Reference number(s)
4448-A

Specialty Guideline Management
Lupkynis

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Lupkynis	voclosporin

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

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

Limitations of Use

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

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Initial requests

Medical records (e.g., chart notes, laboratory reports) documenting the presence of autoantibodies relevant to systemic lupus erythematous (SLE) (e.g., antinuclear antibodies [ANA] by immunofluorescence [IFA] 1:80 or higher, anti-double-stranded DNA [anti-ds DNA], anti-Smith [anti-Sm], antiphospholipid antibodies, low complement proteins), or kidney biopsy supporting the diagnosis.

Continuation requests

Medical records (e.g., chart notes, lab reports) documenting disease stability or improvement.

Prescriber Specialties

This medication must be prescribed by or in consultation with a rheumatologist, nephrologist, or a specialist in the treatment of lupus nephritis.

Exclusions

Coverage will not be provided for members using Lupkynis in combination with cyclophosphamide.

Coverage Criteria

Active Lupus Nephritis[1-6]

Authorization of 12 months may be granted for treatment of active lupus nephritis in members 18 years of age or older when all of the following criteria are met:

- The member meets either of the following:
  - Lupus nephritis is confirmed on kidney biopsy
  - If a kidney biopsy is not feasible or if the member is not a candidate for kidney biopsy, prior to initiating therapy, the member is positive for autoantibodies relevant to SLE (e.g., ANA by IFA 1:80 or higher, anti-ds DNA, anti-Sm, antiphospholipid antibodies, low complement proteins)
- Member has clinically active lupus renal disease and is receiving background therapy with mycophenolate mofetil (MMF) with corticosteroids.
- Member must have an estimated glomerular filtration rate (eGFR) greater than 45 mL/min per 1.73 m^2.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

References

1. Lupkynis [package insert]. Rockville, MD: Aurinia Pharma U.S., Inc,; October 2025.
2. Rovin BH, Solomons N, Pendergraft WF 3rd, et al. A randomized, controlled double-blind study comparing the efficacy and safety of dose-ranging voclosporin with placebo in achieving remission in patients with active lupus nephritis. Kidney Int. 2019 Jan;95(1):219-231.
3. Rovin BH, Adler SG, Barratt J, et al. 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(15):S1-S69.
4. Gordon C, Amissah-Arthru MB, Gayed M, et al. The British Society for Rheumatology guideline for the management of systemic lupus erythematosus in adults. Rheumatology (Oxford). 2018; 57(1):e1-e45.
5. Petri M, Orbai A-M, Alarcon GS, et al. Derivation and Validation of Systemic Lupus International Collaborating Clinics (SLICC) Classification Criteria for Systemic Lupus Erythematosus. Arthritis Rheum. 2012; 64:2677-2686. URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3409311/. Accessed January 15, 2026.
6. Fanouriakis A, Kostopoulou M, Alunno A, et al. EULAR recommendations for the management of systemic lupus erythematosus with kidney involvement: 2025 update. Ann Rheum Dis. January 2026;85(1):75-90. URL: https://ard.eular.org/article/S0003-4976%2825%2904412-7/fulltext. Accessed March 14, 2026.