BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

SPEVIGO® (spesolimab-sbzo) injection

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

Section A. Acute flare of Generalized Pustular Psoriasis
SPEVIGO (spesolimab-sbzo) intravenous injection
Per FDA-label: IV infusion is to be administered by a healthcare professional in a healthcare setting only

- **Criteria for therapy:** Spevigo (Spesolimab-sbzo) *intravenous* injection is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in or is in consultation with a Dermatologist

  2. Individual is 12 years of age or older weighing at least 40 kilograms

  3. Individual has a confirmed diagnosis of an **acute flare** of Generalized Pustular Psoriasis (GPP) per ERASPEN criteria (see Definitions section) as indicated by **ALL** of the following:

a. Primary, sterile, macroscopically visible pustules on the skin and **ALL** of the following:
    i. With or without systemic inflammation
    ii. With or without plaque-type psoriasis
    iii. Flare is either relapsing (>1 episode) or persistent (>3 months)
b. Pustules occur outside of any psoriatic plaques
c. Previous or current evidence of fever, and/or asthenia (weakness), and/or myalgia, and/or elevated C-reactive protein, and/or leukocytosis with peripheral blood neutrophilia above the upper limit of normal (ULN)

4. Individual is **ONE** of the following:
    a. **NOT** currently receiving subcutaneous Spevigo and **ALL** of the following:
        i. **Acute** GPP flare is moderate-to-severe in intensity as indicated by **ALL** of the following (see Definitions section):
            1. Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of at least 3 (moderate)
            2. Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) pustulation sub-score of at least 2 (mild)
            3. Presence of new pustules or worsening of existing pustules
            4. Presence of erythema and pustules on at least 5% of body surface area (BSA)
    b. **IS** currently receiving subcutaneous Spevigo as *prevention* therapy and **ALL** of the following:
        i. Is experiencing a new or recurring moderate-to-severe **acute flare** of GPP (i.e., previously received and completed treatment for acute episode; is now experiencing another **acute flare**)
        ii. Last dose of intravenous Spevigo was 12 weeks ago
        iii. There is documentation that previous treatments with intravenous Spevigo for **acute** episodes of GPP result in **BOTH** of the following:
            1. GPPPGA total score of 0 or 1
            2. GPPPGA pustulation sub-score of 0
        iv. Individual is on other maintenance therapy (e.g., acitretin, methotrexate, cyclosporine) for the prevention of acute GPP flares
        v. Individual has not developed any contraindications or other significant adverse drug effects from previous use of Spevigo that may exclude continued use such as:
            1. Hypersensitivity reactions including drug reaction with eosinophilia and systemic symptoms (DRESS)
            2. Serious infusion reactions

5. **If available**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

6. Individual does **NOT** have **ANY** of the following:
    a. Evidence of active or serious infections including opportunistic infections, fungal infections, active or latent TB, clinically important localized infections, or sepsis
    b. Concurrent administration of live vaccines
    c. Synovitis–acne–pustulosis–hyperostosis–osteitis (SAPHO) syndrome
    d. Plaque psoriasis without pustular psoriasis
    e. Erythrodermic psoriasis
    f. Palmoplantar pustulosis
    g. Atopic dermatitis

h. Crohn's disease
i. Ulcerative colitis
j. Hidradenitis suppurativa
k. Use of intravenous form for prevention of GPP

7. There is no concomitant use with biologic immunomodulators (e.g., Adbry, Dupixent, rituximab, Enbrel, Otezla, Xolair, etc.) or combination use of JAK inhibitors (Cibinqo, Olumiant, Rinvoq, Xeljanz, etc.)

