09-J4000-36

Original Effective Date: 11/15/22

Reviewed: 11/13/24

Revised: 01/01/25

Subject: Spesolimab-sbzo (Spevigo®) Subcutaneous Injection and Intravenous Infusion

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Spesolimab (Spevigo) is an interleukin-36 receptor (IL36R) antagonist that was first approved by the U.S. Food and Drugs Administration (FDA) in September 2022 as an intravenous (IV) infusion for the treatment of generalized pustular psoriasis (GPP) flares in adults. In March 2024, a subcutaneous (SC) formulation of spesolimab was FDA-approved along with a revised indication. Use of the IV product was expanded to included children at least 12 years of age. The new indication is stated as “for the treatment of GPP in adults and pediatric patients 12 years of age and older and weighing at least 40 kg”. The dosing information separates the use of IV product for the treatment of GPP flare, while the SC product is for the treatment of GPP when not experiencing a flare. The binding of spesolimab to IL36R prevents the downstream activation of pro-inflammatory and pro-fibrotic pathways; however, the precise mechanism linking reduced IL36R activity and the treatment of flares of GPP is unclear. Spesolimab is the first treatment specifically approved for GPP and the first IL-36 receptor antagonist to be approved by the FDA. Prior to FDA-approval, spesolimab was granted orphan drug designation in 2018 for the treatment of GPP.. Spesolimab is also being investigated for the treatment of inflammatory bowel disease (IBD) and other skin diseases, such as palmoplantar pustulosis and hidradenitis suppurativa. Another IL36R antagonist, imsidolimab (from AnaptysBio) is currently in Phase 3 development for the treatment of GPP flares. Based on the estimated completion date of the Phase 3 GEMINI-1 study, imsidolimab could receive an FDA decision in 2025.

Generalized pustular psoriasis (GPP) is a rare form of psoriasis that presents as a multisystemic skin disease characterized by recurrent pustular eruptions. The major forms of GPP include acute GPP and generalized annular pustular psoriasis. The European Rare and Severe Psoriasis Expert Network (ERASPEN) provide the following consensus definition for the diagnosis of GPP: primary, sterile,

macroscopically visible pustules on non-acral skin (excluding cases where pustulation is restricted to psoriatic plaques) with the following three subclassifications: (1) with or without systemic inflammation, (2) with or without psoriasis vulgaris, and (3) either relapsing (>1 episode) or persistent (>3 months). GPP should only be diagnosed when the condition has relapsed at least once or when it persists for more than 3 months. Also, a drug reaction such as acute generalized exanthematous pustulosis (AGEP) should be actively ruled out. Acute GPP occurs in about two-thirds of GPP cases and is characterized by the abrupt onset of numerous sterile pustules, widespread erythema, and can include sepsis and serious renal, hepatic, or respiratory abnormalities and may lead to death. About two-thirds of GPP patients experience one or more flares per year. Generalized annular pustular psoriasis is a subacute and typically milder form of GPP characterized by the formation of annular erythematous plaques studded by pustules. GPP most commonly occurs in middle-aged adults (40 and 60 years of age). The annular form of GPP is the most common presentation in children. The worldwide GPP prevalence estimates vary widely with published data from France, Japan, and South Korea estimate a prevalence of 1.76, 7.46, and 88 to 124 cases per million, respectively. Epidemiologic studies have not been conducted in the U.S.; however, claims data analysis estimates at least 15,000 unique cases in the U.S. Without treatment, the course of GPP can be prolonged with periods of resolution and flares that may recur over the course of years. Patients typically require continued therapy to avoid flare resurgence. For less severe, stable disease, retinoids (e.g., acitretin) and methotrexate are often used as initial treatments. For severe acute disease, cyclosporine, infliximab, interleukin (IL)-17 inhibitors [e.g., ixekizumab (Taltz), secukinumab (Cosentyx), brodalumab (Siliq)] and IL-23 inhibitors [e.g., guselkumab (Tremfya), risankizumab (Skyrizi)] are often used to rapidly control symptoms.

