

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. 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. Documentation that the member is at least 18 years of age.
3. Prior to initiating therapy, documentation that 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. Documentation that the member is receiving background therapy with mycophenolate mofetil (MMF) and with corticosteroids.
5. Documentation that the member has a baseline eGFR > 45ml/min per 1.73 m² and baseline urine protein-creatinine ratio (UPCR) has been provided and both eGFR and UPCR will be assessed at regular intervals thereafter.
6. Documentation that the member has failed to respond adequately to Benlysta (belimumab) with standard immunosuppressive therapy (e.g., corticosteroids and MMF or cyclophosphamide).

IV. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III with documentation of achieving or maintaining 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 $>20\%$.

V. QUANTITY LIMIT

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

VI. REFERENCES

1. Lupkynis [package insert]. Victoria, Canada: Aurinia Pharmaceuticals Inc.; April 2024.
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.