Suggestions and sample letter template for Spevigo® (spesolimab-sbzo) for subcutaneous injection:

Letter of Medical Necessity: SPEVIGO SC

These are suggestions for the type of information to consider when a letter of medical necessity is appropriate. Consider including a statement of medical necessity along with other types of letters and appeals if they are not as comprehensive. If using the sample letter template on the next page, submit it on your letterhead.

Core information:

- When injections are HCP-administered, provide the name of the administering facility and its NPI, if different from the prescriber's
- Include the patient's insurance information: their ID #, group #, and the reference # of the denial and its date
- Include all relevant codes for treatment with SPEVIGO SC*:
  — Diagnosis code[1]: ICD-10 L40.1
  — HCPCS code and modifier[2,3]: J1747-JB
- Specify the dosing regimen—whether your patient is starting on the 600-mg SC loading dose followed by 300 mg every 4 weeks thereafter, or has received an IV infusion and is starting on the 300-mg SC dose every 4 weeks
- Clearly establish the diagnosis of generalized pustular psoriasis (GPP) as distinct from plaque psoriasis
- It is essential that the submission be complete. Document that all requirements for the plan's prior authorization and step therapy have been met or explain why they are not appropriate for the patient. While the requirements of most plans are consistent with the SPEVIGO Prescribing Information, some are more restrictive

Suggestions:

- If this letter of medical necessity is being submitted to support an appeal, restate the reason for the denial, which must be provided to you when a prior authorization request is denied. Include the denial reference number and the date of the denial
- Provide chart notes or medical records as supporting documentation
- **Keep in mind that, unless the reviewer has a background in rare dermatologic conditions, he or she may not be familiar with GPP, its severity, and how it differs from plaque psoriasis.** The reviewer may also not be aware that SPEVIGO is FDA-approved for the treatment of GPP in adults and children 12 years of age and older who weigh at least 88 pounds (40 kg). It is not known if SPEVIGO is safe and effective in children under 12 years of age or who weigh less than 88 pounds (40 kg).[4]

It is always the responsibility of the health care provider or entity completing the prior authorization appeal to consult directly with each individual payer to ensure adherence to that payer's requirements.

Letter templates are available from your LEO Pharma Field Reimbursement Manager or the SPEVIGO website.

*Verify billing codes before submitting.

HCP, healthcare professional; HCPCS, Healthcare Common Procedural Coding System; ICD-10, International Classification of Diseases, 10th Revision; NPI, National Provider Identifier: SC, subcutaneous.

References: 1. Index to diseases and injuries: psoriasis. Centers for Disease Control and Prevention; National Center for Health Statistics—ICD-10-CM. Accessed July 9, 2026. https://icd10cmtool.cdc.gov/?fy=FY2026&query=generalized%20pustular%20psoriasis **2**. Drugs, administered by injection HCPCS code range J0013-J7176. Codify by AAPC. Accessed July 9, 2026. https://www.aapc.com/codes/hcpcs-codes-range/210/370 **3**. Modifiers. Noridian Healthcare Solutions. Updated July 6, 2026. Accessed July 9, 2026. https://med.noridianmedicare.com/web/jfb/topics/modifiers **4**. Elewski B, Lebwohl MG. Management of chronic generalized pustular psoriasis: a review and expert opinion. *J Psoriasis Psoriatic Arthritis*. 2025;10(2):58-66. doi:10.1177/24755303251318976

Please see additional Important Safety Information throughout and full Prescribing Information.

Spevigo® (spesolimab-sbzo) injection

Sample

Letter of Medical Necessity

[Date]
[Health Plan]
[Address]

[Patient Name]
[Member ID Number, Group Number]
[DOB]
[Denial reference # and date of denial]

RE: **Letter of Medical Necessity for use of Spevigo® (spesolimab-sbzo) for subcutaneous injection**
(ICD-10 L40.1, HCPCS J1747-JB)

To whom it may concern:

I am writing as the treating physician of [patient name]. My name is [HCP name], [board-certified in specialty, NPI #].

