UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1359-5
Program	Prior Authorization/Notification
Medications	Lupkynis® (voclosporin)
P&T Approval Date	6/2021, 6/2022, 6/2023, 6/2024, 6/2025
Effective Date	9/1/2025

1. Background:

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).

Limitation of use:
Safety and efficacy of Lupkynis have not been established in combination with cyclophosphamide. Use of Lupkynis is not recommended in this situation.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Lupkynis** will be approved based on **ALL** of the following criteria:

   a. Diagnosis of active lupus nephritis

   -AND-

   b. Prescribed in combination with a background immunosuppressive therapy regimen (e.g., mycophenolate mofetil and corticosteroids)

   -AND-

   c. Patient is not receiving Lupkynis in combination with cyclophosphamide

   Authorization will be issued for 12 months.

B. Reauthorization

1. **Lupkynis** will be approved based on the following criteria:

   a. Documentation of positive clinical response to Lupkynis therapy

   -AND-

   b. Prescribed in combination with a background immunosuppressive therapy regimen (e.g., mycophenolate mofetil and corticosteroids)

   -AND-

c. Patient is not receiving Lupkynis in combination with cyclophosphamide

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program.
- Supply limitations may be in place.

4. References:

1. Lupkynis [package insert]. Rockville, MD: Aurinia Pharma U.S., Inc.; April 2024.

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Change Control	
6/2021	New program.
6/2022	Annual review with no changes to clinical criteria.
6/2023	Annual review with no changes to clinical criteria. Added state mandate footnote.
6/2024	Annual review. Updated authorization lengths to 12 months.
6/2025	Annual review with no changes to clinical criteria. Updated reference.