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) flares in adults.

POLICY

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

A. Chart notes or medical record documentation of affected area(s).
B. Laboratory results, GPP severity assessment (e.g., Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) score), if applicable.

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

Criteria for Initial Approval
Authorization may be granted for the treatment of a generalized pustular psoriasis (GPP) flare when all of the following criteria are met:

A. The member is 18 years of age or older.

B. The member has a diagnosis of Generalized Pustular Psoriasis (GPP) as defined by the presence of primary, sterile, visible pustules on non-acral skin where pustulation is NOT restricted to psoriatic plaques.
C. The member is experiencing a persistent GPP flare of moderate-to-severe intensity as defined by all of the following:
    1. Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of ≥3
    2. The presence of new or worsening pustules
    3. GPPGA pustulation sub score of at least 2 (mild)
    4. At least 5% of body-surface area with erythema and the presence of pustules

Approval will be for **one 900 mg dose (2 vials)**.

Approval Duration (1 week)

Continuation of Therapy

Authorization of one additional 900 mg dose (2 vials) given one week after the initial dose may be granted for the treatment of the same GPP flare when the following criteria are met:

A. The member is still experiencing persistent symptoms of an acute GPP flare of moderate-to-severe intensity, as defined all of the following:
    1. Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of ≥2
    2. GPPGA pustulation sub score of ≥2
    3. The second infusion will take place no sooner than one week after the initial infusion
B. The member will not take in combination with another biologic being used for GPP

Approval will be for **one 900 mg dose (2 vials)**.

Approval Duration (1 week)

Other:

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)* within 6 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. 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.

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

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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*Some content reprinted from CVSHealth

POLICY HISTORY

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