The safety and efficacy of IV spesolimab leading to initial FDA approval was assessed in a phase 2, randomized, double-blind, placebo-controlled study (EFFISAYIL-1, NCT03782792) of adult subjects with flares of generalized pustular psoriasis (GPP). Subjects were randomized if they had a flare of GPP of moderate-to-severe intensity, as defined by (1) a Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of at least 3 (moderate) [the total GPPPGA score ranges from 0 (clear) to 4 (severe)], (2) the presence of fresh pustules (new appearance or worsening of pustules), (3) GPPPGA pustulation sub score of at least 2 (mild), and (4) at least 5% of body surface area (BSA) covered with erythema and the presence of pustules. Subjects were required to discontinue systemic and topical therapy for GPP prior to receiving study drug. A total of 53 subjects were randomized (2:1) to receive a single IV dose of spesolimab 900 mg (n=35) or placebo (n=18) (administered over 90 minutes) during the double-blind portion of the study. The study population consisted of 32% men and 68% women. The mean age was 43 years (range of 21 to 69 years); 55% of subjects were Asian and 45% were White. Most subjects included in the study had a GPPPGA pustulation sub score of 3 (43%) or 4 (36%), and subjects had a GPPPGA total score of 3 (81%) or 4 (19%). In this study, 25% of subjects had been previously treated with biologic therapy for GPP. At baseline acute flare, of the subjects with white blood cell count (WBC) assessments, 45% and 31% of subjects in the spesolimab and placebo groups, respectively, had (WBC) $>12x10^9$/L. Seventeen percent and 11% of subjects in the spesolimab and placebo groups, respectively, had temperature >38° Celsius. Of the subjects with WBC assessments, 12% and 6% of subjects in the spesolimab and placebo groups, respectively, had both WBC $>12x10^9$/L and temperature >38° Celsius.

The primary endpoint of the study was the proportion of subjects with a GPPPGA pustulation sub score of 0 (indicating no visible pustules) at Week 1 after treatment. In the spesolimab group 19 of 35 subjects

(54%) met the primary endpoint versus 1 of 18 subjects (6%) in the placebo group [49% risk difference (95% CI: 21 to 67%)]. Subjects in either treatment group who continued to experience flare symptoms at Week 1 were eligible to receive a single open-label IV dose of spesolimab 900 mg (second dose and first dose for subjects in the spesolimab and placebo groups, respectively). At Week 1, 12 (34%) subjects and 15 subjects (83%) in the spesolimab and placebo groups, respectively, received open label spesolimab. In the 12 subjects who were randomized to spesolimab and received an open-label dose at Week 1, 5 (42%) subjects had a GPPPGA pustulation sub score of 0 at Week 2 (one week after their second dose of spesolimab). The study did not include sufficient numbers of subjects to determine if there are differences in response according to biological sex, age, race, baseline GPPPGA pustulation sub score, and baseline GPPPGA total score.

POSITION STATEMENT:

Comparative Effectiveness

The Food and Drug Administration has deemed the subcutaneously-administered drug(s) or biological product(s) in this coverage policy to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, coverage (i.e., administration) of the subcutaneous formulation of spesolimab in a provider-administered setting such as an outpatient hospital, ambulatory surgical suite, physician office, or emergency facility is not considered medically necessary. This statement does not apply to the intravenous (IV) formulation of spesolimab (Spevigo).

SUBCUTANEOUS SPEVGIO (PHARMACY BENEFIT)

The initiation of subcutaneous spesolimab (Spevigo) **meets the definition of medical necessity** when **ALL** of the following criteria are met ("1" to "7"):

1. Member has a diagnosis of generalized pustular psoriasis (GPP)
2. The member has moderate-to-severe GPP, **AND** has a history of 2 or more GPP flares – supportive medical record documentation is required
3. The member is **NOT** currently experiencing an acute GPP flare
4. Spesolimab is prescribed by, or in consultation with, a dermatologist
5. Member is at least 12 years of age or older and weight at least 40 kg (88 lbs), **OR** the member's age and weight are supported in the FDA-approved labeling for spesolimab
6. Member will **NOT** be using subcutaneous spesolimab in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]; Otezla (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
7. The dosage of subcutaneous spesolimab does not exceed 600 mg (four 150 mg injections) x 1 loading dose, followed by 300 mg (two 150 mg injections) administered subcutaneously 4 weeks later and every 4 weeks thereafter
    - QL: 150 mg/mL prefilled syringe – 2 syringes/28 days

