# Spevigo (spesolimab-sbzo)

## NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

## BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

## DESCRIPTION

The intent of the Spevigo (spesolimab-sbzo) policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines, and clinical studies. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Spevigo is 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.

## POLICY

Documentation
Submission of the following information is necessary to initiate the prior authorization review:

A. Generalized pustular psoriasis (GPP) flare
   1. Chart notes or medical record documentation of clinical presentation of pustules and affected area(s).
   2. Genetic test results, laboratory results, biopsy results, GPP severity assessment (e.g., Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) score), if applicable.

B. Generalized pustular psoriasis (GPP) when not experiencing a flare
   1. Initial requests:
      i. Chart notes or medical record documentation of history of GPP, including history of flares.

ii. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties
This medication must be prescribed by or in consultation with a dermatologist.

Criteria for Initial Approval
**Generalized pustular psoriasis (GPP) flare**
Authorization of 1 month may be granted for the treatment of generalized pustular psoriasis (GPP) flares in members 12 years of age or older when all of the following criteria are met:
A. Member is presenting with primary, sterile, macroscopically visible pustules (new or worsening) on non-acral skin (excluding cases where pustulation is restricted to psoriatic plaques).
B. Member has at least one of the following documented:
1. IL36RN, CARD14, AP1S3, MPO or SERPINA gene mutation.
2. Skin biopsy confirming presence of Kogoj's spongiform pustules.
3. Systemic symptoms or laboratory abnormalities commonly associated with GPP flare (e.g., fever, asthenia, myalgia, elevated C-reactive protein [CRP], leukocytosis, neutrophilia [above ULN]).
4. GPP flare of moderate-to-severe intensity (e.g., at least 5% body surface area is covered with erythema and the presence of pustules; Generalized Pustular Psoriasis Physician Global Assessment [GPPPGA] total score of greater or equal to 3).

**Generalized pustular psoriasis (GPP) when not experiencing a flare**
Authorization of 12 months may be granted for treatment of generalized pustular psoriasis in members 12 years of age or older when all of the following criteria are met:
A. Member has a known documented history of GPP (either relapsing [greater than 1 episode] or persistent [greater than 3 months]).
B. Member meets either of the following:
1. Member has had a history of at least two moderate-to-severe GPP flares (e.g., at least 5% body surface area is covered with erythema and the presence of pustules; Generalized Pustular Psoriasis Physician Global Assessment [GPPPGA] total score of greater or equal to 3).
2. Member has a history of flaring while on concomitant treatment (e.g., retinoids, methotrexate, cyclosporine).
C. Member currently has clear to almost clear skin.

Continuation of Therapy
**A. Generalized pustular psoriasis (GPP) flare**
All members 12 years of age or older (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

**B. Generalized pustular psoriasis (GPP) when not experiencing a flare**
Authorization of 12 months may be granted for all members 12 years of age or older (including new members) who are using the requested medication for GPP when not experiencing a flare and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Other:
For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST], an interferon-release assay [IGRA])* within 12 months of initiating therapy for

persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

* If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Spevigo (spesolimab-sbzo) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limit

Spevigo (spesolimab-sbzo) 450 mg/7.5mL vial – up to 4 vials per year
Spevigo prefilled syringe 150 mg/mL – 2 PFS per 28 days
Spevigo prefilled syringe 300 mg/2 mL – 2 PFS per 28 days

Appendix

**Generalized Pustular Psoriasis Physician Global Assessment**

| Score | Erythema | Pustules | Scaling |
|---|---|---|---|
| **0 (clear)** | Normal or post-inflammatory hyperpigmentation | No visible pustules | No scaling or crusting |
| **1 (almost clear)** | Faint, diffuse pink or slight red | Low-density occasional small discrete pustules (noncoalescent) | Superficial focal scaling or crusting restricted to periphery of lesions |
| **2 (mild)** | Light red | Moderate density grouped discrete small pustules (noncoalescent) | Predominantly fine scaling or crusting |
| **3 (moderate)** | Bright red | High density pustules with some coalescence | Moderate scaling or crusting covering most or all lesions |
| **4 (severe)** | Deep fiery red | Very high-density pustules with pustular lakes | Severe scaling or crusting covering most or all lesions |

* Individual score per body region = body region factor (head = 0.1, upper limb = 0.2, trunk = 0.3, lower limb = 0.4) x body region area score x sum of component severity scores in body region.
Total GPPASI score = sum of individual score from all body regions

## PROCEDURES AND BILLING CODES

**To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.**

- J1747 - Injection, spesolimab-sbzo, 1 mg (effective 4/1/2023)
- J3490 Unclassified drugs
- J3590 Unclassified biologics

- C9399 Unclassified drugs or biologicals

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## POLICY HISTORY

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