Clinical Policy: Voclosporin (Lupkynis)

Reference Number: ERX.SPA.408
Effective Date: 01.22.21
Last Review Date: 05.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Voclosporin is a calcineurin inhibitor.

FDA Approved Indication(s)
Voclosporin (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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 ≥ 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) ≥ 1.5 mg/mg;
   b. UPCR ≥ 2 mg/mg and LN Class V;
6. Prescribed in combination with a background immunosuppressive therapy (e.g., mycophenolate, azathioprine) and a systemic corticosteroid (e.g., prednisone);
7. Dose does not exceed 47.4 mg (6 capsules) per day.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
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 ≤ 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 ≥ 60 ml/min/1.73 m^2 with low dose steroids (e.g., prednisone);

3. Prescribed in combination with a background immunosuppressive therapy (e.g., mycophenolate, azathioprine) and a systemic corticosteroid (e.g., prednisone);
4. If request is for a dose increase, new dose does not exceed 47.4 (6 capsules) mg per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 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.; January 2021. Available at: https://www.lupkynis.com/. Accessed June 15, 2021.
2. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Identifier NCT03021499, Aurinia Renal Response in Active Lupus With Voclosporin (AURORA) Available at: https://www.clinicaltrials.gov/ct2/show/NCT03021499. Accessed June 22, 2020.
3. Weening J, Vivette D, Schwartz M, et al. The Classification of Glomerulonephritis in Systemic Lupus Erythematosus Revisited. JASN February 2004, 15(2)241-250.
4. Drug Monographs. Clinical Pharmacology. Tampa, FL: Gold Standard Inc.; 2020. Available at: http://www.clinicalpharmacology-ip.com. Accessed June 22, 2020.

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. 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
Policy created pre-emptively	06.22.20	08.20
Drug is now FDA approved - criteria updated per FDA labeling: eGFR requirement removed, cyclophosphamide as an option for concurrent immunosuppressive therapy w/Lupkynis removed as this is not recommended per the labeling, and concurrently prescribed with "non-biologic" immunosuppressive therapy was changed to "background" immunosuppressive therapy; rheumatology specialist added, criterion for diagnosis of SLE added, clarification of maximum dose as 6 capsules/day added.	02.23.21	05.21
Removed requirement for prior trial of immunosuppressive therapy to align with FDA labeling.	06.15.21	

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.