UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2240-4
Program	Prior Authorization/Medical Necessity
Medications	Lupkynis™ (voclosporin)
P&T Approval Date	6/2021, 6/2022, 9/2022, 9/2023
Effective Date	12/1/2023

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. Provider attestation to **one** of the following:

      (1) Diagnosis is biopsy proven

      -OR-

      (2) Biopsy is contraindicated in the patient

   -AND-

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

   -AND-

   d. Patient is not receiving Lupkynis in combination with **either** of the following:

      (1) Cyclophosphamide
      (2) Benlysta (belimumab)

   -AND-

e. Prescribed by **one** of the following:

(1) Nephrologist
(2) Rheumatologist

Authorization will be issued for 6 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 **either** of the following:

(1) Cyclophosphamide
(2) Benlysta (belimumab)

-AND-

d. Prescribed by **one** of the following:

(1) Nephrologist
(2) Rheumatologist

-AND-

e. **One** of the following:

(1) Patient has been on Lupkynis therapy for less than 12 months
(2) Patient has completed 12 or more months of Lupkynis therapy and the provider attests that the benefit of continuation of therapy exceeds the risk in light of the patient's treatment response and risk of worsening nephrotoxicity

Authorization will be issued for 6 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.; January 2021.
2. Weening JJ, D'Agati VD, Schwartz MM, et al. The classification of glomerulonephritis in systemic lupus erythematosus revisited [published correction appears in Kidney Int. 2004 Mar;65(3):1132]. *Kidney Int*. 2004;65(2):521-530.
3. Bomback AS, Appel GB; Lupus nephritis: Diagnosis and classification. In: UpToDate, Waltham, MA. (Accessed on March 31, 2021)
4. Hahn BH, McMahon MA, Wilkinson A, et al. American College of Rheumatology guidelines for screening, treatment, and management of lupus nephritis. *Arthritis care & research.* 2012;64(6):797-808.
5. Wilhelmus S, Bajema IM, Bertsias GK, et al. Lupus nephritis management guidelines compared. *Nephrology, dialysis, transplantation : official publication of the European Dialysis and Transplant Association - European Renal Association.* 2016;31(6):904-913.
6. Rovin BH, Caster DJ, Cattran DC, et al. Management and treatment of glomerular diseases (part 2): conclusions from a Kidney Disease: Improving Global Outcomes (KDIGO) Controversies Conference. *Kidney international.* 2019;95(2):281-295.
7. Rovin BH, Adler SG, Barratt J, et al. Executive summary of the KDIGO 2021 Guideline for the Management of Glomerular Diseases. *Kidney Int*. 2021;100(4):753-779.

Program	Prior Authorization/Medical Necessity - Lupkynis (voclosporin)
Change Control	
6/2021	New program.
6/2022	Annual review with no change to clinical criteria. Updated reference. Added state mandate footnote.
9/2022	Removed criteria requiring progression or response failure to immunosuppressive induction therapy. Removed state mandate trial footnote.
9/2023	Annual review with no change to clinical criteria.