

<b>Policy Name:</b>	<b>Lupkynis (voclosporin)</b>	<b>Policy#:</b>	<b>2831P</b>
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## Purpose of the Policy

The purpose of this policy is to define coverage criteria for Lupkynis (voclosporin)

## Statement of the Policy

Health Alliance Medical Plans will approve the use of Lupkynis (voclosporin) under the specialty pharmacy benefit if the following criteria are met.

## Criteria

### 1. Coverage Criteria for the Treatment of Lupus Nephritis

- 1.1 Documented diagnosis of active lupus nephritis with an eGFR > 45mL/min/1.73 m<sup>2</sup>
- 1.2 Age 18 years or older
- 1.3 Ordered by or in consultation with a nephrologist (kidney doctor), rheumatologist (musculoskeletal doctor), or immunologist (immune system doctor)
- 1.4 Documented trial of glucocorticoids (such as prednisone) with mycophenolate mofetil (MMF) or cyclophosphamide for at least 3 months

### 2. Exclusion Criteria

- 2.1 Patient with an eGFR ≤ 45mL/min/1.73 m<sup>2</sup>
- 2.2 Patient with severe liver dysfunction
- 2.3 Concurrent use of strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin)
- 2.4 Lupkynis will not be covered in combination with Saphnelo or Benlysta

### 3. Managed Dose Limit

- 3.1 There will be an MDL in place of #90 capsules per 30 days

### 4. Approval Period

- 4.1 Initial Approval: 12 months
- 4.2 Subsequent Approval: 12 months with documentation of positive response to therapy

## CPT Codes

## HCPCS Codes

## References

1. Lupkynis (voclosporin) [prescribing information]. Rockville, MD: Aurinia Pharmaceuticals Inc; January 2021.

2. Rovin BH, Solomons N, Pendergraft WF 3rd, et al; 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;95(1):219-231.
3. Rovin BH, Adler SG, Barratt J, et al (Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group). KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. *Kidney Int.* 2021 Oct;100(4S):S1-S276.
4. 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 Jun;64(6):797-808.

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