Spevigo® (spesolimab)
(Subcutaneous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided for 12 months.
- Renewal: Prior authorization validity may be renewed every 12 months thereafter.

****Note:**

- **If patient is NOT transitioning from IV to SC maintenance:** Prior authorization validity will be provided for the loading dose for 1 month, with maintenance dosing authorized for the remainder of the 12 month validity period.
- **Patient IS transitioning from IV to SC maintenance dosing due to a recent flare:** Prior authorization validity will be provided for 12 months for maintenance therapy.

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 (300 mg) every 28 days

III. Initial Approval Criteria

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

- ONE of the following:
  - The patient has a diagnosis of generalized pustular psoriasis (GPP) AND ALL of the following:
    - The patient has moderate to severe GPP; **AND**
    - The patient has a history of 2 or more flares; **AND**
    - The patient is NOT currently experiencing an acute flare; **OR**
  - The patient has another FDA labeled indication for the requested agent; **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**
- ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table**§**):
  - The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors); **OR**
  - The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
    - The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent; **AND**
    - There is support for the use of combination therapy (copy of support required, i.e., clinical trials, phase III studies, guidelines); **AND**
- The patient does NOT have any FDA labeled contraindications to the requested agent

IV. Renewal Criteria

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

- The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review]; **AND**
- The patient has had clinical benefit with the requested agent; **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 (Please refer to "Agents NOT to be used Concomitantly" table**§**):
  - The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors); **OR**
  - The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
    - The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent; **AND**

- There is support for the use of combination therapy (copy of support required, i.e., clinical trials, phase III studies, guidelines); **AND**

- The patient does NOT have any FDA labeled contraindications to the requested agent

§ Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly Abrilada (adalimumab-afzb) Actemra (tocilizumab) Adalimumab Adbry (tralokinumab-ldrm) Amjevita (adalimumab-atto) Arcalyst (rilonacept) Avsola (infliximab-axxq) Benlysta (belimumab) Bimzelx (bimekizumab-bkzx) Cibinqo (abrocitinib) Cimzia (certolizumab) Cinqair (reslizumab) Cosentyx (secukinumab) Cyltezo (adalimumab-adbm) Dupixent (dupilumab) Ebglyss (lebrikizumab-lbkz) Enbrel (etanercept) Entyvio (vedolizumab) Fasenra (benralizumab) Hadlima (adalimumab-bwwd) Hulio (adalimumab-fkjp) Humira (adalimumab) Hyrimoz (adalimumab-adaz) Idacio (adalimumab-aacf) Ilaris (canakinumab) Ilumya (tildrakizumab-asmn) Imuldosa (ustekinumab-srlf) Inflectra (infliximab-dyyb) Infliximab Kevzara (sarilumab) Kineret (anakinra) Leqselvi (deuruxolitinib) Litfulo (ritlecitinib) Nemluvio (nemolizumab-ilto) Nucala (mepolizumab) Olumiant (baricitinib) Omvoh (mirikizumab-mrkz) Opzelura (ruxolitinib) Orencia (abatacept) Otezla (apremilast) Otulfi (ustekinumab-aauz) Pyzchiva (ustekinumab-ttwe) Remicade (infliximab) Renflexis (infliximab-abda) Riabni (rituximab-arrx)

§ Contraindicated as Concomitant Therapy
Rinvoq (upadacitinib) Rituxan (rituximab) Rituxan Hycela (rituximab/hyaluronidase human) Ruxience (rituximab-pvvr) Saphnelo (anifrolumab-fnia) Selarsdi (ustekinumab-aekn) Siliq (brodalumab) Simlandi (adalimumab-ryvk) Simponi (golimumab) Simponi ARIA (golimumab) Skyrizi (risankizumab-rzaa) Sotyktu (deucravacitinib) Spevigo (spesolimab-sbzo) subcutaneous injection Stelara (ustekinumab) Taltz (ixekizumab) Tezspire (tezepelumab-ekko) Tofidence (tocilizumab-bavi) Tremfya (guselkumab) Truxima (rituximab-abbs) Tyenne (tocilizumab-aazg) Tysabri (natalizumab) Velsipity (etrasimod) Wezlana (ustekinumab-auub) Xeljanz (tofacitinib) Xeljanz XR (tofacitinib extended release) Xolair (omalizumab) Yuflyma (adalimumab-aaty) Yusimry (adalimumab-aqvh) Zeposia (ozanimod) Zymfentra (infliximab-dyyb)

V. Dosage/Administration

Indication	Dose
Generalized Pustular Psoriasis (GPP)	Treatment of GPP When Not Experiencing a Flare • 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: • 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.	

Indication	Dose
• 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.	

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 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

VII. References

1. Spevigo prescribing information. Boehringer Ingelheim Pharmaceuticals, Inc. May 2025.
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.
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 A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health

plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

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)
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.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC