ALASKA MEDICAID
Prior Authorization Criteria

Lupkynis™ (voclosporin)

FDA INDICATIONS AND USAGE[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.

APPROVAL CRITERIA[1,2,3,4]

1. Patient is 18 years of age or older **AND**;
2. Prescribed by or in consultation with a rheumatologist or nephrologist **AND**;
3. Patient has a diagnosis of lupus nephritis confirmed by:
    a. International Society of Nephrology/Renal Pathology Society (ISN/RPS) biopsy-proven active Class III or IV lupus nephritis alone or in combination with Class V lupus nephritis **AND**;
    b. Urine protein to creatinine (UPCR) ratio ≥ 1.5 mg/mg for Class III or IV OR UPCR ≥ 2 mg/mg for Class V **AND**;
4. The medication is being used concurrently with mycophenolate mofetil and a systemic corticosteroid; OR patient is not a candidate for mycophenolate mofetil and a systemic corticosteroid due to inadequate efficacy, significant intolerance, or contraindication with these medications **AND**;
5. The prescriber must submit current labs including liver function tests, urine protein to creatinine (UPCR) ratio, serum potassium levels, and baseline estimated glomerular filtration rate (eGFR). eGFR must be assessed every two weeks for the first month, and every four weeks thereafter.

DENIAL CRITERIA[1]

1. Failure to meet approval criteria **OR**;
2. Patient is pregnant **OR**;
3. Patient has a baseline eGFR ≤ 45 mL/min/1.73m2 **OR**;
4. Patient has a baseline blood pressure >165/105 mmHg **OR**;
5. Patient is taking cyclophosphamide **OR**;
6. Patient requires concomitant strong CYP3A4 inhibitors (i.e. ketoconazole, clarithromycin) **OR**;
7. Patient has severe hepatic impairment.

CAUTIONS[1]

- Monitor patients closely for nephrotoxicity and neurotoxicity.
- Hypertension has been observed and may require antihypertensive therapy.
- Consider obtaining electrocardiograms and monitoring electrolytes in patients at high risk.
- Live vaccines should be avoided while on therapy.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 6 months if the prescriber documents the patient has disease improvement and/or stabilization OR improvement in the slope of decline.

QUANTITY LIMIT

- 180 capsules per 30 days

REFERENCES / FOOTNOTES:

1. Lupkynis [package insert]. Rockvale, MD; Aurinia; January 2021.
2. Li Y, Palmisano M, Sun D, Zhou Sl. Pharmacokinetic disposition difference between cyclosporine and voclosporin drives their distinct efficacy and safety profiles in clinical studies. Clin Pharmacol. 2020;12:83-96.
3. Rovin BH, 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. Gasparotto M, et al. Lupus nephritis: clinical presentations and outcomes in the 21st century. Rheumatology (Oxford). 2020;59(Suppl5):v39-v51. doi:10.1093/rheumatology/keaa381