Reference number(s)
5580-A

Specialty Guideline Management Spevigo

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Spevigo	spesolimab-sbzo

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 Indications[1]

For the treatment of generalized pustular psoriasis (GPP) 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.

Documentation

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

Generalized Pustular Psoriasis (GPP) Flare

- Chart notes or medical record documentation of clinical presentation of pustules and affected area(s).

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- Genetic test results, laboratory results, biopsy results, GPP severity assessment (e.g., Generalized Pustular Psoriasis Physician Global Assessment [GPPPGA] score), if applicable.

GPP When Not Experiencing a Flare

Initial requests

- Chart notes or medical record documentation of history of GPP, including history of flares.
- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties

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

Coverage Criteria

Generalized Pustular Psoriasis (GPP) Flare[1-7,10,11]

Authorization of 1 month may be granted for treatment of GPP flares in members 12 years of age or older when all of the following criteria are met:

- Member is presenting with primary, sterile, macroscopically visible pustules (new or worsening) on an erythematous base (excluding cases where pustulation is restricted to psoriatic plaques).
- Member has at least one of the following documented:
  - IL36RN, CARD14, AP1S3, MPO, or SERPINA gene variant.
  - Skin biopsy confirming presence of Kogoj's spongiform pustules.
  - Systemic symptoms or laboratory abnormalities commonly associated with GPP flare (e.g., fever, asthenia, myalgia, elevated C-reactive protein [CRP], leukocytosis, neutrophilia [above the upper limit of normal (ULN)]).
  - 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 than or equal to 3).

GPP When Not Experiencing a Flare[1,6,8]

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

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

Continuation of Therapy

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 requirements in the coverage criteria.

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.

Other[1,9]

Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 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.

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