

Spevigo (spesolimab-sbzo)
 Effective 11/01/2024

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	Spevigo IV is restricted to the medical benefit Spevigo SC is available under the pharmacy and medical benefits		

Overview

Spevigo (spesolimab-sbzo) 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 kilograms.

Spevigo is available in intravenous and subcutaneous formulations. The subcutaneous formulations is approved for the treatment of GPP when not experiencing a flare. The intravenous formulation is approved for the treatment of a GPP flare and is administered as a single 900 mg dose; if flare symptoms persist, an additional 900 mg dose can be administered one week later.

Coverage Guidelines

Authorization may be granted for members who are new to the plan within the last 90 days currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

Spevigo IV:

1. The member is 12 years of age or older
2. The member weighs at least 40 kilograms
3. The member has a diagnosis of generalized pustular psoriasis (GPP), as evidenced by primary, sterile, macroscopically visible pustules on non-acral skin (excluding cases when pustulation is restricted to psoriatic plaques)
4. The requested medication is prescribed by or in consultation with a dermatology specialist
5. Documentation the member is presenting with a moderate-to-severe flare of GPP, as defined by at least ONE of the following:

- a. Generalized Pustular Psoriasis Physician Global Assessment [GPPPGA] total score greater than or equal to 3
- b. GPPPGA pustulation score greater than or equal to 2
- c. At least 5% of body surface area is covered with erythema and presence of pustules
- d. Presence of fresh pustules (new appearance or worsening of pustules)
- e. Systemic symptoms or laboratory abnormalities commonly associated with GPP flare (e.g., fever, asthenia, myalgia, elevated C-reactive protein [CRP], leukocytosis, neutrophilia [above ULN]).

Spevigo SC:

- 1. The member has a diagnosis of generalized pustular psoriasis (GPP)
- 2. The member has a Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of 0 or 1
- 3. The member is 12 years of age or older
- 4. The member weighs at least 40 kilograms
- 5. The requested medication is prescribed by or in consultation with a dermatology specialist
- 6. The member is NOT experiencing a flare of GPP

Continuation of Therapy

Reauthorization may be granted when the following criteria are met:

Spevigo IV:

- 1. Documentation that an additional dose for the GPP flare is required (e.g., increase in GPPGA total score or pustulation subscore)

Spevigo SC:

- 1. Documentation of positive response to therapy with Spevigo

Limitations

- 1. **IV formulation:** Initial approvals and reauthorizations will be granted for 1 month
- 2. **SC formulation:** Initial approvals and reauthorizations will be granted for 12 months
- 3. The following quantity limitations apply:

Drug Name and Dosage Form	Quantity Limitations
Spevigo SC prefilled syringe	4 syringes per 28 days

References

- 1. Bachelez H, Choon SE, Marrakchi S, et al. Trial of Spesolimab for Generalized Pustular Psoriasis. *N Engl J Med.* 2021;385(26):2431-2440.
- 2. Choon SE, Navarini AA, Pinter A. Clinical Course and Characteristics of Generalized Pustular Psoriasis. *Am J Clin Dermatol.* 2022 Jan;23(Suppl 1):21-29.
- 3. Fujita H, Gooderham M, Romiti R. Diagnosis of Generalized Pustular Psoriasis. *Am J Clin Dermatol.* 2022;23(Suppl 1):31-38.
- 4. Ly K, Beck KM, Smith MP, Thibodeaux Q, Bhutani T. Diagnosis and screening of patients with generalized pustular psoriasis. *Psoriasis (Auckl).* 2019;9:37-42.
- 5. Morita A, Strober B, Burden AD, et al. Efficacy and safety of subcutaneous spesolimab for the prevention of generalized pustular psoriasis flares (Effisayil 2): an international, multicentre, randomized, placebo-controlled trial. *Lancet.* 2023;402:1542-1551.



6. 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.
7. Spevigo [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; March 2024.
8. Zheng M, Jullien D, Eyerich K. The Prevalence and Disease Characteristics of Generalized Pustular Psoriasis. *Am J Clin Dermatol*. 2022;23(Suppl 1):5-12.

Review History

01/11/2023 – Created and Reviewed for January P&T. Effective 03/01/2023

08/14/2024 – Reviewed for August P&T. Added Spevigo SC to the policy for treatment of GPP. Updated criteria for Spevigo IV. Updated approvable age for Spevigo IV to 12 years of age and added minimum weight of 40 kg to align with updated FDA package labeling. Differentiated diagnosis requirements for GPP vs for GPP flare. Removed IL36RN, CARD14, and AP1S3 gene mutations from criteria. Updated Spevigo IV reauthorization criteria to require documentation that an additional dose for GPP flare is required. Removed TB screening requirement. Clarified step therapy language to indicate member must be new to the plan within the past 90 days. Effective 11/1/2024.

