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 a calcineurin-inhibitor immunosuppressant 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, lab reports) documenting the presence of autoantibodies relevant to systemic lupus erythematous (SLE) (e.g., ANA, anti-ds DNA, anti-Sm, antiphospholipid antibodies, complement proteins), or kidney biopsy supporting the diagnosis.

Continuation requests

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

Exclusions

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

Coverage Criteria

Active lupus nephritis[1-4]

Authorization of 12 months may be granted for the treatment of active lupus nephritis when all of the following criteria are met:

- Prior to initiating therapy, the member is positive for autoantibodies relevant to SLE (e.g., ANA, anti-ds DNA, anti-Sm, antiphospholipid antibodies, complement proteins) or lupus nephritis was confirmed on kidney biopsy.
- Member has clinically active lupus renal disease and is receiving background therapy with mycophenolate mofetil (MMF) with corticosteroids.
- Member must have an eGFR > 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,; April 2024.

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 22, 2025.