In my clinical judgment, SPEVIGO SC is medically necessary for [patient name], whom I have diagnosed with generalized pustular psoriasis (GPP) and who has previously had [number] GPP flares. SPEVIGO SC is FDA-approved to treat GPP.[1] While other agents have been used off-label to treat GPP, in a recent comprehensive review, support for systemic therapies has been assessed as "limited" or "no evidence." The support for biologics that are used off-label is based on retrospective, prospective, and open-label studies, none of which had a placebo arm or were assessed with a validated scoring tool and were also assessed as "limited" or "no evidence" (Puig et al., 2024).[2]

GPP is a chronic condition. GPP flares can be unpredictable and life-threatening.[1] In the Effisayil® 2 trial, SPEVIGO SC reduced the relative risk of GPP flares by 84% vs placebo over 48 weeks (secondary endpoint).[3,4]

I have included documentation of the following (plans may not require all criteria listed):

- Age (≥12 years) _____ Weight (at least 88 lbs/40 kg): _____
- Patient has been diagnosed with GPP: ( ) Yes ( ) No
- Confirmation that patient is not experiencing a flare (GPPPGA score of 0 or 1[4]): ( ) Yes ( ) No
- Number of **prior** GPP flares of moderate-to-severe intensity _____ (plans may require 1 or 2)
- Negative TB test within the past 12 months: ( ) Yes ( ) No
- Documentation that prior therapies, such as acitretin, cyclosporine, methotrexate, or infliximab, have failed to prevent GPP flares or are inappropriate for this patient (required by some plans[5])
- Patient is not receiving other biologics for treatment of GPP

The appropriate dosage regimen for this patient is:
[**OPTION 1: A loading dose is not required.** SPEVIGO 300 mg SC every 4 weeks in accordance with the product label.[4] This patient received an IV infusion of SPEVIGO on [date]. SPEVIGO SC may be self-injected or administered by HCP[4] (HCPCS J1747-JB).]

[**OPTION 2: A loading dose is required.** A loading dose of SPEVIGO 600 mg SC followed by SPEVIGO 300 mg SC 4 weeks later and every 4 weeks thereafter. SPEVIGO SC may be self-injected or administered by HCP[4] (HCPCS J1747-JB).]

Site of service: 600-mg loading dose, if required: ☐ Hospital-affiliated outpatient ☐ Group practice ☐ Home ☐ Other_____
300-mg dose: ☐ Hospital-affiliated outpatient ☐ Group practice ☐ Home (If hospital-affiliated, provide justification.)

In conclusion, [patient name] has a confirmed diagnosis of GPP, a chronic condition with an unpredictable clinical course.[1] The [enclosed] prescribing information supports the use of SPEVIGO for the treatment of GPP.[4] In addition, the National Psoriasis Foundation advocates for timely support of FDA-approved treatments for GPP.[6]

I attest that the clinical information is accurate and complete. I am available at [phone #] for a peer-to-peer review.

Sincerely,

[Health care provider's name, signature, and contact information]

[Enc:]
[SPEVIGO Prescribing Information]
[Patient clinical diagnostic records and related laboratory reports]

*The 600-mg loading dose must be HCP-administered when given as four 150-mg doses but can be self-injected when given as two 300-mg doses by patients 12 and older.

References: 1. Elewski B, Lebwohl MG. Management of chronic generalized pustular psoriasis: a review and expert opinion. *J Psoriasis Psoriatic Arthritis*. 2025;10(2):58-66. doi:10.1177/24755303251318976 **2**. Puig L, Fujita H, Thaçi D, et al. Current treatments for generalized pustular psoriasis: a narrative summary of a systematic literature search. *Dermatol Ther (Heidelb)*. 2024;14(9):2331-2378. doi:10.1007/s13555-024-01230-z **3**. Morita A, Strober B, Burden AD, et al. Efficacy and safety of subcutaneous spesolimab for the prevention of generalised pustular psoriasis flares (Effisayil 2): an international, multicentre, randomised, placebo-controlled trial. *Lancet*. 2023;402(10412):1541-1551. doi:10.1016/S0140-6736(23)01378-8 **4**. SPEVIGO (spesolimab-sbzo) injection. Prescribing information. LEO Pharma Inc; 2026. **5**. Data on file. MMIT (July 22, 2026). LEO Pharma Inc; 2026. **6**. 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. doi:10.1016/j.jaad.2023.09.080

