sup>) is a calcineurin inhibitor.

### **FDA Approved Indication(s)**

Lupkynis is indicated in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis (LN).

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

### **Policy/Criteria**

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Lupkynis is **medically necessary** when the following criteria are met:

#### **I. Initial Approval Criteria**

##### **A. Lupus Nephritis (must meet all):**

1. Diagnosis of LN with kidney biopsy confirming one of the following (a, b, or c):
  - a. LN class III (focal);
  - b. LN class IV (diffuse segmental or global);
  - c. LN class V (membranous);
2. Prescribed by or in consultation with a nephrologist or rheumatologist;
3. Age  $\geq$  18 years;
4. Member has a confirmed diagnosis of systemic lupus erythematosus;
5. Evidence of one of the following (a or b):
  - a. Urine protein/creatinine ratio (UPCR)  $\geq$  1.5 mg/mg;
  - b. UPCR  $\geq$  2 mg/mg and LN Class V;
6. Prescribed in combination with both of the following (a and b):
  - a. Background immunosuppressive therapy (e.g., mycophenolate, azathioprine);
  - b. Systemic corticosteroid (e.g., prednisone);
7. Lupkynis is not prescribed concurrently with cyclophosphamide or a biologic (e.g., Benlysta<sup>®</sup>, Gazyva<sup>®</sup>, Saphnelo<sup>®</sup>, rituximab);
8. Dose does not exceed 47.4 mg (6 capsules) per day.

**Approval duration: 12 months**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

**II. Continued Therapy**

**A. Lupus Nephritis (must meet all):**

1. Member meets one of the following (a or b):
  - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
  - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy as evidenced by one of the following (a, b, or c):
  - a. Reduced level of proteinuria measured by UPCR  $\leq 0.5$  mg/mg from baseline with low dose steroids (e.g., prednisone);
  - b. No reduction from baseline in eGFR of greater than 20% with low dose steroids (e.g., prednisone);
  - c. eGFR  $\geq 60$  ml/min/1.73 m<sup>2</sup> with low dose steroids (e.g., prednisone);
3. Prescribed in combination with both of the following (a and b):
  - a. Background immunosuppressive therapy (e.g., mycophenolate, azathioprine);
  - b. Systemic corticosteroid (e.g., prednisone);
4. Lupkynis is not prescribed concurrently with cyclophosphamide or a biologic (e.g., Benlysta, Gazyva, Saphnelo, rituximab);
5. If request is for a dose increase, new dose does not exceed 47.4 mg (6 capsules) per day.

**Approval duration: 12 months**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

- a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

### III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

### IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

eGFR: estimated glomerular filtration rate

FDA: Food and Drug Administration

LN: lupus nephritis

UPCR: urine protein/creatinine ratio

*Appendix B: Therapeutic Alternatives*

Not applicable

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s):
  - Patients concomitantly using strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin)
  - Known serious or severe hypersensitivity reaction to Lupkynis or any of its excipients
- Boxed warning(s): malignancies and serious infection

### V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|------------|----------------|--------------|
| LN         | 23.7 mg PO BID | 47.4 mg/day  |

### VI. Product Availability

Capsule: 7.9 mg

### VII. References

1. Lupkynis Prescribing Information. Rockville, MD: Aurinia Pharmaceuticals, Inc.; October 2025. Available at: <https://www.lupkynis.com/>. Accessed January 13, 2026.

2. Rovin BH, Teng YKO, Ginzler EM, et al. Efficacy and safety of voclosporin versus placebo for lupus nephritis (AURORA 1): a double-blind, randomised, multicentre, placebo-controlled, phase 3 trial [published correction appears in Lancet. 2021 May 29;397(10289):2048.
3. Kidney Disease: Improving Global Outcomes (KDIGO) Lupus Nephritis Work Group. KDIGO 2024 Clinical Practice Guideline for the management of lupus nephritis. *Kidney Int.* 2024;105(1S):S1-S69.KDI.
4. Sammaritano LR, Askanase A, Bermas BL, et al. 2024 American College of Rheumatology (ACR) Guideline for the screening, treatment, and management of lupus nephritis. *Arthritis Rheumatol.* 2025;77(9):1115-1135.
5. Fanouriakis A, Kostopoulou M, Alunno A, et al. 2019 update of the EULAR recommendations for the management of systemic lupus erythematosus. *Annals of the Rheumatic Diseases* 2019;78:736-745.
6. Fanouriakis A, Kostopoulou M, Andersen J, et al. EULAR recommendations for the management of systemic lupus erythematosus: 2023 update. *Ann Rheum Dis.* 2024;83(1):1529.
7. Fanouriakis A, Kostopoulou M, Anders HJ, et al. EULAR recommendations for the management of systemic lupus erythematosus with kidney involvement: 2025 update. *Ann Rheum Dis.* 2026;85(1):75-90.
8. Weening J, Vivette D, Schwartz M, et al. The Classification of Glomerulonephritis in Systemic Lupus Erythematosus Revisited. *JASN* February 2004, 15(2)241-250.
9. Petri M, Orbai AM, Alarcón GS, et al. Derivation and validation of the Systemic Lupus International Collaborating Clinics classification criteria for systemic lupus erythematosus. *Arthritis Rheum.* 2012; 64:2677.

| Reviews, Revisions, and Approvals  | Date     | P&T Approval Date |
|--|----------|-------------------|
| 2Q 2022 annual review: no significant changes; references reviewed and updated.  | 02.05.22 | 05.22             |
| Template changes applied to other diagnoses/indications and continued therapy section.   | 10.03.22 |                   |
| 2Q 2023 annual review: no significant changes; references reviewed and updated.  | 02.08.23 | 05.23             |
| Added criteria for member’s treatment response and risk of worsening nephrotoxicity for requests exceeding > 12 months of Lupkynis therapy and revised continued approval duration to 6 months based on time to complete response with Lupkynis.   | 12.14.23 | 02.24             |
| 2Q 2024 annual review: added exclusion for concurrent treatment with cyclophosphamide or a biologic; revised continued approval duration to 12 months and removed treatment response criterion for requests exceeding 12 months of Lupkynis based on updated 2024 KDIGO lupus nephritis management guideline; references reviewed and updated. | 02.22.24 | 05.24             |
| 2Q 2025 annual review: no significant changes; references reviewed and updated.  | 02.26.25 | 05.25             |

| Reviews, Revisions, and Approvals   | Date     | P&T Approval Date |
|---|----------|-------------------|
| 2Q 2026 annual review: no significant changes; revised initial approval duration from 6 to 12 months; added Gazyva as an example of a biologic that is excluded for concurrent use; references reviewed and updated.<br>Added ICHRA line of business. | 04.09.26 | 05.26             |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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