BlueCross BlueShield Federal Employee Program

LUPKYNIS
(voclosporin)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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.