INDICATION

SPEVIGO is indicated 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.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

SPEVIGO is contraindicated in patients with severe or life-threatening hypersensitivity to spesolimab-sbzo or to any of the excipients in SPEVIGO. Reported hypersensitivity reactions have included drug reaction with eosinophilia and systemic symptoms (DRESS) and anaphylaxis.

WARNINGS AND PRECAUTIONS

Infections: SPEVIGO may increase the risk of infections. In patients with a chronic infection or a history of recurrent infection, consider the potential risks and expected clinical benefits of treatment prior to prescribing SPEVIGO. Treatment with SPEVIGO is not recommended in patients with any clinically important active infection until the infection resolves or is adequately treated. Instruct patients to seek medical advice if signs or symptoms of clinically important infection occur during or after treatment with SPEVIGO. If a patient develops a clinically important active infection, discontinue SPEVIGO therapy until the infection resolves or is adequately treated.

Risk of Tuberculosis: Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with SPEVIGO. Avoid use of SPEVIGO in patients with active TB infection. Consider initiating anti-TB therapy prior to initiating SPEVIGO in patients with latent TB or a history of TB in whom an adequate course of treatment cannot be confirmed. Monitor patients for signs and symptoms of active TB during and after SPEVIGO treatment.

Hypersensitivity and Infusion-Related Reactions:

- Serious hypersensitivity reactions, including anaphylaxis and delayed reactions such as drug reaction with eosinophilia and systemic symptoms (DRESS), have been reported during and following administration of SPEVIGO. These reactions can occur with the first dose or subsequent doses.
- SPEVIGO is contraindicated in patients with severe or life-threatening hypersensitivity to spesolimab-sbzo or to any of the excipients in SPEVIGO. If a patient develops signs of anaphylaxis or other serious hypersensitivity, discontinue SPEVIGO immediately and initiate appropriate treatment.
- If a patient develops mild or moderate hypersensitivity during an intravenous infusion or other infusion-related reactions, stop SPEVIGO infusion and consider appropriate medical therapy (eg, systemic antihistamines and/or corticosteroids). Upon resolution of the reaction, the infusion may be restarted at a slower infusion rate with gradual increase to complete the infusion.

Vaccinations: Prior to initiating SPEVIGO for treatment of GPP, complete all age-appropriate vaccinations according to current immunization guidelines. Avoid use of live vaccines in patients during and for at least 16 weeks after treatment with SPEVIGO. No specific studies have been conducted in SPEVIGO-treated patients who have recently received live viral or live bacterial vaccines.

ADVERSE REACTIONS

Intravenous SPEVIGO for Treatment of GPP Flare (Study Effisayil-1): Most common adverse reactions reported in ≥5% of patients treated with SPEVIGO in the clinical trial were asthenia and fatigue, headache, nausea, pruritus and prurigo, infusion site hematoma and bruising, and urinary tract infection (UTI).

Specific Adverse Reactions

- **Infections:** The most frequent adverse reactions that occurred in subjects treated with intravenous SPEVIGO were infections. During the 1-week placebo-controlled period in Study Effisayil-1, infections were reported in 14% of subjects treated with SPEVIGO compared with 6% of subjects treated with placebo. Serious infection (UTI) was reported in 1 subject (3%) in the SPEVIGO group and no subjects in the placebo group. Infections observed through Week 1 in Study Effisayil-1 in subjects treated with SPEVIGO were mild (29%) to moderate (71%).
- **Drug Reaction With Eosinophilia and Systemic Symptoms (DRESS):** Two cases of DRESS were reported in Study Effisayil-1 in subjects with GPP who were treated with intravenous SPEVIGO. RegiSCAR DRESS validation scoring (with the following categories: "no," "possible," "probable," or "definite" DRESS) was applied to the reported cases. Reported cases were assessed as "no DRESS" and "possible DRESS."

