

Spevigo (spesolimab-sbzo)
Effective 03/01/2023

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 type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
Specialty Limitations	N/A		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Exceptions	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029

Overview

Spevigo (spesolimab-sbzo) is approved for the treatment of generalized pustular psoriasis (GPP) flares in adults.

Coverage Guidelines

Authorization may be granted for members who are new to the plan currently receiving treatment with Spevigo, 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:

1. The patient is 18 years of age or older
2. The member has a diagnosis of generalized pustular psoriasis (GPP) (either relapsing [greater than 1 episode] or persistent [greater than 3 months])
3. The provider specialty is dermatology or consult notes are provided.
4. The member is presenting with primary, sterile, macroscopically visible pustules on non-acral skin (excluding cases where pustulation is restricted to psoriatic plaques).
5. Provider documents ONE of the following:
 - a. IL36RN, CARD14, or AP1S3 gene mutation.
 - b. Skin biopsy confirming presence of Kogoj's spongiform pustules.
 - c. Systemic symptoms or laboratory abnormalities commonly associated with GPP flare (e.g., fever, asthenia, myalgia, elevated C-reactive protein [CRP], leukocytosis, neutrophilia [above ULN]).
 - d. 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

Authorization may be granted for members who meet all initial authorization criteria and achieve or maintain positive response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

1. Initial approvals and reauthorizations will be granted for 1 month
2. For all indications: Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB).
 - a. Note: Members who have received Spevigo or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from requirements related to TB screening in this Policy.

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 September 8, 2022 from: <https://www.cdc.gov/tb/topic/testing/tbtesttypes.htm>.

Review History

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

