UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2341-1
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
Effective Date	8/1/2024

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[2,3]:

      (1) Presence of primary, sterile, macroscopically visible pustules on non-acral skin
      (2) Pustulation is not restricted to 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*

-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), Stelara (ustekinumab), Skyrizi (risankizumab)]

-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. <u>Reauthorization</u>

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

   a. Documentation of positive clinical response to therapy (e.g., reduction in the rate and/or number of GPP 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), Stelara (ustekinumab), Skyrizi (risankizumab)]

   -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.; March 2024.
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.

Program	Prior Authorization/Medical Necessity – Spevigo® (spesolimab-sbzo)
Change Control	
5/2024	New program.