Approval duration: 6 months

- If the member is **NOT** transitioning from IV to SC maintenance - approve subcutaneous spesolimab loading dose for 1 month, then maintenance dose can be approved for the remainder of 6 months
- Patient is transitioning from IV to SC maintenance dosing due to a recent flare - approve 6 months for maintenance therapy

Continuation of subcutaneous spesolimab (Spevigo) **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "6"):

1. An authorization or reauthorization for subcutaneous spesolimab (Spevigo) has been previously approved by Florida Blue [Note: members not previously approved for the requested agent will require initial evaluation review]
2. Member has had clinical benefit with subcutaneous spesolimab
3. Spesolimab is prescribed by, or in consultation with, a dermatologist
4. Member is at least 12 years of age or older and weight at least 40 kg (88 lbs), **OR** the member's age and weight are supported in the FDA-approved labeling for spesolimab
5. Member will **NOT** be using subcutaneous spesolimab in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]; Otezla (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
6. The dosage does not exceed 300 mg subcutaneously once every 4 weeks
   - QL: 150 mg/mL prefilled syringe – 2 syringes/28 days

Approval duration: 12 months

INTRAVENOUS SPEVGIO (MEDICAL BENEFIT)

The administration of IV spesolimab (Spevigo) **meets the definition of medical necessity** when **ALL** of the following criteria are met ("1" to "8"):

1. Member has a diagnosis of generalized pustular psoriasis (GPP) as confirmed by **ALL** of the following ("a" to "d"):
   a. Presence of primary, sterile, macroscopically visible pustules on non-acral skin (i.e., skin not located on peripheral body parts such as ears, hands, and feet)
   b. If there is co-existing plaque psoriasis vulgaris, the pustulation is **NOT** restricted to only inside the psoriatic plaques (i.e., occurs outside of the plaques)
   c. Pustulation has occurred at least once prior **OR** current pustulation has persists for more than 3 months
   d. Other pustulating skin disorders have been ruled out, such as drug-triggered acute generalized exanthematous pustulosis (AGEP) and synovitis-acne-pustulosis-hyperostosis-osteitis (SAPHO) syndrome

2. **EITHER** of the following ("a" or "b"):
    a. Member has **NOT** previously received IV spesolimab in that past 2 weeks, **AND** the member is experiencing a GPP flare of moderate-to-severe intensity as defined by **ALL** of the following ("i" to "iv"):
        i. Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of at least 3 (moderate) or greater
        ii. GPPPGA pustulation sub-score of at least 2 (i.e., moderate to very high-density pustules) or great
        iii. Presence of fresh pustules (new appearance or worsening of pustules)
        iv. At least 5% of member's body surface area (BSA) is covered with erythema and the presence of pustules
    b. **BOTH** of the following ("i" and "ii"):
        i. Member has previously received IV spesolimab for a prior GPP flare in that past 2 weeks, **AND** the member is still experiencing persistent symptoms of an acute flare of GPP of moderate to severe intensity, as defined by **BOTH** of the following:
            - GPPPGA total score of at least 2 (mild) or greater
            - GPPPGA pustulation sub score of at least 2 (i.e., moderate to very high-density pustules) or greater
        ii. The second infusion of spesolimab will occur no sooner than one week after the first infusion
3. Spesolimab is prescribed by, or in consultation with, a dermatologist
4. Member is at least 12 years of age or older and weight at least 40 kg (88 lbs), **OR** the member's age and weight are supported in the FDA-approved labeling for spesolimab
5. Member will **NOT** be using IV spesolimab in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]; Otezla (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
6. Member was **NOT** previously refractory to treatment with IV spesolimab for a GPP flare [refractory defined as unable to achieve a GPPPGA score of 0 or 1 after two doses of spesolimab]
7. Member has **NOT** received more than two doses of IV spesolimab for their current GPP flare [a new GPP flare following clinical resolution of a prior flair is excluded from this requirement]
8. Dosage of spesolimab does not exceed 900 mg given as a single IV infusion

Approval duration: 4 weeks (to allow a single dose of treatment)

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL

PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved

- 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.
- 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 (IV) Spevigo for Treatment of GPP Flare: Four weeks after treatment with IV Spevigo, initiate or reinitiate subcutaneous Spevigo at a dose of 300 mg (two 150 mg injections) administered every 4 weeks. A loading dose is not required following treatment of a GPP flare with IV Spevigo
- Intravenous Dosage for Treatment of GPP Flare
    - The recommended dose is a single 900 mg dose by IV infusion over 90 minutes. If GPP flare symptoms persist, an additional IV 900 mg dose (over 90 minutes) may be administered one week after the initial dose.
- Evaluate patients for tuberculosis (TB) infection. Initiation is not recommended in patients with active TB infection. Consider initiating treatment of latent TB prior to initiation of spesolimab.

