

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Spevigo under the patient's prescription drug benefit.

Description:

FDA-Approved Indication

For the treatment of generalized pustular psoriasis (GPP) flares in adults.

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Spevigo

Policy/Guideline:

Documentation:

Submission of the following information is necessary to initiate the prior authorization review:

- A. Chart notes or medical record documentation of history of GPP.
- B. Chart notes or medical record documentation of clinical presentation of pustules and affected area(s).
- C. Genetic test results, laboratory results, biopsy results, GPP severity assessment (e.g., Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) score), if applicable.

Prescriber Specialty:

This medication must be prescribed by or in consultation with a dermatologist.

Criteria for Initial Approval:

Authorization of 1 month may be granted for treatment of generalized pustular psoriasis flares in adult members when all of the following criteria are met:

- A. Member has a known documented history of GPP (either relapsing [greater than 1 episode] or persistent [greater than 3 months]).
- B. Member is presenting with primary, sterile, macroscopically visible pustules on nonacral skin (excluding cases where pustulation is restricted to psoriatic plaques).
- C. Member has at least one of the following documented:
 - 1. IL36RN, CARD14, or AP1S3 gene mutation.



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Coverage Policy/Guideline

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Effective Date: 8/31/2023			Last Review Date:	6/30/2023
Applies to:	⊠Illinois	□Florida	⊠Florida Kids	
	□New Jersey	⊠Maryland	□Michigan	
	🛛 Pennsylvania Kids	□Virginia	□Arizona	

- 2. Skin biopsy confirming presence of Kogoj's spongiform pustules.
- 3. Systemic symptoms or laboratory abnormalities commonly associated with GPP flare (e.g., fever, asthenia, myalgia, elevated C-reactive protein [CRP], leukocytosis, neutrophilia [above ULN]).
- 4. GPP flare of moderate-to-severe intensity (e.g., at least 5% body surface area is covered with erythema and the presence of pustules; Generalized Pustular Psoriasis Physician Global Assessment [GPPPGA] total score of greater or equal to 3).

Continuation of Therapy:

All adult members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

Approval Duration and Quantity Restrictions:

Approval: 1 month

Quantity Level Limit: 4 vials (2 doses) per 14 days

References:

- 1. Spevigo [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; September 2022.
- 2. Bachelez H, Choon SE, Marrakchi S, et al. Trial of Spesolimab for Generalized Pustular Psoriasis. *N Engl J Med*. 2021;385(26):2431-2440.
- 3. 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.
- 4. Fujita H, Gooderham M, Romiti R. Diagnosis of Generalized Pustular Psoriasis. *Am J Clin Dermatol.* 2022;23(Suppl 1):31-38.
- 5. 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.
- 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. 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.
- 8. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on November 14, 2022 from: https://www.cdc.gov/tb/topic/testing/tbtesttypes.htm.