JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS139
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	Subject **Lupkynis**	*Revision Date*	10/20/2021
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Lupkynis

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I. POLICY

Lupkynis (voclosporin) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Lupkynis** may be approved for patients who meet the following:
   1. Patient is 18 years of age or older
   2. Documented diagnosis of active lupus nephritis with renal disease
   3. Patient is positive for auto-antibodies associated with SLE (defined as ANA titer = 1:80 or greater OR anti-dsDNA=30 IU/mL or higher)
      a. *Due to lab variability in standards for positive values, consideration will be given if the reported lab results do not meet the values listed above but are reported as "positive" from that lab*
   4. Patient has failed to respond adequately to at least 2 of the following standard therapies:
      a. Corticosteroids
      b. Anti-malarials (hydroxychloroquine, chloroquine)
      c. Non-biologic immunosuppressants (azathioprine, methotrexate, cyclosporine, oral cyclophosphamide)
   5. Patient has an estimated glomerular filtration rate (eGFR) >45 mL/min/m^2
   6. Patient will be utilizing Lupkynis concomitantly with standard therapies
   7. Prescriber must be a rheumatologist or nephrologist

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 6 months of therapy
B. Continuation of therapy may be approved in 6-month intervals with documentation showing a beneficial response to treatment, evidenced by at least one of the following:

1. Reduction of daily dosing of required oral corticosteroids
2. Documented improvement in functional impairment
3. Reduction in number of symptom exacerbations

IV. EXCLUSIONS

A. Lupkynis will not be covered for the following:
   1. Patients less than 18 years of age
   2. Concomitant use with biologics, or cyclophosphamide
   3. Patients with a current or medical history of the following:
      a. HIV infection, or another severe viral infection (hepatitis B, hepatitis C, etc.)
      b. congenital or acquired immunodeficiency, or malignancy
      c. lymphoproliferative disease, or previous total lymphoid irradiation
      d. tuberculosis
   4. Any indications that are not FDA-approved, or guideline-supported

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Lupkynis [Prescribing Information]. Rockville, MD: Aurinia Pharmaceuticals Inc; January 2021.
2. Rovin BH, et al. Efficacy and safety of voclosporin versus placebo for lupus nephritis (AURORA 1): a double-blind, randomised, multicentre, placebo-controlled, phase 3 trial. Lancet. 2021 May 29;397(10289):2070-2080.
3. Hahn BH, McMahon MA, Wilkinson A, et al. American College of Rheumatology guidelines for screening, treatment, and management of lupus nephritis. Arthritis Care Res. 2012;64(6):797-808.
4. 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 Int. 2019; 95(2):281-95.
5. Institute for Clinical and Economic Review. Belimumab and Voclosporin for Lupus Nephritis: Effectiveness and Value. Final Report. April 16, 2021. Available at: www.icer.org. Accessed September 30, 2021.
6. 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.

VI. APPROVALS

Signature on file at JHHC

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