ConnectiCare

Commercial & HealthCare Exchange PA Criteria
Effective: 6/9/2021

Prior Authorization: LUPKYNIS™ (voclosporin)

Products Affected: LUPKYNIS (voclosporin) oral capsules

Medication Description:
LUPKYNIS is a calcineurin-inhibitor immunosuppressant. The mechanism of voclosporin suppression of calcineurin has not been fully established. 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.

Covered Uses: Active lupus nephritis (LN)

Exclusion Criteria:
- Patients concomitantly using strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin) because these medications can significantly increase exposure to LUPKYNIS which may increase the risk of acute and/or chronic nephrotoxicity.
- Patients who have had a known serious or severe hypersensitivity reaction to LUPKYNIS or any of its excipients.
- Safety and efficacy of Lupkynis have NOT been established in combination with cyclophosphamide.

Required Medical Information:
1. Diagnosis
2. Previous therapies tried
3. Measurements of kidney function (eGFR, CrCl)

Age Restrictions: 18 years of age or older.

Prescriber Restrictions: Prescribed by or in consultation with a nephrologist or rheumatologist

Coverage Duration: 24 weeks for initial treatment and 12 months for continuation of therapy

Other Criteria:

I. Initial Approval Criteria
(must meet all):

1. Patient has diagnosis of active lupus nephritis; AND
2. The medication will be used in combination with a background immunosuppressive therapy regimen (~~with~~ e.g. mycophenolate mofetil (MMF) and corticosteroids); AND
3. Patient has a baseline eGFR > 45 mL/min/1.73 m2 (unless the benefit exceeds the risk of cute and/or chronic nephrotoxicity)

II. Continued Therapy

1. Member is responding positively to therapy as determined by the prescriber; AND
2. Member has not experienced unacceptable toxicity from the drug (Consider the risks and benefits of LUPKYNIS treatment beyond one year in light of the patient's treatment response and risk of worsening nephrotoxicity. Some other precautions include hyperkalemia, QT prolongation, and Pure Red Cell Aplasia).

References:

1.LUPKYNIS (voclosporin) capsules [Package Insert]. Rockville, MD. Aurinia Pharma U.S., Inc. Updated January 11, 2021. Accessed April 23, 2021. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=9f489295-1156-52c7-5fd0-5c4c52f9b813

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New policy	New policy	All	6/9/2021