Approval duration: Up to 3 doses in a 12-week period
Recommended *intravenous* dosage for treatment of acute GPP flare is a single 900 mg dose

If flare symptoms persist, an additional 900 mg dose may be given 1-week after the initial dose

Qualification for dose at week 1 includes GPPPGA total score and GPPPGA pustulation sub-score ≥ 2

A third dose may be given up to week 12 if there is ≥ 2-point increase in both GPPPGA total score and GPPP pustulation sub-score ***after*** *achieving a clinical response* of GPPPGA total score of 0 or 1

Per FDA-label: IV infusion is to be administered by a healthcare professional in a healthcare setting only

Section B. Prevention Generalized Pustular Psoriasis
SPEVIGO (spesolimab-sbzo) subcutaneous injection

- **Criteria for initial therapy:** Spevigo (spesolimab-sbzo) *subcutaneous* injection is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Dermatologist

2. Individual is 12 years of age (weighing at least 40 kg) or older

3. Individual is **NOT** experiencing an acute flare of GPP as indicated by **BOTH** of the following:
   a. Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score is 0 or 1
   b. Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) pustulation sub score 0

4. Requested agent will be used to prevent acute GPP flares

5. Individual has a confirmed diagnosis of Generalized Pustular Psoriasis (GPP) per ERASPEN criteria (see Definitions section) as indicated by **ALL** of the following:
   a. Historical evidence of primary, sterile, macroscopically visible pustules on the skin and **ALL** of the following:
      i. With or without systemic inflammation
      ii. With or without plaque-type psoriasis
      iii. Either relapsing (>1 episode) or persistent (>3 months)
   b. Historical evidence GPP flares present with fever, and/or asthenia (weakness), and/or myalgia, and/or elevated C-reactive protein, and/or leukocytosis with peripheral blood neutrophilia above the upper limit of normal (ULN)

c. Evidence GPP flares are associated with at least 5% body surface area covered with erythema and pustules

6. Individual has a history of at least **TWO** GPP flares of moderate-to-severe intensity in the past (12-months) or has a history of flares during other preventive treatment or following attempts at dose reduction or discontinuation of concomitant preventive medications

7. Individual has completed **ALL** the following **baseline tests** before initiation of treatment and will have continued monitoring as clinically appropriate:
   a. Documentation of an evaluation for active or latent tuberculosis
   b. Age-appropriate vaccinations have been completed

8. **If available**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

9. Individual has documented failure (after at least 4 months use), contraindication per FDA label, intolerance, or is not a candidate for **ONE** the following:
   a. Acitretin
   b. Methotrexate
   c. Cyclosporine

10. There is no concomitant use with biologic immunomodulators (e.g., Adbry, Dupixent, rituximab, Enbrel, Otezla, Xolair, etc.) or combination use of JAK inhibitors (Cibinqo, Olumiant, Rinvoq, Xeljanz, etc.)

11. Individual does **NOT** have **ANY** of the following:
    a. Evidence of active or serious infections including opportunistic infections, fungal infections, active or latent TB, clinically important localized infections, or sepsis
    b. Concurrent administration of live vaccines
    c. Synovitis–acne–pustulosis–hyperostosis–osteitis (SAPHO) syndrome
    d. Plaque psoriasis without pustular psoriasis
    e. Erythrodermic psoriasis
    f. Palmoplantar pustulosis
    g. Atopic dermatitis
    h. Crohn's disease
    i. Ulcerative colitis
    j. Hidradenitis suppurativa
    k. Use of intravenous form for prevention of GPP

Initial approval duration: 6 months

Subcutaneous dosage for treatment of GPP when **NOT** experiencing an acute GPP flare:
Administer a subcutaneous loading dose of 600 mg (four 150 mg injections), followed by 300 mg (two 150 mg injections) subcutaneously 4 weeks later and *every 4 weeks* thereafter

Subcutaneous use **After intravenous** for treatment of acute GPP flare:
Four weeks after treatment with intravenous, initiate or reinitiate subcutaneous at a dose of 300 mg (two 150 mg injections) administered *every 4 weeks*

PHARMACY COVERAGE GUIDELINE

SPEVIGO® (spesolimab-sbzo) injection

- **Criteria for continuation of coverage (renewal request):** Spevigo (spesolimab-sbzo) *subcutaneous* injection considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Dermatologist