Subcutaneous SPEVIGO for Treatment of GPP When Not Experiencing a Flare (Study Effisayil-2): Regarding the exposure-adjusted incidence rates for subjects on randomized treatment prior to receiving rescue treatment for flare or completing trial without a flare, the rate per 100-patient years for injection site reaction (including erythema, pain, swelling, induration, urticaria, and warmth at the injection site) was 31.6 for the subcutaneous SPEVIGO cohort (600 mg loading dose followed by 300 mg every 4 weeks) vs 12.7 for the placebo cohort. The rate per 100-patient years for UTI was 18 for SPEVIGO vs 0 for placebo. The rate per 100-patient years for pruritus was 8.8 for SPEVIGO vs 0 for placebo. The rate per 100-patient years for arthralgia was 13.3 for SPEVIGO vs 6 for the placebo cohort. There were 3 subjects who discontinued subcutaneous SPEVIGO due to treatment-emergent adverse events of psoriasis compared to no subjects in the placebo cohort who discontinued placebo for any treatment-emergent adverse event.

Safety in Study Effisayil-2 After Flare: In Effisayil-2, subjects who experienced a GPP flare and received at least one dose of an open-label single intravenous 900 mg dose of SPEVIGO were treated with open-label subcutaneous SPEVIGO 300 mg. These subjects (n=19) received subcutaneous dosing at every 12 weeks, which could have been increased to every 4 weeks based on GPPPGA total score or pustulation subscore increased by ≥1 from any previous open-label maintenance visit. The reported safety profile of open-label subcutaneous SPEVIGO use after treatment of GPP flare with open-label intravenous SPEVIGO use was consistent with the safety profiles of use of SPEVIGO from Trial Effisayil-1 and randomized controlled data from Trial Effisayil-2.

Please see additional Important Safety Information throughout and full Prescribing Information.

IMPORTANT SAFETY INFORMATION, cont'd

Clinical Development of Spesolimab-sbzo

- **Guillain-Barre Syndrome (GBS):** Among approximately 835 subjects exposed to spesolimab-sbzo during clinical development, GBS was reported in 3 subjects who received various doses of spesolimab-sbzo via various methods of administration in clinical trials for unapproved indications.

SPECIFIC POPULATIONS

Pediatric Use: The safety and effectiveness of SPEVIGO for the treatment of GPP have been established in pediatric patients 12 years of age and older and weighing at least 40 kg. Use of SPEVIGO for this indication is supported by data from a randomized, placebo-controlled study, which included 6 pediatric subjects 14 to 17 years of age with a history of GPP treated with subcutaneous SPEVIGO (Study Effisayil-2), and evidence from an adequate and well-controlled study of intravenous SPEVIGO in adults with GPP (Study Effisayil-1), with additional pharmacokinetic analyses showing similar drug exposure levels in adults and pediatric subjects 12 years of age and older and weighing 40 kg or more. The safety and effectiveness of SPEVIGO in pediatric patients younger than 12 years of age or in pediatric patients weighing less than 40 kg have not been established.

Please see Prescribing Information for SPEVIGO, including Medication Guide and Instructions for Use.

The information herein is for educational purposes and does not constitute legal advice. When completing a prior authorization request or an appeal, it is the responsibility of the health care provider to ensure adherence to the payer's requirements. Payers' public and nonpublic requirements may change, and LEO Pharma undertakes no obligation to provide updated information with respect to such requirements. Under no circumstances should any product or ancillary supplies that are received free of charge be billed to any third-party payer. LEO Pharma cannot and will not guarantee coverage, and nothing herein shall be construed to create such a guarantee.

The LEO Pharma logo and Spevigo® are registered trademarks of LEO Pharma A/S.
© 2026 LEO Pharma Inc. All rights reserved.

September 2026 | MAT-99936