Original Effective Date: 05/01/2021
Current Effective Date: 12/09/2023
Last P&T Approval/Version: 10/25/2023
Next Review Due By: 10/2024
Policy Number: C21124-A

Lupkynis (voclosporin)

PRODUCTS AFFECTED

Lupkynis (voclosporin)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Active Lupus Nephritis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. ACTIVE LUPUS NEPHRITIS:
1. Documented diagnosis of systemic lupus erythematosus (SLE)
   AND
2. Documentation of kidney biopsy with a histologic diagnosis of lupus nephritis Classes III, IV,

V to confirm diagnosis of active lupus nephritis [DOCUMENTATION REQUIRED]
AND

3. Documentation the member does not have baseline eGFR ≤45 mL/min/1.73 m2 OR the prescriber attests that the benefit exceeds the increased risk of acute and/or chronic nephrotoxicity
AND
4. Prescriber attests member does not have severe hepatic impairment
AND
5. Prescriber attests member has a baseline blood pressure ≤ 165/105mmHg
AND
6. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Lupkynis (voclosporin) include: Patients concomitantly using strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin), known serious or severe hypersensitivity reaction to LUPKYNIS or any of its excipients]
AND
7. Prescriber attests Lupkynis (voclosporin) will NOT be used concurrently with cyclophosphamide
NOTE: Safety and efficacy of Lupkynis have not been established in combination with cyclophosphamide. Use of Lupkynis is not recommended in this situation.
AND
8. Prescriber attests Lupkynis (voclosporin) will be used concurrently with appropriate background immunosuppressive therapy (i.e., mycophenolate mofetil and corticosteroids)

CONTINUATION OF THERAPY:

A. ACTIVE LUPUS NEPHRITIS

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history (Note: Review Rx history for compliance)
AND
2. Documentation of member response to therapy as evidenced by both of the following [DOCUMENTATION REQUIRED]:
(a) UPCR of ≤ 0.5mg/mg
AND
(b) eGFR is ≥ 60 ml/min/1.73m2 OR has not decreased more than 30% from baseline
NOTE: If member has an eGFR < 60 ml/min/1.73m2 and it is reduced from baseline by >30%, Lupkynis should be discontinued
NOTE: If the member has not experienced therapeutic benefit by 24 weeks, consider discontinuation of LUPKYNIS.
AND
3. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
AND
4. Prescriber attests Lupkynis (voclosporin) is being used concurrently with appropriate background immunosuppressive therapy (i.e., mycophenolate mofetil and corticosteroids)

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a nephrologist OR rheumatologist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:
Maximum quantity 47.4 mg/day

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Cyclosporine Analogs

FDA-APPROVED USES:
Indicated in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis
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.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information
State Marketplace
Texas (Source: Texas Statutes, Insurance Code)
"Sec. 1369.654. PROHIBITION ON MULTIPLE PRIOR AUTHORIZATIONS.
(a) A health benefit plan issuer that provides prescription drug benefits *may not require an enrollee to receive more than one prior authorization annually* of the prescription drug benefit for *a prescription drug prescribed to treat an autoimmune disease, hemophilia, or Von Willebrand disease*.
(b) This section does not apply to:
(1) opioids, benzodiazepines, barbiturates, or carisoprodol;
(2) prescription drugs that have a typical treatment period of less than 12 months;
(3) drugs that:
(A) have a boxed warning assigned by the United States Food and Drug Administration for use; and
(B) must have specific provider assessment; or
(4) the use of a drug approved for use by the United States Food and Drug Administration in a manner other than the approved use."

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
The recommended starting dose of LUPKYNIS is 23.7 mg twice a day.
Use LUPKYNIS in combination with mycophenolate mofetil (MMF) and corticosteroids

Safety and efficacy of LUPKYNIS have not been established in combination with cyclophosphamide.
Use of LUPKYNIS is not recommended in this situation

Dosage of LUPKYNIS is based on the patient's eGFR. Modify LUPKYNIS dosage based on eGFR

- Assess eGFR every 2 weeks for the first month, and every 4 weeks thereafter
- If eGFR is <60 mL/min/1.73 m and reduced from baseline by >20% and <30%, reduce the dose by 7.9 mg twice a day. Reassess eGFR within 2 weeks; if eGFR is still reduced from baseline by >20%, reduce the dose again by 7.9 mg twice a day
- If eGFR is <60 mL/min/1.73 m and reduced from baseline by ≥30%, discontinue LUPKYNIS. Reassess eGFR within 2 weeks; consider re-initiating LUPKYNIS at a lower dose (7.9 mg twice a day) only if eGFR has returned to ≥80% of baseline
- For patients who 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

Monitor blood pressure every 2 weeks for the first month after initiating LUPKYNIS, and as clinically indicated thereafter. For patients with BP >165/105 mmHg or with hypertensive emergency, discontinue LUPKYNIS and initiate antihypertensive therapy.

If the patient does not experience therapeutic benefit by 24 weeks, consider discontinuation of LUPKYNIS.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Lupkynis (voclosporin) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Lupkynis (voclosporin) include: Patients concomitantly using strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin), known serious or severe hypersensitivity reaction to LUPKYNIS or any of its excipients.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Lupkynis CAPS 7.9MG

REFERENCES

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Available Dosage Forms	Q4 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Contraindications/Exclusions/Discontinuation References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file