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 and pediatric patients 12 years of age and older and weighing at least 40 kg.

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. Generalized pustular psoriasis (GPP) flare
1. Chart notes or medical record documentation of history of GPP.
2. Chart notes or medical record documentation of clinical presentation of pustules and affected area(s).
3. Genetic test results, laboratory results, biopsy results, GPP severity assessment (e.g., Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) score), if applicable.

B. Generalized pustular psoriasis (GPP) when not experiencing a flare
1. Initial requests:
   - **i.** Chart notes or medical record documentation of history of GPP, including history of flares.
   - ii. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

III. PRESCRIBER SPECIALTIES

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

IV. CRITERIA FOR INITIAL APPROVAL

A. Generalized pustular psoriasis (GPP) flare
Authorization of 1 month may be granted for treatment of generalized pustular psoriasis flares in members 12 years of age or older when all of the following criteria are met:

1. Member has a known documented history of GPP (either relapsing [greater than 1 episode] or persistent [greater than 3 months]).
2. Member is presenting with primary, sterile, macroscopically visible pustules (new or worsening) on non-acral skin (excluding cases where pustulation is restricted to psoriatic plaques).
3. Member has at least one of the following documented:
   i. IL36RN, CARD14, or AP1S3 gene mutation.
   ii. Skin biopsy confirming presence of Kogoj's spongiform pustules.
   iii. Systemic symptoms or laboratory abnormalities commonly associated with GPP flare (e.g., fever, asthenia, myalgia, elevated C-reactive protein [CRP], leukocytosis, neutrophilia [above ULN]).
   iv. 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).

B. Generalized pustular psoriasis (GPP) when not experiencing a flare

Authorization of 12 months may be granted for treatment of generalized pustular psoriasis in members 12 years of age or older when all of the following criteria are met:

1. Member has a known documented history of GPP (either relapsing [greater than 1 episode] or persistent [greater than 3 months]).
2. Member meets either of the following:
   i. Member has had a history of at least two moderate-to-severe GPP flares (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).
   ii. Member has a history of flaring while on concomitant treatment (e.g., retinoids, methotrexate, cyclosporine).
3. Member currently has clear to almost clear skin.

V. CONTINUATION OF THERAPY

A. Generalized pustular psoriasis (GPP) flare

All members 12 years of age or older (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

B. Generalized pustular psoriasis (GPP) when not experiencing a flare

Authorization of 12 months may be granted for all members 12 years of age or older (including new members) who are using the requested medication for GPP when not experiencing a flare and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

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

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EFFECTIVE DATE 8/30/2024

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