

Spevigo® (spesolimab) (Intravenous)

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I. Length of Authorization

Coverage will be provided for 1 month and may not be renewed.

II. Dosing Limits

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

- Load: 900 billable units (900 mg) on days 1 and 8
- Maintenance: 300 billable units (300mg) every 28 days

III. Initial Approval Criteria

Target Agent(s) will be approved when ALL of the following are met:

- The patient has a diagnosis of generalized pustular psoriasis (GPP); **AND**
- The patient is experiencing a moderate to severe flare of GPP as defined by ONE of the following:
 - The patient has a Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of 3 or greater; **OR**
 - The patient has a Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) pustulation subscore of 2 or greater; **OR**
 - The patient has erythema and pustules covering 5% or greater of body-surface area (BSA); **OR**
 - The patient has new appearance or worsening of pustules; **AND**
- If the patient has an FDA labeled indication, then ONE of the following:
 - The patient's age is within FDA labeling for the requested indication for the requested agent; **OR**
 - There is support for using the requested agent for the patient's age; **AND**

- The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis; **AND**
- ONE of the following:
 - The patient does NOT have active or latent tuberculosis (TB); **OR**
 - The patient has latent tuberculosis (TB) and the patient has begun or completed therapy for latent TB prior to initiating with the requested agent; **AND**
- The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors, Phosphodiesterase 4 (PDE4) inhibitors) for the requested indication; **AND**
- The patient does NOT have any FDA labeled contraindications to the requested agent; **AND**
- The requested quantity (dose) is within FDA labeled dosing for the requested indication; **AND**
- The patient has not received 2 or more infusions for the current flare

IV. Renewal Criteria

- Coverage may not be renewed

V. Dosage/Administration

Indication	Dose
Generalized Pustular Psoriasis (GPP)	<u>Treatment of GPP Flare</u> <ul style="list-style-type: none"> • 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.
NOTE: <ul style="list-style-type: none"> • Intravenous infusion of Spevigo is only to be administered by a healthcare professional in a healthcare setting. 	

VI. Billing Code/Availability Information

HCPCS Code(s):

- J1747 – Injection, spesolimab-sbzo, 1 mg; 1 billable unit = 1 mg
*(*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 or billed with the JB modifier for subcutaneous injection of the drug.)*

NDC(s):

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

VII. References

1. Spevigo prescribing information. Boehringer Ingelheim Pharmaceuticals, Inc. March 2024.
2. Choon, S.E., Navarini, A.A. & Pinter, A. Clinical Course and Characteristics of Generalized Pustular Psoriasis. *Am J Clin Dermatol* 23 (Suppl 1), 21–29 (2022). <https://doi.org/10.1007/s40257-021-00654-z>.
3. Choon SE, Lai NM, Mohammad NA, et al. Clinical profile, morbidity, and outcome of adult-onset generalized pustular psoriasis: analysis of 102 cases seen in a tertiary hospital in Johor, Malaysia. *Int J Dermatol* 2014; 53:676.
4. Ly K, Beck KM, Smith MP, Thibodeaux Q, Bhutani T. Diagnosis and screening of patients with generalized pustular psoriasis. *Psoriasis (Auckl)*. 2019 Jun 20;9:37-42. doi: 10.2147/PTT.S181808. PMID: 31417859; PMCID: PMC6592018.
5. Fujita, H., Gooderham, M. & Romiti, R. Diagnosis of Generalized Pustular Psoriasis. *Am J Clin Dermatol* 23 (Suppl 1), 31–38 (2022). <https://doi.org/10.1007/s40257-021-00652-1>.
6. Falto-Aizpurua LA, Martin-Garcia RF, Carrasquillo OY, et al. Biological therapy for pustular psoriasis: a systematic review. *Int J Dermatol* 2020; 59:284.

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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
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
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