2. Individual is **NOT** experiencing an acute flare of GPP as indicated by **BOTH** of the following:
    a. Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score is 0 or 1
    b. Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) pustulation sub score 0

3. Requested agent will be used to prevent acute GPP flares

4. Individual has a confirmed diagnosis of Generalized Pustular Psoriasis (GPP) per ERASPEN criteria (see Definitions section) as indicated by **ALL** of the following:
    a. Historical evidence of primary, sterile, macroscopically visible pustules on non-acral skin (excluding cases where pustulation is restricted to psoriatic plaques) and **ALL** of the following:
        i. With or without systemic inflammation
        ii. With or without plaque-type psoriasis
        iii. Either relapsing (>1 episode) or persistent (>3 months)
    b. Historical evidence GPP flares present with fever, and/or asthenia (weakness), and/or myalgia, and/or elevated C-reactive protein, and/or leukocytosis with peripheral blood neutrophilia above the upper limit of normal (ULN)
    c. Evidence GPP flares are associated with at least 5% body surface area covered with erythema and pustules

5. Individual has documentation of positive clinical response to therapy defined as **TWO** of the following:
    a. Achieves and maintains Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score is 0 or 1
    b. Achieves and maintains a Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) pustulation sub score 0
    c. Historical increase in time to next GPP flare (flare defined by a GPPPGA pustulation sub score of ≥2 and an increase in GPPPGA total score by ≥2 from baseline)
    d. Reduced occurrence of at least one GPP flare

6. Individual has been adherent with the medication

7. **If available**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

8. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use such as:
    a. Active infection
    b. Anaphylaxis
    c. Drug reaction with eosinophilia and systemic symptoms (DRESS)
    d. Guillain-Barre syndrome

9. There is no concomitant use with biologic immunomodulators (e.g., Adbry, Dupixent, rituximab, Enbrel, Otezla, Xolair, etc.) or combination use of JAK inhibitors (Cibinqo, Olumiant, Rinvoq, Xeljanz, etc.)

10. Individual does **NOT** have **ANY** of the following:
    a. Evidence of active or serious infections including opportunistic infections, fungal infections, active or latent TB, clinically important localized infections, or sepsis
    b. Concurrent administration of live vaccines
    c. Synovitis–acne–pustulosis–hyperostosis–osteitis (SAPHO) syndrome
    d. Plaque psoriasis without pustular psoriasis
    e. Erythrodermic psoriasis
    f. Palmoplantar pustulosis
    g. Atopic dermatitis
    h. Ulcerative colitis
    i. Crohn's disease
    j. Hidradenitis suppurativa
    k. Use of intravenous form for prevention of GPP

Renewal duration: 12 months

Subcutaneous dosage for treatment of GPP when **Not** experiencing a flare:
Administer a subcutaneous loading dose of 600 mg (four 150 mg injections), followed by 300 mg (two 150 mg injections) subcutaneously 4 weeks later and *every 4 weeks* thereafter

Subcutaneous use **after intravenous** for treatment of acute GPP flare:
Four weeks after treatment with intravenous, initiate or reinitiate subcutaneous at a dose of 300 mg (two 150 mg injections) administered *every 4 weeks*

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**

2. **Off-Label Use of Cancer Medications**

Benefit Type:

Pharmacy Benefit:
Spevigo SQ

Medical Benefit:
Spevigo IV

Coding:

HCPCS: J1747

PHARMACY COVERAGE GUIDELINE

SPEVIGO® (spesolimab-sbzo) injection

Description:

Spevigo (spesolimab-sbzo) 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 who weigh at least 40 kg. It is a humanized monoclonal IgG1 antibody that inhibits interleukin-36 (IL-36) signaling by specifically binding to the IL36R. Binding of spesolimab-sbzo to IL36R prevents the subsequent activation of IL36R by its ligands (IL-36 α, β and γ) and downstream activation of pro-inflammatory and pro-fibrotic pathways. The precise mechanism linking reduced IL36R activity and the treatment of flares of GPP is unclear.

