Neighborhood Health Plan OF RHODE ISLAND™
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Spevigo® (spesolimab)
(Intravenous)

Effective Date: 04/01/2023
Review Date: 03/16/2023, 12/07/2023, 01/04/2024, 07/17/2024, 04/09/2025, 09/17/2025
Pharmacy Scope for Subcutaneous (SC) and Intravenous (IV) Formulations: Medicaid
Medical Scope for Intravenous (IV) Formulation: Medicaid, Commercial, Medicare

I. Length of Authorization

- Treatment of GPP Flare: Coverage will be provided for two IV doses (900mg each) for 1 month and may not be renewed.
- Treatment of GPP When Not Experiencing a Flare: Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Spevigo 150 mg/mL single-dose pre-filled syringe for subcutaneous use
  - Loading: 4 syringes x 1 dose only (post limit of 4 ml per 28 days or daily dose of 0.143)
  - Maintenance: 2 syringes every 4 weeks (2 ml per 28 days or daily dose of 0.08)
- Spevigo 300mg/2mL single-dose pre-filled syringe for subcutaneous use
  - Loading: 2 syringes x 1 dose only (post limit of 4 ml per 28 days or daily dose of 0.143)
  - Maintenance: 1 syringe every 4 weeks (2 ml per 28 days or daily dose of 0.08)
- Spevigo 450 mg/7.5 mL single-dose vial for intravenous use: 4 vials one time only (30 ml total)

B. Max Units (per dose and over time) [HCPCS Unit]:

- Treatment of GPP Flare *(IV formulation ONLY)*
  - 900 billable units (900 mg) [2 vials] on day 1 and 8 [1800 units total]

III. Summary of Evidence

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 and weighing at least 40kg. Spevigo carries warnings of increased risk of infections, tuberculosis, and infusion-related reactions. Adverse reactions reported with Spevigo use differ based on whether the patient is experiencing a flare. When experiencing a flare, the most common adverse events reported include asthenia, fatigue. When not experiencing a flare, the most common adverse events reported include injection site reaction, urinary tract infection, arthralgia, and pruritis. A randomized, double-blind, placebo-controlled study was conducted to evaluate the clinical efficacy and safety of IV Spevigo in adult subjects with flares of GPP. Subjects were randomized (2:1) to receive a single IV dose of 900mg Spevigo (N=35) or placebo (N=18) during the double-blind portion of the study. The primary endpoint of the study was the proportion of subjects with a Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) pustulation sub score of 0 (indicating no visible pustules) at Week 1 after treatment. The results of the trial demonstrated that 54% (19/35) of participants receiving IV Spevigo achieved a GPPPGA pustulation sub score of 0, compared to 6% (6/18) in the placebo group (49% risk reduction [95% CI: 21,67]. A randomized, double-blind, placebo-controlled study evaluated the efficacy and safety of Spevigo for SC administration in adults and pediatric subjects (12 years of age and older and weighing at least 40kg) with a history of at least two GPP flares of moderate-to-severe intensity in the past year. The primary endpoint of the study was the time to the first GPP flare up to Week 48, defined by a GPPPGA pustulation sub score ≥ 2 and an increase in GPPPGA total score by ≥ 2 from baseline. Results of the study demonstrated that 10% of 30 participants receiving SC Spevigo had a GPP flare, compared to 52% of 31 participants in the placebo group, with an 84% reduction in the risk of GPP flares compared to placebo [HR 0.16 (95% CI: 0.05, 0.54); p=0.0005] and no flares after week 4.

IV. Initial Approval Criteria[1,2,4,5,6]

Coverage for IV Spevigo is provided in the following conditions:

> Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

- Patient is at least 12 years of age and weighs at least 40 kg; **AND**
- Patient has received all age-appropriate vaccinations according to current immunization guidelines prior to initiating treatment; **AND**
- Prescribed by, or in consultation with, a specialist in dermatology; **AND**

Universal Criteria [1-3,6]

- Patient does not have any of the following conditions:
  - Synovitis-acne-pustulosis-hyperostosis-osteitis (SAPHO) syndrome
  - Primary erythrodermic psoriasis vulgaris
  - Primary plaque psoriasis vulgaris without presence of pustules or with pustules that are restricted to psoriatic plaques**
  - Drug-triggered Acute Generalized Exanthematous Pustulosis (AGEP)**; **AND**

- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient will not receive live vaccines (viral and/or bacterial) during therapy; **AND**
- Patient will not be on concomitant treatment with systemic immunosuppressants (e.g., retinoids, cyclosporine, methotrexate, etc.) or other topical agents (e.g., corticosteroids, calcipotriene, tacrolimus, etc.); **AND**
- Patient is not on concurrent treatment with a TNF-inhibitor, any other biologic drug or targeted synthetic drug (i.e., Otezla (apremilast), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), etc.); **AND**

