

SPECIALTY GUIDELINE MANAGEMENT

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.

III. CRITERIA FOR INITIAL APPROVAL

Active lupus nephritis

Authorization of 12 months may be granted for the treatment of active lupus nephritis when all of the following criteria are met:

1. Prior to initiating therapy, the member is positive for autoantibodies relevant to SLE.
2. Member has clinically active lupus renal disease and is receiving background therapy with mycophenolate mofetil (MMF) with corticosteroids.
3. Member must have an eGFR \geq 45ml/min per 1.73 m².

IV. CONTINUATION OF THERAPY

Authorization of 12 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 low disease activity or improvement in signs and symptoms of the condition.

I. REFERENCES

1. Lupkynis [package insert]. Victoria, Canada: Aurinia Pharmaceuticals Inc.; January 2021.

Reference number(s)
4448-A

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.