STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Services
Prior Authorization Criteria
Lupkynis® (Voclosporin)
Effective 5/26/2021

Prior Authorization Request Form

***Lupkynis**, a calcineurin inhibitor immunosuppressant, is indicated in combination with a background immunosuppressive therapy regimen for the treatment of adults with active lupus nephritis.*

CRITERIA FOR APROVAL:

1. The patient must have a diagnosis of active lupus nephritis (LN); **AND**
2. Patient is positive for autoantibodies (anti-nuclear antibody [ANA] and anti-double-stranded DNA [anti-dsDNA]); **AND**
3. Patient has International Society of Nephrology/Renal Pathology Society (ISN/RPS) biopsy-proven active Class III or IV lupus nephritis alone or in combination with Class V lupus nephritis; **AND**
4. Patient has Urine protein to creatinine (UPCR) ratio ≥ 1.5 mg/mg for Class III or IV OR UPCR ≥ 2 mg/mg for Class V; **AND**
5. Patient must be ≥ 18 years of age; **AND**
6. Patient has an estimated glomerular filtration rate (eGFR) > 45 mL/min/m2; **AND**
7. Lupkynis must be prescribed by, or in consultation with, a nephrologist or rheumatologist; **AND**
8. Patient is using (for a minimum of 3-months) and will continue to use background immunosuppressive therapy for LN with a corticosteroid ***AND*** mycophenolate mofetil or azathioprine; **AND**
9. Patient must have been trialed on Benlysta for ninety (90) days and experienced inadequate response or therapeutic failure, unless otherwise contraindicated.

Approval Duration:

Initial approval: will be for 3 months.

An additional 3 months of therapy may be granted if the following criteria are met:

1. Patient must continue to meet initial approval criteria; **AND**
2. Demonstrate continued documented compliance; **AND**
3. There is no evidence of toxicity from Lupkynis; **AND**
4. Documentation is provided indicating stabilization of disease or an absence of disease progression.

Note: Safety and efficacy have not been established in combination with cyclophosphamide and is not recommended. The recommended starting dose is 23.7 mg twice daily taken on an empty stomach, used in combination with mycophenolate mofetil and corticosteroids. Dose modifications are required based on estimated glomerular filtration rate (eGFR). Lupkynis is not recommended if baseline eGFR is ≤ 45 mL/min/1.73 m2 unless the benefit exceeds the risk. The manufacturer recommends discontinuation of Lupkynis if therapeutic benefit is not apparent by Week 24.

All requests for additional therapy beyond 24 weeks may be considered on a case-by-case basis by the medical director.

References:

1). Lexi-Comp Clinical Application 5/2021

2). Lupkynis Package Insert 5/2021

3) UpToDate Article: Lupus nephritis: Initial and subsequent therapy for focal or diffuse lupus nephritis. (accessed 5/2021)