  ****NOTE*:** Only applies to patients receiving treatment for a GPP flare

Generalized Pustular Psoriasis (GPP) † Φ [1-3,6]

- Patient is experiencing an acute, moderate-to-severe intensity disease flare as defined by the following:
  - Documentation that patient has a known documented history of GPP (either relapsing [greater than 1 episode] or persistent [greater than 3 months]); **AND**
    - Documentation that patient is presenting with primary, sterile, macroscopically visible pustules (new or worsening) on non-acral skin (excluding cases where pustulation is restricted to psoriatic plaques); **AND**
  - Documentation that patient has at least one of the following documented:
    - IL36RN, CARD14, or AP1S3 gene mutation; **OR**
    - Skin biopsy confirming presence of Kogoj's spongiform pustules; **OR**
    - Systemic symptoms or laboratory abnormalities commonly associated with GPP flare (e.g., fever, asthenia, myalgia, elevated C-reactive protein [CRP], leukocytosis, neutrophilia [above ULN]); **OR**
    - GPP flare of moderate-to-severe intensity with at least 5% body surface area covered with erythema and the presence of pustules; **AND**
  - Documentation that patient has 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)] **¥ AND** a GPPPGA pustulation sub score of at least 2 (mild); **AND**
  - Total dose of Spevigo does not exceed two doses per single GPP flare
    - (Note: If the patient has been treated with Spevigo for a previous GPP flare, then a new (different) GPP flare may be treated with up to two doses of Spevigo); **OR**

- Patient is NOT currently experiencing a disease flare; **AND**
  - Documentation that patient has a known documented history of GPP (either relapsing [greater than 1 episode] or persistent [greater than 3 months]); **AND**
  - Documentation that physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., GPPPGA, Dermatology Quality of Life Index (DLQI), Psoriasis Symptom Scale, etc.); **AND**
  - Documentation that patient has a GPPPGA total score of 0 (clear) or 1 (almost clear) **¥**; **AND**
  - Documentation that patient meets either of the following:

- Patient has a history of at least 2 GPP flares of moderate-to-severe intensity (e.g., at least 5% body surface area covered with erythema and the presence of pustules, Generalized Pustular Psoriasis Physician Global Assessment [GPPPGA] total score of at least 3 (moderate) **¥** and GPPPGA pustulation sub score of at least 2 (mild); **OR**
- Patient has a history of flaring while on concomitant treatment (e.g., retinoids, methotrexate, cyclosporine).

¥Physician's Global Assessment for Generalized Pustular Psoriasis (GPPPGA) [7]
Erythema 0 = Clear: Normal or post-inflammatory hyperpigmentation 1 = Almost Clear: Faint, diffuse pink or slight red 2 = Mild: Light red 3 = Moderate: Bright red 4 = Severe: Deep fiery red
Pustules 0 = Clear: No visible pustules 1 = Almost Clear: Low density occasional small discrete (non-coalescent) pustules 2 = Mild: Moderate density grouped discrete small pustules (non-coalescent) 3 = Moderate: High density pustules with some coalescence 4 = Severe: Very high-density pustules with pustular lakes
Scaling/crusting 0 = Clear: No scaling and no crusting 1 = Almost Clear: Superficial focal scaling or crusting restricted to periphery of lesions 2 = Mild: Predominantly fine scaling or crusting 3 = Moderate: Moderate scaling or crusting covering most or all of lesions 4 = Severe: Severe scaling or crusting covering most or all lesions
*Composite mean score = (erythema + pustules + scaling)/3 Total GPPGA score given is: 0 if mean is 0 for all three components, 1 if mean is 0 to <1.5, 2 if mean is 1.5 to <2.5, 3 if mean is 2.5 to <3.5, 4 if mean is ≥3.5

† FDA Approved Indication(s); **‡** Compendia recommended indication(s); **Φ** Orphan Drug

V. Renewal Criteria[1,2,4,5,6]

Coverage for IV Spevigo can be renewed based upon the following criteria:

- Patients continues to meet universal and other indication-specific relevant criteria identified in section IV; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: infections, hypersensitivity reactions [including anaphylaxis and delayed reactions such as drug reaction with eosinophilia and systemic symptoms (DRESS)], etc.; **AND**

Treatment of GPP Flare

- Coverage may not be renewed.

