Date Effective: 7/1/21
Reviewed: 4/2021, 3/2022, 3/2023, 3/2024 Scope: Medicaid

LUPKYNIS (voclosporin)

POLICY

I. 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 Indication
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.

II. EXCLUSIONS

Coverage will not be provided for members using Lupkynis in combination with cyclophosphamide or Benlysta (belimumab).

III. DOCUMENTATION

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

1. For initial requests, baseline estimated glomerular filtration rate (eGFR) and baseline urine protein-creatinine ratio (UPCR) and medical records (e.g., chart notes, lab reports) documenting the presence of autoantibodies relevant to systemic lupus erythematosus SLE (e.g., ANA, anti-ds DNA, anti-Sm, antiphospholipid antibodies, complement proteins), or kidney biopsy supporting the diagnosis.
2. For continuation requests, current eGFR and current UPCR and Medical records (e.g., chart notes, lab reports) documenting disease stability or improvement.

IV. CRITERIA FOR INITIAL APPROVAL

Active lupus nephritis
Authorization of 6 months may be granted for the treatment of active lupus nephritis when all of the following criteria are met:

1. The medication is prescribed by or in consultation with a nephrologist or rheumatologist.
2. Member is at least 18 years of age.
3. 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.
4. Member is receiving background therapy with mycophenolate mofetil (MMF) and with corticosteroids.
5. Member must have an eGFR > 45ml/min per 1.73 m^2, and renal function (eGFR) will be assessed at regular intervals thereafter.
6. Member has failed to respond adequately to Benlysta (belimumab) with standard immunosuppressive therapy (e.g., corticosteroids and MMF or cyclophosphamide).

V. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III who achieve or maintain a positive clinical response as evidenced by an improvement in UPCR (i.e. ≤0.5 mg/mg) and eGFR ≥60 mL/min/1.73 m2 or no confirmed decrease from baseline in eGFR of >20%.

VI. QUANTITY LIMIT

Lupkynis (voclosporin) 7.9 mg has a quantity limit of 6 capsules per day.

VII. REFERENCES

1. Lupkynis [package insert]. Victoria, Canada: Aurinia Pharmaceuticals Inc.; December 2023.
2. Rovin BH, Solomons N, Pendergraft WF 3rd, Dooley MA, Tumlin J, Romero-Diaz J, Lysenko L, Navarra SV, Huizinga RB; AURA-LV Study Group. 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.