Spevigo® (spesolimab)
(Intravenous)

Document Number: IC-0674

Last Review Date: 10/03/2022
Date of Origin: 10/03/2011
Dates Reviewed: 10/2022

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. Initial Approval Criteria [1-3]

Coverage is provided in the following conditions:

- 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

IV. Renewal Criteria [1-3]

Coverage may not be renewed.

V. Dosage/Administration

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.

VI. Billing Code/Availability Information

HCPCS Code:

- J3590 – Unclassified biologics

NDC:

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

VII. References

1. Spevigo [package insert]. Ridgefield, NJ; Boehringer Ingelheim Pharmaceuticals, Inc.; September 2022. Accessed September 2022.
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