UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2341-3
Program	Prior Authorization/Medical Necessity
Medication	*Spevigo® (spesolimab-sbzo) injection *This program applies to the subcutaneous formulations of Spevigo
P&T Approval Date	5/2024, 5/2025, 10/2025
Effective Date	1/1/2026

1. Background:

Spevigo 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 40 kg.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Spevigo** will be approved based on **all** of the following criteria:

   a. Diagnosis of generalized pustular psoriasis (GPP) based on **both** of the following:

      (1) Presence of primary, sterile, macroscopically visible pustules on erythematous base
      (2) Pustulation is not restricted to the acral region or within psoriatic plaques

-AND-

   b. **Both** of the following:

      (1) Used to prevent GPP flares
      (2) Patient is not currently experiencing a GPP flare

-AND-

   c. **One** of the following:

      (1) Patient has been established on therapy with Spevigo for GPP under an active UnitedHealthcare medical benefit prior authorization

-OR-

      (2) **Both** of the following:

         (a) Patient is currently on Spevigo therapy for GPP as documented by claims history or submission of medical records (Document date and duration of therapy)

-AND-

(b) Patient has not received a manufacturer supplied sample at no cost in the prescriber's office, or via manufacturer's patient assistance programs (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Spevigo*

-OR-

(3) **All** of the following:

(a) Patient has **not** previously been treated with Spevigo

-AND-

(b) During the previous 12 months prior to initiating subcutaneous Spevigo the patient has had one or more moderate to severe GPP flares based on one of the following:

i. Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score ≥ 3 (moderate)
ii. GPPPGA pustulation subscore ≥ 2 (mild)
iii. Erythema and pustules cover ≥ 5% of body-surface area
iv. New appearance or worsening of pustules

-AND-

(c) Prescriber attests that the patient has experienced flares of a severity and/or frequency such that they would clinically benefit from prophylactic therapy with subcutaneous Spevigo

-AND-

d. Patient is **not** receiving Spevigo in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab)] for treatment of the same indication

-AND-

e. Prescribed by a dermatologist

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or via manufacturer's patient assistance programs shall be required to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

B. Reauthorization

1. **Spevigo** will be approved based on **all** of the following criteria:

   a. Documentation of positive clinical response to therapy [e.g., preventing flares, reducing frequency of flares, prolonging time between flares, controlling signs and symptoms of GPP (e.g. pustules, erythema, pain, itching) between flares]

   -AND-

   b. Reduction in the utilization of therapy (e.g., intravenous **Spevigo**) used for GPP flares

   -AND-

   c. Patient is **not** receiving Spevigo in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab)] for treatment of the same indication

   -AND-

   d. Prescribed by a dermatologist

   Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Spevigo [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; May 2025.
2. Bachelez H, Choon SE, Marrakchi S, et al. Trial of Spesolimab-sbzo for Generalized Pustular Psoriasis. N Engl J Med. 2021;385(26):2431-2440. doi:10.1056/NEJMoa2111563.
3. Navarini AA, Burden AD, Capon F, et al. European consensus statement on phenotypes of pustular psoriasis. J Eur Acad Dermatol Venereol. 2017;31(11):1792-1799. doi:10.1111/jdv.14386.
4. Armstrong AW, Elston CA, Elewski BE, et al. Generalized pustular psoriasis: A consensus statement from the National Psoriasis Foundation. *J Am Acad Dermatol*. 2024;90(4):727-730. doi:10.1016/j.jaad.2023.09.080

5. Choon SE, van de Kerkhof P, Gudjonsson JE, et al. International Consensus Definition and Diagnostic Criteria for Generalized Pustular Psoriasis From the International Psoriasis Council. *JAMA Dermatol*. 2024;160(7):758-768. doi:10.1001/jamadermatol.2024.0915
6. Barker JN, Casanova E, Choon SE, et al. Global Delphi consensus on treatment goals for generalized pustular psoriasis. *Br J Dermatol*. 2025;192(4):706-716. doi:10.1093/bjd/ljae491

Program	Prior Authorization/Medical Necessity – Spevigo® (spesolimab-sbzo)
Change Control	
5/2024	New program.
5/2025	Annual review. Revised diagnostic criteria per consensus guidelines. Updated combination use language. Updated references.
10/2025	Added coverage criteria for self- or caregiver-administered subcutaneous loading dose. Updated references.