

Dear Healthcare Professional,

Please note that the sample physician letter of medical exception on page 3 of this resource includes general guidance related to fulfilling prior authorizations (PAs). **Please modify the content in the letter as needed based on your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.** For additional guidance, a PA tips and checklist resource is also included.

Please be aware that PA requirements may vary according to the health plan. For instance, the plan may require that only the patient submit a letter. In this case, it is the responsibility of the Healthcare Professional (HCP) to provide appropriate supporting documentation under separate cover.

Use of the information in this document does not guarantee that the health plan will provide reimbursement for SPEVIGO® (spesolimab-sbzo) injection and it is not intended to be a substitute for, or an influence on, your independent medical judgment.

Before sending the letter of medical necessity to the health plan, please remove the title that states, “[Sample Letter of Medical Exception: Physician]” and corresponding instructions below the title in brackets.

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 $\geq 5\%$ 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%).

Please see additional Important Safety Information on the next page and full [Prescribing Information](#) including [Medication Guide](#) and [Instructions for Use](#).

 **Spevigo**[®]
(spesolimab-sbzo) injection

IMPORTANT SAFETY INFORMATION (Cont'd)

ADVERSE REACTIONS (Cont'd)

Specific Adverse Reactions (Cont'd)

- **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 GPPGA 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.

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 additional Important Safety Information on the next page and full [Prescribing Information](#) including [Medication Guide](#) and [Instructions for Use](#).

 **Spevigo**[®]
(spesolimab-sbzo) injection



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[Sample Letter of Medical Exception: Physician]

[Please modify the content in the letter as needed based on your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

[Date]
[Health Plan Name]
ATTN: [Department]
[Medical/Pharmacy Director Name (if available)]
[Health plan address]
[City, State, ZIP code]

[Patient's Name] [Patient's
plan-specific member ID]
[Patient's Date of Birth]
[Case number]
[Dates of service]

RE: Letter of Medical Exception for SPEVIGO subcutaneous

Dear [Medical/Pharmacy Director Name],

I am writing to request a medical exception for SPEVIGO subcutaneous for [Patient's Name], who has a history of Generalized Pustular Psoriasis (GPP). This condition is characterized by widespread painful pustules over large areas of the body, along with systemic symptoms such as fever. Disease flares are unpredictable and can progress into life-threatening complications, including cardiorespiratory failure, renal failure, hepatic failure, and/or sepsis.¹ It is my professional opinion that my patient should be placed on SPEVIGO subcutaneous as it is the only FDA-approved treatment for the treatment of GPP when not experiencing a flare.

I have been treating [Patient's Name], [a/an] [age]-year-old [male/female], since [Date] to manage their GPP. My rationale for prescribing SPEVIGO subcutaneous is: [Include relevant medical information and why SPEVIGO is the most appropriate treatment option. An example may include prior GPP flare history, including GPPPGA score, BSA, medical history, clinical notes, TB test etc.].

In my medical judgment, this patient is an appropriate candidate for SPEVIGO treatment. I have included the US Food and Drug Administration (FDA) approval letter for SPEVIGO subcutaneous, as well as patient's medical records.

Thank you for your prompt attention to this matter and for your consideration and anticipated approval of SPEVIGO subcutaneous for my patient.

Sincerely,

[Physician's signature]

[Physician name]
[Physician NPI]
[Name of practice]
[Phone number]

Enclosures: [List and attach additional documents, which may include Prescribing Information, clinical notes/medical records, US Food and Drug Administration approval letter, clinical studies and efficacy data, and/or clinical practice guidelines]

This letter is provided as an example and is meant for educational purposes only. SPEVIGO cannot guarantee insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to include the proper information and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

References: 1. Crowley JJ, et al. *Postgrad Med.* 2021;133(3):330-334.

Please see Important Safety Information on first page and full [Prescribing Information](#) including [Medication Guide](#) and [Instructions for Use](#).

PA TIPS AND CHECKLIST

Tips for Handling PA Requirements From Health Plans

This document provides a checklist and relevant tips that may be useful when creating a letter of medical necessity. Some plans have specific coverage authorization forms that must be utilized to document a letter of medical necessity. Follow the patient's plan requirements when requesting SPEVIGO® (spesolimab-sbzo) injection to avoid treatment delays. Please contact third-party payers directly for specific information on their current coverage policies.

UNDERSTAND HEALTH PLAN REQUIREMENTS

- Be sure to fulfill any plan-specific guidelines and/or requirements for authorizing treatment

PROVIDE CORRECT IDENTIFICATION (ID) NUMBERS

- Indicate the individual provider ID number versus the group practice/facility provider ID number on the prescription form
- Obtain the patient ID number from his or her insurance card
- Provide correct ICD-10-CM diagnosis code(s) for the condition/diagnosis

INCLUDE SUPPORTING DOCUMENTS^a

- Whenever possible, submit all required supporting documents with the PA request. For example, a health plan may need documentation showing the results from any laboratory testing
- Include a photocopy of the patient's health plan prescription card (front and back)

CHECK FOR THE STATEMENT OF MEDICAL NECESSITY

- The statement of medical necessity may need to be updated and/or resubmitted. This form is usually valid for 12 months from the original dated signature

BE AWARE OF DEADLINES

- Prepare in advance and collect any required documents to meet all deadlines for PA submission

FOLLOW UP

- If you do not receive a decision within 5 to 7 days, be sure to follow up via phone or email

MAINTAIN COMPLETE RECORDS

- Keep a copy of everything you submit for the PA. Keep a log of every phone call you make to the patient's health plan, including the date and the name of the person with whom you spoke

^aPlease be aware that PA requirements may vary according to health plan. For instance, the plan may require that only the patient submit a letter. In this case, it is the responsibility of the HCP to provide appropriate supporting documentation under separate cover.

PA TIPS AND CHECKLIST (CONT'D)

PA Submission Checklist

PA criteria may vary by plan. Please be sure to consult the website for the patient's insurer to confirm PA criteria, if available. Here is a checklist of the forms and documents you may need to submit to a health plan to obtain PA. Be sure to fill out all requested information.

- Sender and recipient contact information (eg, fax number, email address)
- Completed prescription form
- Copy of the patient's health insurance card and/or prescription card (front and back), including all relevant membership numbers
- Supporting documentation (as required)^a
 - PA form specific to health plan
 - Patient history and physical findings/diagnosis
 - Complete test and lab results
 - Chart notes from HCP or clinician
 - Hospital admission or emergency department notes, if applicable or relevant
 - Patient authorization and notice of release of information

Confirm receipt of documentation for all PA submissions and query for additional information if criteria are unclear.

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