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

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

I. Length of Authorization

Coverage will be provided for two doses (900mg each) and may not be renewed.

II. Dosing Limits

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

- Spevigo 450 mg/7.5 mL solution in an SDV: 4 vials one time only

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

- 900 mg (2 vials) on day 1 and 8

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 participants receiving IV Spevigo 54% (N=19) achieved a GPPPGA pustulation sub score of 0, compared to 6% (N=18) in the placebo group. In a randomized, double-blind placebo-controlled study evaluating 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. 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% (N=3) of participants receiving SC Spevigo had a GPP flare, compared to 52% participants (N=16) in the placebo group.

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

Coverage is provided in the following conditions:

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

- Patient is at least 18 years of age; **AND**
- 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**

Universal Criteria [1-3]

- 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 during therapy; **AND**
- Patient is not on concurrent treatment with a TNF-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast, tofacitinib, baricitinib, upadacitinib, etc.); **AND**

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

- Patient is experiencing an acute, moderate-to-severe intensity disease flare as defined by the following:
  - GPP-PGA total score of at least 3 (moderate) or greater; **AND**
  - Presence of fresh pustules (new appearance or worsening of pustules); **AND**
  - GPP-PGA pustulation sub score of at least 2 (mild); **AND**
  - At least 5% of body surface area (BSA) covered with erythema and the presence of pustules.; **AND**
- Patient will not use concomitantly with systemic immunosuppressants (e.g., retinoids, cyclosporine, methotrexate, etc.) or other topical agents (e.g., corticosteroids, calcipotriene, tacrolimus, etc.)

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

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

Coverage may not be renewed.

VI. Dosage/Administration[1,4]

Indication	Dose
Generalized Pustular Psoriasis (GPP)	Administer as a single 900 mg dose by intravenous infusion over 90 minutes, if flare symptoms persist, an additional intravenous 900 mg dose may be administered one week after the initial dose.

VII. Billing Code/Availability Information

HCPCS Code:

- J1747 injection, spesolimab-sbzo, 1mg

NDC:

- Spevigo 450 mg/7.5 mL (60 mg/mL) two-pack single-dose vial (SDV): 00597-0035-xx

VIII. References

1. Spevigo [package insert]. Ridgefield, NJ; Boehringer Ingelheim Pharmaceuticals, Inc.; September 2022. Accessed November 2023.
2. Bachelez H, Choon SE, Marrakchi S, et al; Effisayil 1 Trial Investigators. Trial of Spesolimab for Generalized Pustular Psoriasis. N Engl J Med. 2021 Dec 23;385(26):2431-2440. doi: 10.1056/NEJMoa2111563.
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.
5. 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 Nov;45(11):1235–1270. Crossref. PubMed. ISI

Appendix 1 – Covered Diagnosis Codes

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

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

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 Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered 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)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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 INTEGRITY (Medicare-Medicaid Plan) 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.