Dose Adjustments

- Hepatic impairment - Specific guidelines for dosage adjustments in hepatic impairment are not available; it appears that no dosage adjustments are needed.
- Renal impairment - Specific guidelines for dosage adjustments in renal impairment are not available; it appears that no dosage adjustments are needed.

Drug Availability

- Single-dose vials (for IV use)
    - Each carton contains two single-dose 450 mg/7.5 mL (60 mg/mL) glass vials - NDC 00597-0035-10.
    - Must be refrigerated, store at 2°C to 8°C (36°F to 46°F) in original carton to protect from light. Do not freeze. Prior to use, may store unopened vials at room temperature, 20°C to 25°C (68°F to 77°F), for up to 24 hours in the original carton to protect from light.
- Prefilled syringes (for subcutaneous use)
    - Each carton contains two single-dose 150 mg/mL prefilled syringes - NDC 00597-0620-20
    - Must be refrigerated, store between 2°C to 8°C (36°F to 46°F) in original carton to protect from light. Do not freeze. Do not use if frozen even if it has been thawed.

PRECAUTIONS:

Boxed Warning

- None

Contraindications

- Severe or life-threatening hypersensitivity to spesolimab-sbzo or to any of the excipients in Spevigo

Precautions/Warnings

- **Infections**: Spesolimab may increase the risk of infections. Treatment with spesolimab is not recommended during any clinically important active infection. Instruct patients to seek medical advice if signs or symptoms of clinically important infection occur during or after treatment. If a clinically important active infection develops discontinue spesolimab until the infection resolves or is adequately treated.
- **Tuberculosis (TB)**: Evaluate patients for TB prior to initiating treatment with spesolimab.
- **Hypersensitivity and Infusion-Related Reactions**: Hypersensitivity including drug reaction with eosinophilia and systemic symptoms (DRESS) and infusion-related reactions may occur. If a serious hypersensitivity reaction occurs, discontinue spesolimab immediately and initiate appropriate treatment.
- **Vaccinations**: Avoid use of live vaccines during and for at least 16 weeks after treatment with spesolimab.

BILLING/CODING INFORMATION:

HCPCS Coding

J1747	Injection, spesolimab-sbzo, 1 mg

ICD-10 Diagnosis Codes That Support Medical Necessity

40.1	Generalized pustular psoriasis

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

DEFINITIONS:

None

RELATED GUIDELINES:

Infliximab Products [infliximab (Remicade), infliximab-dyyb (Inflectra), infliximab-abda (Renflexis), and infliximab-axxq (Avsola)], 09-J0000-39

OTHER:

NOTE: The list of biologic immunomodulator agents not permitted as concomitant therapy can be found at Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.

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 (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 or all lesions
4 (severe)	Deep fiery red	Very high-density pustules with pustular lakes	Severe scaling or crusting covering most or all lesions
Composite mean score = (erythema + pustules + scaling)/3; total GPPGA score given is 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.			

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 11/13/24.

GUIDELINE UPDATE INFORMATION:

11/15/22	New Medical Coverage Guideline.
04/01/23	Revision: Added HCPCS code J1747 and deleted code J3590.

01/01/24	Review and revision to guideline consisting of updating the references.
02/15/24	Revision to guideline consisting of increasing the approval duration to 4 weeks.
07/15/24	Revision to guideline consisting of updating the description section, position statement, dosage/administration, precautions, other section, and reference based on an expanded indication for Spevigo including the availability of a new subcutaneous formulation.
01/01/25	Review and revision to guideline consisting of updating the other section and references. New drugs added to the list of drugs that are not permitted for use in combination.