What more can be done for patients who aren't reaching treatment goals?

Not an actual patient

Patient with lupus nephritis who remains stable on MMF + steroids but has not reached treatment goals

Natalie S., 36-year-old patient with lupus nephritis

- Natalie was diagnosed with lupus nephritis 1 year ago and treated with MMF + steroids
- Follow-up appointments showed improvement; however, she was not reaching EULAR/ERA–EDTA-recommended treatment goals[1]
  - UPCR remains above recommendation of ≤0.5-0.7 mg/mg
  - Steroid use remains above recommendation of ≤7.5 mg/day
- Her physician is concerned that she may be at risk for poor outcomes and is considering adding treatment

EULAR/ERA–EDTA=European League Against Rheumatism and European Renal Association–European Dialysis and Transplant Association; MMF=mycophenolate mofetil; UPCR=urine protein/creatinine ratio.

Indications

LUPKYNIS is indicated in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis (LN). *Limitations of Use*: Safety and efficacy of LUPKYNIS have not been established in combination with cyclophosphamide. Use of LUPKYNIS is not recommended in this situation.

Important Safety Information

BOXED WARNINGS: MALIGNANCIES AND SERIOUS INFECTIONS – Increased risk for developing malignancies and serious infections with LUPKYNIS or other immunosuppressants that may lead to hospitalization or death.

Please see additional Important Safety Information and Prescribing Information including Boxed Warning and Medication Guide for LUPKYNIS.

Lupkynis™ (voclosporin) capsules 7.9 mg

Clinical history

Natalie S., 36-year-old patient with lupus nephritis

Lupus nephritis diagnosed 1 year ago

Biopsy findings at baseline

- ISN Class III
- Focal proliferative lupus nephritis affecting 40% of glomeruli
- Subendothelial and mesangial immune deposition

SLE history

- Diagnosed with SLE 2 years prior

Current medications

- MMF (3 g/day)
- Prednisone (10 mg/day)
- Hydroxychloroquine (200 mg BID)
- Hormonal IUD
- ACE inhibitor

Laboratory findings and vitals

	Baseline (12 months prior)	6 months prior	Present day
UPCR (mg/mg)	1.8	1.2	1.2
Serum albumin (g/dL)	3.0	3.2	3.2
Urine microscopy	5 RBC/HPF	2 RBC/HPF	No active sediment
eGFR (mL/min/1.73 m²)	90	90	90
Serum creatinine (mg/dL)	0.8	0.8	0.8
C3 (mg/dL)	70	80	78
C4 (mg/dL)	10	12	9
Anti-dsDNA (IU/mL)	115	70	75
BP (mmHg)	120/80	119/79	118/78
Weight (lbs)	150	155	168

This is a hypothetical case study. This resource is intended to help you determine the types of patients who may be appropriate for treatment with LUPKYNIS. This representation was not designed to assess efficacy for an individual patient subgroup.

BID=twice daily; BP=blood pressure; eGFR=estimated glomerular filtration rate; SLE=systemic lupus erythematosus.

Reaching treatment goals can help improve outcomes for patients with lupus nephritis[1]

EULAR/ERA–EDTA guidelines reinforce the importance of early response to treatment and reduction in steroid use[1]

- Reduction in proteinuria of at least 25% by 3 months and 50% by 6 months
- UPCR target ≤0.5-0.7 mg/mg by 12 months
- Steroids reduced to ≤7.5 mg/day by 3 to 6 months

LUPKYNIS™ (voclosporin) can help more patients achieve treatment goals vs standard of care (MMF + steroids) alone[2,3,a]

- LUPKYNIS offers significantly greater complete renal response rates and faster proteinuria reductions vs standard of care alone while reducing steroid use[b]
- Consistent efficacy observed across racial and ethnic subgroups[4,c]

To learn more about how LUPKYNIS can help your patients with lupus nephritis, **visit LUPKYNISpro.com**

[a]The AURORA Phase 3 trial was a randomized, double-blind, placebo-controlled trial of LUPKYNIS 23.7 mg BID in combination with MMF (target 2 g/day) and corticosteroids (n=179) vs placebo BID in combination with MMF and corticosteroids (n=178) in adults with class III or IV (alone or in combination with class V) or class V lupus nephritis. Efficacy was established on the basis of complete renal response at Week 52. Key secondary endpoints included complete renal response at Week 24, partial renal response (50% reduction in UPCR from baseline) at Weeks 24 and 52, time to UPCR ≤0.5 mg/mg, and time to 50% reduction in UPCR.[2,5]

[b]The primary efficacy endpoint of complete renal response was defined as a confirmed UPCR of ≤0.5 mg/mg; eGFR ≥60 mL/min/1.73 m^2 or no confirmed decrease from baseline in eGFR of >20% or no treatment- or disease-related eGFR-associated event at time of assessment; presence of sustained, low-dose steroids (≤10 mg prednisone from Weeks 44-52); and no administration of rescue medications. Proteinuria reduction was based on time to UPCR of ≤0.5 mg/mg.[2]

[c]Post hoc analysis; the study was not powered to detect differences in the treatment effect between these subgroups; therefore, results from this post hoc analysis should be interpreted with caution.

