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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Topical Products	**Original Policy Date:**	September 30, 2022
Subject:	Spevigo	**Page:**	1 of 5

Last Review Date: March 8, 2024

Spevigo

Description

Spevigo (spesolimab-sbzo)

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 indicated for the treatment of generalized pustular psoriasis (GPP) flares in adults (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 18 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Spevigo may be considered **medically necessary** if the conditions indicated below are met.

Spevigo may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Generalized pustular psoriasis (GPP) flares

AND ALL of the following:

1. GPP flare is of moderate-to-severe intensity (e.g., at least 5% of body surface area covered with erythema and the presence of pustules)
2. Patient has had an inadequate treatment response, intolerance, or contraindication to **ONE** of the following:
    a. Methotrexate
    b. Cyclosporine
    c. Oral retinoid
3. Prescriber agrees to monitor for hypersensitivity reactions, including drug reaction with eosinophilia and systemic symptoms (DRESS)
4. Result for latent TB infection is negative **OR** result was positive for latent TB

and patient completed treatment (or is receiving treatment) for latent TB
5. Absence of active infection (including tuberculosis)
6. **NOT** used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
7. **NOT** given concurrently with live vaccines

Prior – Approval *Renewal* Requirements

None

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 4 single-dose vials

Duration 12 months

Prior – Approval *Renewal* Limits

None

Rationale

Summary

Spevigo is an interleukin-36 receptor antagonist that is indicated for the treatment of generalized pustular psoriasis (GPP) flares in adult patients. 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 18 years of age 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.;

September 2022.
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.

Policy History

Date	Action
September 2022	Addition to PA
December 2022	Annual review
September 2023	Annual review
March 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.

Appendix 1 - List of DMARDs

Biological disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
abatacept	Orencia
adalimumab	Humira
anakinra	Kineret
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade/Avsola/Inflectra/Renflexis
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan/Riabni/Ruxience/Truxima
sarilumab	Kevzara
secukinumab	Cosentyx
spesolimab-sbzo	Spevigo
tildrakizumab-asmn	Ilumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

Targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
apremilast	Otezla
baricitinib	Olumiant
deucravacitinib	Sotyktu
tofacitinib	Xeljanz/XR
upadactinib	Rinvoq