Treatment of GPP When Not Experiencing a Flare

- Documentation of disease response compared to baseline, as indicated by a decrease in number

and/or frequency of GPP flares, stabilization or improvement in GPPPGA total score, improvement in Dermatology Quality of Life Index (DLQI), and/or improvement in Psoriasis Symptom Scale (PSS)

Initiating/Reinitiating Subcutaneous Maintenance Therapy after Treatment of a GPP Flare

- After receiving intravenous treatment for a GPP flare, patients may be initiated on subcutaneous maintenance therapy *(Refer to Section IV for criteria and Section VI for dosing)*; **OR**
- Patients experiencing a GPP flare while receiving subcutaneous maintenance therapy may receive up to two intravenous doses to treat the flare *(Refer to Section IV for criteria and Section VI for dosing)*

VI. Dosage/Administration[1,4]

Indication	Dose
Generalized Pustular Psoriasis (GPP)	Treatment of GPP Flare ***(IV administration ONLY)*** • Administer as a single 900 mg dose by intravenous infusion over 90 minutes. • If GPP flare symptoms persist, an additional intravenous 900 mg dose may be administered one week after the initial dose. Treatment of GPP When Not Experiencing a Flare ***(SC administration ONLY)*** • Administer a loading dose of 600 mg followed by 300 mg subcutaneously 4 weeks later and every 4 weeks thereafter. Initiating or Reinitiating **Subcutaneous** Spevigo After Treatment of a GPP Flare with **Intravenous** Spevigo • Four weeks after treatment of a GPP flare with **intravenous** Spevigo, initiate or reinitiate **subcutaneous** Spevigo for treatment of GPP at a dose of 300 mg administered every 4 weeks. • A subcutaneous loading dose is not required following treatment of a GPP flare with intravenous Spevigo.
NOTE: • Intravenous infusion of Spevigo is only to be administered by a healthcare professional in a healthcare setting. • When using Spevigo 300 mg/2 mL prefilled syringe: ◦ If the healthcare professional determines that it is appropriate, a patient 12 years of age or older may self-inject or the caregiver may administer the loading dose and the subsequent doses of Spevigo after proper training in subcutaneous injection technique. In pediatric patients 12 years of age and older, administer Spevigo under the supervision of an adult. • When using Spevigo 150 mg/mL prefilled syringe:	

• If required, the 600 mg subcutaneous loading dose of Spevigo is to be administered by a healthcare professional. • For subsequent 300 mg doses, if the healthcare professional determines that it is appropriate, a patient 12 years of age and older may self-inject or the caregiver may administer Spevigo after proper training in subcutaneous injection technique. In pediatric patients 12 to 17 years of age, administer Spevigo under the supervision of an adult.

VII. Billing Code/Availability Information

HCPCS Code:

- J1747 injection, spesolimab-sbzo, 1mg; 1 billable unit = 1 mg *(IV formulation ONLY)*
- *(***Note**: CMS generally creates codes for products themselves, without specifying a route of administration in the code descriptor, as there might be multiple routes of administration for the same product. Drugs that fall under this category should be billed with ~~either~~ the JA modifier for the intravenous infusion of the drug; coverage of the SC formulation is only available on the pharmacy benefit)*

NDC:

- Spevigo 150 mg/mL two-pack single-dose pre-filled syringe for subcutaneous use: 0597-0620- xx
- Spevigo 300 mg/2 mL one or two-pack single-dose pre-filled syringe for subcutaneous use: 0597-7705- xx
- Spevigo 450 mg/7.5 mL (60 mg/mL) two-pack single-dose vial (SDV): 00597-0035-xx

VIII. References

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1. Spevigo [package insert]. Ridgefield, NJ; Boehringer Ingelheim Pharmaceuticals, Inc.; March 2024. Accessed September 2025.
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3. Choon SE, Lebwohl MG, Marrakchi S, et al. Study protocol of the global Effisayil 1 Phase II, multicentre, randomised, double-blind, placebo-controlled trial of spesolimab in patients with generalized pustular psoriasis presenting with an acute flare. BMJ Open. 2021 Mar 30;11(3):e043666. doi: 10.1136/bmjopen-2020-043666.
4. Navarini AA, Burden AD, Capon F, et al. European consensus statement on phenotypes of pustular psoriasis. J Eur Acad Dermatol Venereol. 2017 Nov;31(11):1792–1799. Crossref. PubMed. ISI.
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6. Morita A, Choon SE, Bachelez H, et al. Design of Effisayil™ 2: A Randomized, Double-Blind, Placebo-Controlled Study of Spesolimab in Preventing Flares in Patients with Generalized Pustular Psoriasis. Dermatol Ther (Heidelb). 2023 Jan;13(1):347-359. doi: 10.1007/s13555- 022-00835-6. Epub 2022 Nov 5. PMID: 36333618; PMCID: PMC9823166.

7. Burden AD, Bachelez H, Choon SE, et al. The Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) score: online assessment and validation study of a specific measure of GPP disease activity, British Journal of Dermatology, Volume 189, Issue 1, July 2023, Pages 138–140, https://doi.org/10.1093/bjd/ljad071.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
L40.1	Generalized pustular psoriasis

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100- 2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA

L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Policy Rationale:

Spevigo was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Spevigo according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.