Spesolimab (Spevigo®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

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.

II. 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.

III. PRESCRIBER SPECIALTIES

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

IV. CRITERIA FOR INITIAL APPROVAL

Generalized pustular psoriasis (GPP) flare
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 non-acral 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.
    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).

V. CONTINUATION OF THERAPY

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

VI. OTHER

Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]* within 6 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

* If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

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 6, 2023 from: https://www.cdc.gov/tb/topic/testing/tbtesttypes.htm.

EFFECTIVE DATE 7/31/2024

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