Pharmacy Policy Bulletin: J-1374 Spevigo (spesolimab-sbzo) Subcutaneous – Commercial and Healthcare Reform	
Number: J-1374	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Injectable = Yes w/ Prior Authorization **Quantity Limits (1., 2., 3., or 4.):** 1. Rx Mgmt Quantity Limits = Safety/Specialty 2. Rx Mgmt Quantity Limits = Safety/Specialty + Dose Opt 3. Rx Mgmt Quantity Limits = Safety/Specialty + Dose Opt + Watchful **4.** Rx Mgmt Performance = MRxC = Yes **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1374-002	**Original Date:** 06/05/2024
Effective Date: 07/18/2025	**Review Date:** 6/25/2025

Drugs Product(s):	• Spevigo (spesolimab-sbzo) subcutaneous
FDA-Approved Indication(s):	• Treatment of generalized pustular psoriasis (GPP) in adults and pediatric patients 12 years of age and older weighing at least 40 kg.

Background:	• Spevigo is a interleukin-36 receptor (IL-36R) antagonist. Spevigo is the first medication to receive FDA approval for the treatment of GPP. • GPP is a severe inflammatory skin condition where reddish, scaly, pus-filled bumps form together and burst. GPP is the rarest form of psoriasis, and at times can be life-threating when widespread pus-filled bumps cover a large portion of the body or is left untreated due to potential systemic complications such as, infections, prerenal insufficiency, and cardiovascular failure. A history of psoriasis may or may not be present. • GPP is a genetic disease that is caused by the alteration of *IL36RN, CARD14*, and *AP1S3* genes and is inherited in an autosomal recessive manner. • The severity of a flare may be assessed using the Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) or the Generalized Pustular Psoriasis Area and Severity Index (GPPASI). Both scales include five grades of

	severity for erythema, scaling, and pustulation corresponding to 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate, and 4 = severe. The GPPPGA score is based on the averages of erythema, scaling, and pustulation. The GPPASI takes the score for each body region, the product of the sum of severity scores and its corresponding body surface area score of erythema, scaling, and pustulation, and is multiplied by a weight factor for each body region. • Possible triggers of GPP flares include corticosteroid withdrawal, exposure to certain medications, or infection; however the underlying cause of flares is unknown in many cases. • Symptoms of GPP may include fever, chills, headache, rapid pulse rate, loss of appetite, nausea, and muscle weakness. • Prescribing Considerations: ○ The subcutaneous (SC) dosage form (prefilled syringe) is only for treatment of GPP when not experiencing a flare. The intravenous (IV) dosage form (vial) is only for treatment of GPP flares. The SC loading dose (600 mg) and IV infusion of Spevigo are only to be administered by a healthcare professional in a healthcare setting. The subsequent 300 mg SC doses may be self-administered or administered by a caregiver if the healthcare professional determines that it is appropriate. ○ A SC loading dose is not required following treatment of a GPP flare with Spevigo IV. ○ Spevigo IV is globally excluded under the pharmacy benefit due to being healthcare professionally administered. ○ If a patient experiences a GPP flare while receiving SC Spevigo, the GPP flare may be treated with IV Spevigo. ○ Spevigo has warnings and precautions for infections, risk of tuberculosis (TB), hypersensitivity and infusion-related reactions, and the administration of live vaccines. ○ Spevigo is contraindicated for use in patients with severe or life-threatening hypersensitivity to Spevigo or to any excipients in Spevigo ○ Patients receiving Spevigo must be monitored for signs and symptoms of infections, infusion site reactions and delayed reactions such as drug reaction with eosinophilia and systemic symptoms (DRESS), and signs and symptoms of TB.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Spevigo SC may be approved when all of the following criteria are met **(A. through G.)**:

A. The member is 12 years of age or older.
B. The member weighs ≥ 40 kg.
C. The member has a diagnosis of generalized pustular psoriasis (GPP) (ICD-10: L40.1).
D. The medication is prescribed by or in consultation with a dermatologist.
E. The member has experienced at least one (1) previous GPP flare that had evidence of fresh pustulation (new or worsening pustules).
F. The member is not currently experiencing a GPP flare.
G. The member requires treatment to prevent future GPP flares.

II. Reauthorization

When a benefit, reauthorization of Spevigo SC may be approved when all of the following criteria are met **(A.)**:

A. The member has experienced positive clinical response to therapy.

III. Quantity Limitations

When prior authorization is approved, Spevigo SC may be authorized in quantities as follows:

Diagnosis	Induction Therapy	Maintenance Therapy
GPP	Four (4) 150 mg prefilled syringes within the first four (4) weeks of therapy	Two (2) 150 mg prefilled syringes every four (4) weeks

IV. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.
  - Note: For induction therapy authorization duration, refer to the Quantity Limitations tables for the respective drug and diagnosis.

Automatic Approval Criteria

None.

References:

1. Spevigo [package insert]. Ridgefield, CT: Boehringer Ingelheim; March 2024.
2. Pustular Psoriasis. American Academy of Dermatology Association. Available at: https://www.aad.org/public/diseases/psoriasis/treatment/medications/pustular#. Accessed April 11, 2025.
3. Bachelez H, Choon SE, Marrakchi S, et al. Trial of Spesolimab for Generalized Pustular Psoriasis. *N Engl J Med* 2021; 385:2431-2440.
4. 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.
5. National Psoriasis Foundation. Generalized Pustular Psoriasis. Available at: https://www.psoriasis.org/generalized-pustular-psoriasis. Accessed April 11, 2025.
6. Armstrong A, Elston C, Elewski B, et al. Generalized pustular psoriasis: A consensus statement from the National Psoriasis Foundation. *J. Am. Acad. Dermatol*. 2024; 90 (4); 727-730
7. Burden A, Choon S, Gottlieb A, et al. Clinical Disease Measures in Generalized Pustular Psoriasis. *Am J Clin Dermatol*. 2022; 23 (Supp 1); 39-50.