Reference number(s)
5582-A

Standard Medicare Part B 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 will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all submissions:

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Generalized Pustular Psoriasis (GPP) Flare

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

Generalized Pustular Psoriasis (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 benefit from therapy.

Coverage Criteria

Generalized Pustular Psoriasis (GPP) Flare[1-3,6]

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 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[1,3,4]

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 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 members 12 years of age or older (including new members) when all of the following criteria are met:

- The member is currently receiving therapy with Spevigo.
- The requested medication is being used to treat GPP when not experiencing a flare.
- The member is receiving benefit from therapy.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Spevigo.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- European consensus statement on phenotypes of pustular psoriasis
- Generalized pustular psoriasis: A consensus statement from the National Psoriasis Foundation

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- International consensus definition and diagnostic criteria for generalized pustular psoriasis from the International Psoriasis Council

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

The European consensus statement on phenotypes of pustular psoriasis defines generalized pustular psoriasis (GPP) as primary, sterile, macroscopically visible pustules on non-acral skin (excluding cases where pustulation is restricted to psoriatic plaques). GPP can either be a relapsing (greater than 1 episode) or persistent (greater than 3 months) condition.

The consensus statement on GPP from the National Psoriasis Foundation states that in their experience, GPP can also occur on acral surfaces.

The international consensus definition and diagnostic criteria for GPP from the International Psoriasis Council has the presence of macroscopically visible sterile pustules on an erythematous base and not restricted to the acral region or within psoriatic plaques as essential diagnostic criteria. Supporting diagnostic criteria include any positive genetic finding (namely IL36RN, MPO, AP1S3, SERPINA, CARD14), biopsy confirmation with the presence of spongiform pustules of Kogoj, abnormal laboratory tests (e.g., hypocalcemia, hypoproteinemia, hypoalbuminemia, abnormal liver or renal functions), neutrophilia, leukocytosis, elevated C-reactive protein (CRP), positive personal or family history of psoriasis, history of recurring flares, fever, fatigue, painful skin, and lakes of pus.

References

1. Spevigo [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; October 2025.
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. 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.
4. Morita A, Choon SE, Bachelez H, et al. Design of Effisayil™ 2: A randomized, double-blind, placebo-controlled study of spesolimab in preventing flares in patients with generalized pustular psoriasis. Dermatol Ther (Heidelb). 2023;13(1):347-359.
5. Armstrong AW, Elston CA, Elewski BE, et al. Generalized pustular psoriasis: A consensus statement from the National Psoriasis Foundation. J Am Acad Dermatol. 2024;90(4):727-730.
6. Choon SE, van de Kerkhof P, Gudjonsson JE, et al. International consensus definition and diagnostic criteria for generalized pustular psoriasis from the International Psoriasis Council. JAMA Dermatol. 2024;160(7):758-768.

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