CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Lupkynis (voclosporin)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Lupkynis is an oral calcineurin inhibitor (CNI) immunosuppressant that is structurally similar to cyclosporine A. It was approved by the FDA in 2021 for the treatment of adults with active lupus nephritis (LN), in combination with background immunosuppressive therapy.
LN is a complication of systemic lupus erythematosus (SLE) and can progress to end stage renal disease (ESRD). Proteinuria is often the first sign of LN, which is evident by an elevated urine protein creatinine ratio (UPCR). Diagnosis is confirmed by a kidney biopsy, which reveals the classification of disease and is used to guide treatment. Dosing is based on estimated glomerular filtration rate (eGFR), with most patients likely to be on the higher end of the dose range. Hypertension is a common side effect and blood pressure monitoring is recommended.

Lupkynis (voclosporin) will be considered for coverage when the following criteria are met:

Lupus Nephritis (LN)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a nephrologist or rheumatologist; AND
3. Member has a documented diagnosis of active lupus nephritis class III, IV, and/or V as confirmed by kidney biopsy; AND
4. Medication must be prescribed in combination with an immunosuppressant regimen i.e., mycophenolate mofetil (MMF) and corticosteroid; AND
5. Chart notes must document baseline eGFR and UPCR; AND
6. eGFR is at least 45 mL/min/1.73m^2 OR it has been determined that the benefit exceeds the risk; AND
7. Member is not on dialysis and has not had a kidney transplant; AND
8. Lupkynis will not be used in combination with cyclophosphamide; AND
9. Member has tried and failed Benlysta.
10. **Dosage allowed/Quantity limit:** Starting dose is 23.7 mg (3 capsules) twice daily (total 6 capsules per day; 3 wallets per 30 days). Modify based on eGFR as directed in prescribing information.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Member has a reduced UPCR (goal is 0.5 mg/mg or less); AND
2. eGFR is at least 60mL/min/1.73m^2 OR has stabilized.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Lupkynis (voclosporin) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
03/24/2021	New policy for Lupkynis created.
08/23/2022	Annual review; no changes.
01/10/2024	Updated references. Added Benlysta step.

References:

1. Lupkynis. [prescribing information]. Rockville, MD: Aurinia Pharma U.S., Inc; 2021.
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]. *Lancet*. 2021;397(10289):2070-2080. doi:10.1016/S0140-6736(21)00578-X
3. Hahn BH, McMahon MA, Wilkinson A, et al. American College of Rheumatology guidelines for screening, treatment, and management of lupus nephritis. *Arthritis Care Res (Hoboken)*. 2012;64(6):797-808. doi:10.1002/acr.21664
4. Fanouriakis A, Kostopoulou M, Cheema K, et al. 2019 Update of the Joint European League Against Rheumatism and European Renal Association-European Dialysis and Transplant Association (EULAR/ERA-EDTA) recommendations for the management of lupus nephritis. *Ann Rheum Dis*. 2020;79(6):713-723. doi:10.1136/annrheumdis-2020-216924
5. 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):15-29. Published 2024 Jan 2. doi:10.1136/ard-2023-224762
6. Rovin BH, Adler SG, Barratt J, et al. Executive summary of the KDIGO 2021 Guideline for the Management of Glomerular Diseases. *Kidney Int*. 2021;100(4):753-779. doi:10.1016/j.kint.2021.05.015

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