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5.99.021

Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Miscellaneous Products	**Original Policy Date:**	February 26, 2021
Subject:	Lupkynis	**Page:**	1 of 5

Last Review Date: September 6, 2024

Lupkynis

Description

Lupkynis (voclosporin)

Background
Lupkynis (voclosporin) is a calcineurin-inhibitor immunosuppressant. Activation of lymphocytes involves an increase in intracellular calcium concentrations that bind to the calcineurin regulatory site and activate calmodulin binding catalytic subunit and through dephosphorylation activates the transcription factor, Nuclear Factor of Activated T-Cell Cytoplasmic (NFATc). The immunosuppressant activity results in inhibition of lymphocyte proliferation, T-cell cytokine production, and expression of T-cell activation surface antigens (1).

Regulatory Status
FDA-approved indication: Lupkynis is a calcineurin-inhibitor immunosuppressant indicated in combination with a background immunosuppressive therapy regiment for the treatment of adult patients with active lupus nephritis (LN) (1).

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 (1).

Lupkynis has a boxed warning regarding increased risk for developing serious infections and malignancies with Lupkynis or other immunosuppressants that may lead to hospitalization or death. Patients should be examined for skin changes and advised to avoid or limit sun exposure and to avoid artificial UV light. Patients should also be monitored for infections including cytomegalovirus and herpes zoster infections (1).

An accurate estimated glomerular filtration rate (eGFR) should be established at baseline. Use of Lupkynis is not recommended in patients with a baseline eGFR ≤45 mL/min/1.73m^2 unless the benefit exceeds the risk; these patients maybe at an increased risk for acute and/or chronic nephrotoxicity (1).

Blood pressure (BP) should be checked at baseline also. Lupkynis should not be initiated in patients with BP > 165/105 mmHg or with hypertensive emergency (1).

If the patient does not experience therapeutic benefit by 24 weeks, discontinuation of Lupkynis should be considered. Safety and efficacy have not been established beyond one year. The rirsk and benefits of longer durations of treatment should be considered in light of the patient's treatment response and risk of worsening nephrotoxicity (1).

The use of live attenuated vaccines should be avoided during treatment with Lupkynis. Inactivated vaccines noted to be safe for administration may not be sufficiently immunogenic during treatment with Lupkynis (1).

The safety and effectiveness of Lupkynis in pediatric patients less than 18 years of age have not been established (1).

Related policies

Benlysta

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Lupkynis may be considered **medically necessary** if the conditions indicated below are met.

Lupkynis may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Lupus nephritis

AND ALL of the following:

1. Must have active lupus nephritis
2. Must be receiving background immunosuppressive therapy (e.g., mycophenolate mofetil and corticosteroids) but **NOT** cyclophosphamide
3. Prescriber agrees to monitor eGFR and blood pressure
4. Prescriber agrees to monitor for serious infections and malignancies
5. **NOT** given concurrently with live vaccines

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Lupus nephritis

AND ALL of the following:

1. Documented clinical benefit from therapy (e.g., increase or stabilization in eGFR and no renal worsening due to disease state or treatment)
2. Prescriber has determined the benefits outweigh the risks of continued treatment with Lupkynis
3. Must be receiving background immunosuppressive therapy (e.g., mycophenolate mofetil and corticosteroids) but **NOT** cyclophosphamide
4. Prescriber agrees to monitor eGFR and blood pressure
5. Prescriber agrees to monitor for serious infections and malignancies
6. **NOT** given concurrently with live vaccines

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Quantity 540 capsules per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits
Same as above

Rationale

Summary
Lupkynis (voclosporin) is a calcineurin-inhibitor immunosuppressant indicated in combination with a background immunosuppressive therapy regiment for the treatment of adult patients with active lupus nephritis. Lupkynis has a boxed warning regarding increased risk for developing serious infections and malignancies with Lupkynis or other immunosuppressants. Safety and efficacy of Lupkynis have not been established in combination with cyclophosphamide. The safety and effectiveness of Lupkynis in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Lupkynis while maintaining optimal therapeutic outcomes.

References
1. Lupkynis [package insert]. Rockville, MD: Aurinia Pharma U.S., Inc.; April 2024.

Policy History

Date	Action
February 2021	Addition to PA
June 2021	Annual editorial review. PA duration changed from 6 months to 12 months per SME.
December 2021	Annual review
June 2022	Annual review

June 2023	Annual review. Changed policy number to 5.99.021
March 2024	Annual review
September 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.