BlueCross BlueShield
Federal Employee Program

SPEVIGO
(spesolimab-sbzo)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Spevigo (spesolimab-sbzo) is a humanized monoclonal immunoglobulin G1 antibody that inhibits interleukin-36 (IL-36) signaling by specifically binding to the IL36R. This prevents the subsequent activation of the IL36R and downstream activation of pro-inflammatory and pro-fibrotic pathways (1).

Regulatory Status

FDA-approved indication: Spevigo is an interleukin-36 receptor antagonist indicated for the treatment of generalized pustular psoriasis (GPP) in adults and pediatric patients 12 years of age and older and weighing at least 40 kg (1).

Spevigo may increase the risk of infections. Treatment with Spevigo is not recommended for use in patients with any clinically important active infection until the infection resolves or is adequately treated (1).

Patients should be evaluated for tuberculosis (TB) infection prior to initiating treatment with Spevigo. Spevigo should not be administered to patients with active TB infection. Anti-TB therapy should be considered prior to initiating Spevigo in patients with latent TB or a history of TB in whom an adequate course of treatment cannot be confirmed (1).

Spevigo-associated hypersensitivity reactions may include immediate reactions such as anaphylaxis and delayed reactions such as drug reaction with eosinophilia and systemic symptoms (DRESS) (1).

The use of live vaccines with Spevigo should be avoided (1).

The safety and effectiveness of Spevigo in pediatric patients less than 12 years of age and weighing less than 40kg have not been established (1).

Summary

Spevigo is an interleukin-36 receptor antagonist that is indicated for the treatment of generalized

pustular psoriasis (GPP) and for prevention of flares. Spevigo may cause hypersensitivity reactions including DRESS. Spevigo should not be given to patients with clinically important active infections, including TB. The safety and effectiveness of Spevigo in pediatric patients less than 12 years of age and weighing less than 40kg have not been established (1).

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

References

1. Spevigo [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; March 2024.
2. Menter A, Gelfand JM, Connor C, et al. Joint AAD-NPF guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020;82:1445-86.