Pustular psoriasis is an uncommon subtype of psoriasis that may present as a generalized pustular skin eruption (generalized pustular psoriasis [GPP]) or a localized pustular skin eruption (acrodermatitis continua of Hallopeau and palmoplantar pustulosis).

Pustular psoriasis can have life-threatening complications. The most acute severe variant (the von Zumbusch-type of GPP) presents with the repeated occurrence of acute onset of widespread erythema, scaling, and sheets of superficial pustules. This form can be associated with malaise, fever, diarrhea, leukocytosis, and hypocalcemia. Potential complications include renal, hepatic, or respiratory abnormalities and sepsis. Patients with acute GPP typically appear systemically ill, and admission to the hospital is often necessary to ensure adequate supportive care. One study reported a mean hospital stay of 10.3 days with a range of 3 to 44 days. Another study reported a mean hospital stay of 11.5 days with 25% of patients admitted to the ICU. The decision to hospitalize a patient is made based upon consideration of the severity of illness, vital sign stability, fluid and electrolyte status, and concern for systemic infection. A mortality rate of 2-16% has been reported and may be underestimated due to lack of identification of cases and cause of death. The most commonly reported cause of death in GPP individuals is related to sepsis and its complications.

The severity and frequency of flares vary between patients and between different flares within the same patient. Patients may have multiple flares per year or one flare every few years. Episodes may last from 2 to 5 weeks but may continue for over 3 months.

Chronic GPP describes the state between acute disease flares and may be characterized by the complete absence of symptoms or the persistence of residual skin symptoms such as erythema and scaling and minor pustulation. It is estimated that up to 50% of GPP individuals suffer from the chronic form of the disease.

European Rare and Severe Psoriasis Expert Network (ERASPEN) characterizes GPP as primary, sterile, and macroscopically visible epidermal pustules on non-acral skin (i.e., of or belonging to the extremities of peripheral body parts). ERASPEN also states that GPP can occur with or without systemic inflammation, with or without plaque psoriasis, and is either relapsing (>1 episode) or persistent (>3 months). Japanese criteria diagnose GPP based on 4 factors: (1) systemic symptoms such as fever or fatigue; (2) systemic or extensive flush accompanied by multiple sterile pustules; (3) neutrophilic subcorneal pustules histologically characterized by Kogoj's spongiform pustules, and (4) the recurrence of these clinical and histologic findings. A definitive diagnosis of GPP in Japan can be made in patients who meet all four criteria and GPP would be suspected in those who meet criteria 2 and criteria 3.

Treatment strategies for GPP are not well-established. Standard treatment for GPP often follows that of plaque psoriasis, despite limited evidence of efficacy of anti-psoriatic drugs. GPP is distinct from plaque psoriasis in clinical presentation, pathophysiology, histopathology, response to therapies, epidemiology, and genetics. Current treatment options for controlling acute flares of GPP and maintenance of response are limited and do not provide sustained efficacy. To date, retinoids, cyclosporine, and methotrexate (MTX) are the most commonly

used nonbiologic systemic agents and are recommended by global guidelines as first-line therapy for patients with GPP.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Types of Psoriasis:

Psoriasis is a chronic disease in which the immune system becomes overactive, causing skin cells to multiply too quickly. Patches of skin become scaly and inflamed, most often on the scalp, elbows, or knees, but other parts of the body can be affected. The symptoms of psoriasis can cycle, flaring for a few weeks or months followed by periods when they subside or go into remission. Mild psoriasis can often be successfully treated with cream or ointments, while moderate and severe psoriasis may require oral medication, injections, or light treatments.

Plaque psoriasis (also known as psoriasis vulgaris). This is the most common kind of psoriasis, and it appears as raised, red patches of skin that are covered by silvery-white scales. The patches usually develop in a symmetrical pattern on the body and tend to appear on the scalp, trunk, and limbs, and especially the elbows and knees.

Pustular psoriasis. In this type of psoriasis, pus-filled bumps (pustules) surrounded by red skin appear. It usually affects isolated areas of the body such as the hands and feet or covers most of the skin's surface that spreads quickly. Symptoms can be triggered by medications, infections, stress, or certain chemicals. It can be life-threatening due to systemic effects and their complications.

