Lupkynis (voclosporin)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Lupkynis drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies in the treatment of lupus nephritis (LN).

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the patient has no exclusions to the prescribed therapy.

FDA-Approved 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.

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Exclusions

Coverage will not be provided for members using Lupkynis in combination with cyclophosphamide.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

1. Initial requests: Medical records (e.g., chart notes, lab reports) documenting the presence of autoantibodies relevant to systemic lupus erythematous (SLE) (e.g., ANA, anti-ds DNA, anti-Sm, antiphospholipid antibodies, complement proteins), or kidney biopsy supporting the diagnosis.
2. Continuation requests: Medical records (e.g., chart notes, lab reports) documenting disease stability or improvement.

Criteria for Initial Approval

Lupkynis (voclosporin) may be considered **medically necessary** for the treatment of lupus nephritis (LN) when all of the following criteria are met:

1. Prior to initiating therapy, the member is positive for autoantibodies relevant to SLE (e.g., ANA, anti-ds DNA, anti-Sm, antiphospholipid antibodies, complement proteins) or lupus nephritis was confirmed on kidney biopsy
2. Member has clinically active lupus renal disease and is receiving background therapy with mycophenolate mofetil (MMF) with corticosteroids
3. The medication is being prescribed by, or in consultation with, a nephrologist or rheumatologist
4. Member must have an eGFR ≥45ml/min per 1.73 m^2

Approval will be for **12 months.**

Continuation of Therapy

The continued treatment with Lupkynis (voclosporin) may be considered **medically necessary** for the treatment of lupus nephritis (LN) in members who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Approval will be for **12 months.**

Lupkynis is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Medication Name	Quantity Limit	FDA-recommended dosing
Lupkynis 7.9 mg capsules	180 capsules per 30 days	Recommended dose: 23.7 mg twice a day Dose Reduction: • If eGFR <60 mL/min/1.73 m^2 and reduced from baseline by >20% and <30%, reduce the dose by 7.9 mg twice a day • For patients that had a decrease in dose due to eGFR, consider increasing the dose by 7.9 mg twice a day for each eGFR measurement that is ≥80% of baseline; do not exceed the starting dose

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- N/A

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POLICY HISTORY

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