CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Ohio Medicaid

DRUG NAME	Lupkynis (voclosporin)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Lupkynis is an oral calcineurin inhibitor (structurally similar to cyclosporine A). It was approved in January 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. 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

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 diagnosis of 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 such as mycophenolate mofetil (MMF) and corticosteroid; AND
5. Chart notes must document baseline eGFR and urine protein creatinine ratio (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.
9. **Dosage allowed/Quantity limit:** Up to 23.7 mg (3 capsules) twice daily (total 6 capsules per day; 3 wallets per 30 days). Dosing is 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
3/24/21	New policy for Lupkynis created.
08/23/2022	Annual review; no changes.

References:

1. Lupkynis. [prescribing information]. Rockville, MD: Aurinia Pharma U.S., Inc; 2021.
2. 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
3. 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;95(1):219-231. doi:10.1016/j.kint.2018.08.025
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

Effective date: 01/01/2023
Revised date: 08/23/2022