Important Safety Information (cont.)

CONTRAINDICATIONS: LUPKYNIS is contraindicated in patients taking strong CYP3A4 inhibitors because of the increased risk of acute and/or chronic nephrotoxicity, and in patients who have had a serious/severe hypersensitivity reaction to LUPKYNIS or its excipients.

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CONTRAINDICATIONS: LUPKYNIS is contraindicated in patients taking strong CYP3A4 inhibitors because of the increased risk of acute and/or chronic nephrotoxicity, and in patients who have had a serious/severe hypersensitivity reaction to LUPKYNIS or its excipients.

WARNINGS AND PRECAUTIONS

Lymphoma and Other Malignancies: Immunosuppressants, including LUPKYNIS, increase the risk of developing lymphomas and other malignancies, particularly of the skin. The risk appears to be related to increasing doses and duration of immunosuppression rather than to the use of any specific agent.

Serious Infections: Immunosuppressants, including LUPKYNIS, increase the risk of developing bacterial, viral, fungal, and protozoal infections (including opportunistic infections), which may lead to serious, including fatal, outcomes.

Nephrotoxicity: LUPKYNIS, like other calcineurin inhibitors (CNIs), may cause acute and/or chronic nephrotoxicity. The risk is increased when CNIs are concomitantly administered with drugs associated with nephrotoxicity.

Hypertension: Hypertension is a common adverse reaction of LUPKYNIS therapy and may require antihypertensive therapy.

Neurotoxicity: LUPKYNIS, like other CNIs, may cause a spectrum of neurotoxicities: severe include posterior reversible encephalopathy syndrome (PRES), delirium, seizure, and coma; others include tremor, paresthesia, headache, and changes in mental status and/or motor and sensory functions.

Hyperkalemia: Hyperkalemia, which may be serious and require treatment, has been reported with CNIs, including LUPKYNIS. Concomitant use of agents associated with hyperkalemia may increase the risk for hyperkalemia.

QTc Prolongation: LUPKYNIS prolongs the QTc interval in a dose-dependent manner when dosed higher than the recommended lupus nephritis therapeutic dose. The use of LUPKYNIS in combination with other drugs that are known to prolong QTc may result in clinically significant QT prolongation.

Immunizations: Avoid the use of live attenuated vaccines during treatment with LUPKYNIS. Inactivated vaccines noted to be safe for administration may not be sufficiently immunogenic during treatment with LUPKYNIS.

Pure Red Cell Aplasia: Cases of pure red cell aplasia (PRCA) have been reported in patients treated with another CNI immunosuppressant. If PRCA is diagnosed, consider discontinuation of LUPKYNIS.

Drug-Drug Interactions: Avoid co-administration of LUPKYNIS and strong CYP3A4 inhibitors or with strong or moderate CYP3A4 inducers. Reduce LUPKYNIS dosage when co-administered with moderate CYP3A4 inhibitors. Reduce dosage of certain P-gp substrates with narrow therapeutic windows when co-administered.

ADVERSE REACTIONS

The most common adverse reactions (≥3%) were glomerular filtration rate decreased, hypertension, diarrhea, headache, anemia, cough, urinary tract infection, abdominal pain upper, dyspepsia, alopecia, renal impairment, abdominal pain, mouth ulceration, fatigue, tremor, acute kidney injury, and decreased appetite.

SPECIFIC POPULATIONS

Pregnancy/Lactation: May cause fetal harm. Advise not to breastfeed.

Renal Impairment: Not recommended in patients with baseline eGFR ≤45 mL/min/1.73 m^2 unless benefit exceeds risk. If used in this population, reduce LUPKYNIS dose.

Hepatic Impairment: For mild or moderate hepatic impairment, reduce LUPKYNIS dose. Avoid use with severe hepatic impairment.

Please see Prescribing Information including Boxed Warning and Medication Guide for LUPKYNIS.

References: 1. Fanouriakis A, Kostopoulou M, Cheema K, et al. 2019 update of the joint European League Against Rheumatism and European Renal Association–European Dialysis and Transplant Association (EULAR/ERA–EDTA) recommendations for the management of lupus nephritis. *Ann Rheum Dis*. 2020;79(6):713-723. **2.** LUPKYNIS [package insert]. Rockville, MD: Aurinia Pharma U.S., Inc., 2021. **3.** Aurinia Pharma U.S., Inc. Data on file. **4.** Arriens C, Polyakova S, Adzerikho I, et al; AURORA Study Group. AURORA phase 3 study demonstrates voclosporin statistical superiority over standard of care in lupus nephritis. Presented at: EULAR European E-Congress of Rheumatology 2020; June 3-Sept 1, 2020. **5.** Gibson K, Parikh S, Saxena A, et al; AURORA Study Group. AURORA phase 3 study demonstrates voclosporin statistical superiority over standard of care in lupus nephritis. Presented at: National Kidney Foundation virtual 2020 Spring Clinical Meetings; March 26-29, 2020.

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