Erythrodermic psoriasis (also known as exfoliative psoriasis). This is a rare but severe form of psoriasis characterized by red, scaly skin over most of the body. It can be triggered by a bad sunburn or taking certain medications, such as corticosteroids. It involves shedding of the skin with exfoliation occurring in large pieces. Almost all cases will need treatment in a hospital setting.

Guttate psoriasis. Is the second most common psoriasis type. This type of psoriasis usually appears in children or young adults, and looks like small, red dots, typically on the torso or limbs. Outbreaks are often triggered by an upper respiratory tract infection, such as strep throat.

Inverse psoriasis (also known as flexural psoriasis). This form of psoriasis appears as smooth, red patches in folds of skin, such as beneath the breasts or in the groin or armpits. Rubbing and sweating can make it worse. It may be misdiagnosed as a fungal or bacterial infection.

Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA)

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 (non-coalescent)	Superficial focal scaling or crusting restricted to periphery of lesions

2 (Mild)	Light red	Moderate density grouped discrete small pustules (non-coalescent)	Predominantly fine scaling or crusting
3 (Moderate)	Bright red	High density pustules with some coalescence	Moderate scaling or crusting covering most of all lesions
4 (Severe)	Deep fiery red	Very high-density pustules with pustular lakes	Severe scaling or crusting covering most of all lesions
Composite mean score = (erythema + pustules + scaling)/ 3; total GPPGA score is given 0 if mean = 0 for all three components, 1 if mean 0 to <1.5, 2 if mean 1.5 to <2.5, 3 if mean 2.5 to <3.5, 4 if mean ≥ 3.5.			

Diagnosis of GPP is based on the consensus diagnostic criteria defined by the European Rare and Severe Psoriasis Expert Network (ERASPEN):

Primary, sterile, macroscopically visible pustules on non-acral skin (excluding cases where pustulation is restricted to psoriatic plaques):

- With or without systemic inflammation
- With or without plaque-type psoriasis
- Either relapsing (>1 episode) or persistent (>3 months)

Resources:

Spevigo (spesolimab-sbzo) product information, revised by Boehringer Ingelheim Pharmaceuticals, Inc. 03-2023. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed May 13, 2025.

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nationwide inpatient database in Japan. J Am Acad Dermatol 2022; 86 (6):1266-74. Accessed May 19, 2024. Re-evaluated June 27, 2025.

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Fujita H, Terui T, Hayama K, et al.: Japanese guidelines for the management and treatment of generalized pustular psoriasis: The new pathogenesis and treatment of GPP. J Dermatol 2018;45:1235-1270. Accessed May 19, 2024. Re-evaluated June 27, 2025.

ClinicalTrials.gov Bethesda (MD): National Library of Medicine (US). Identifier NCT03782792: Effisayil™ 1: Multi-center, Double-blind, Randomized, Placebo-controlled, Phase II Study to Evaluate Efficacy, Safety and Tolerability of a Single Intravenous Dose of Spesolimab (BI 655130) in Patients With Generalized Pustular Psoriasis (GPP) Presenting With an Acute Flare of Moderate to Severe Intensity. Available from: http://clinicaltrials.gov. Last update posted March 09, 2022. Last verified February 2022. Accessed May 18, 2024. Re-evaluated June 27, 2025.

ClinicalTrials.gov Bethesda (MD): National Library of Medicine (US). Identifier NCT04399837: Effisayil™ 2: Multi-center, Randomized, Parallel Group, Double Blind, Placebo Controlled, Phase IIb Dose-finding Study to Evaluate Efficacy and Safety of BI 655130 (Spesolimab) Compared to Placebo in Preventing Generalized Pustular Psoriasis (GPP) Flares in Patients With History of GPP. Available from: http://clinicaltrials.gov. Last update posted December 14, 2023. Last verified November 2023. Accessed May 18, 2024. Re-evaluated June 27, 2025.