Lupkynis (voclosporin)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial request: 6 months Continuation request: 1 year

Medications	Quantity Limit
Lupkynis (voclosporin)	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Lupkynis (voclosporin) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Individual has a diagnosis of active lupus nephritis; **AND**
III. Individual has Class III, IV, or V lupus nephritis showing active or chronic lesions, and confirmed by renal biopsy; **AND**
IV. Documentation is provided that individual has a urinary protein to creatinine ratio of greater than or equal to 1.5; **AND**
V. Documentation is provided that individual has a baseline eGFR of greater than 45 mL/min/1.73 m^2; **AND**
VI. Individual is using in combination with a background immunosuppressive therapy regimen that includes mycophenolate mofetil and corticosteroids.

Continuation of therapy requests for Lupkynis (voclosporin) may be approved if the following criteria are met:

I. Individual is using in combination with background immunosuppressive therapy that includes mycophenolate mofetil and corticosteroids; **AND**
II. Individual did not require rescue medications at any time (for example, rituximab), or repeated use of high dose steroids after 16 weeks following Lupkynis initiation (i.e., more than 10 mg of prednisone, or equivalent, for three (3) or more consecutives days ***or*** for more than seven (7) days in total in an 8 week period); **AND**
III. Documentation is provided for confirmation of a therapeutic renal response (for example, improvement [or no worsening] of the urinary protein to creatinine ratio compared to baseline, or no decrease in eGFR of more than 20% from baseline).

Lupkynis (voclosporin) may not be approved for the following (Label, NCT03021499):

I. Individual is using in combination with cyclophosphamide, belimumab (Benlysta), or anifrolumab-fnia (Saphnelo); **OR**
II. Individual is using concomitantly with strong CYP3A4 inhibitors (for example, ketoconazole, itraconazole, clarithromycin)**; OR**
III. Individual has blood pressure (BP) of greater than 165/105 mmHg, or evidence of a hypertensive emergency; **OR**

IV. Individual has severe hepatic impairment (Child-Pugh C); **OR**
V. Individual has congenital or acquired immunodeficiency; **OR**
VI. Individual has lymphoproliferative disease or previous total lymphoid irradiation; **OR**
VII. Individual has a severe viral infection or known HIV infection; **OR**
VIII. Individual has active tuberculosis (TB).

Note:

Lupkynis has a black box warning for malignancies and serious infections, which may lead to hospitalization or death.

Key References:

1. American College of Rheumatology (ACR). Guidelines for referral and management of systemic lupus erythematosus in adults. Arthritis & Rheumatism. 1999; 42(9): 1785-1796.
2. Aringer M, Costenbader KH, Daikh DI, et. al. 2019 EULAR/ACR Classification Criteria for Systemic Lupus Erythematosus. Arthritis Rheumatol. 2019 Sep; 71(9): 1400-1412. Doi: 10.1002/art.40930. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6827566/. Accessed July 12, 2023.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 12, 2023.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Hahn BH, McMahon M, Wilkinson A, et. Al. American College of Rheumatology Guidelines for Screening, Case Definition, Treatment and Management of Lupus Nephritis. Arthritis Care Res (Hoboken). 2012 Jun; 64(6): 797-808. Doi: 10.1002/acr.21664. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3437757/. Accessed on July 12, 2023.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; Updated periodically.
7. NCT03021499. U.S. National Library of Medicine, ClinicalTrials.gov website. https://clinicaltrials.gov/ct2/show/NCT03021499?term=NCT03021499&draw=2&rank=1.
8. Rovin BH, Solomons N, Pendergraft WF 3rd, et al. 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. doi:10.1016/j.kint.2018.08.025.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.