

## Dear Healthcare Professional,

Please note that the sample physician appeal letter on page 3 of this resource includes general guidance related to appealing treatment decisions. 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, an appeal tips and checklist resource is also included.

Please be aware that appeal requirements may vary according to the health plan. For instance, the plan may require that only the patient submit a letter of appeal. 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 appeal letter to the health plan, please remove the title that states, "[Sample Appeal Letter: 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**<sup>®</sup>  
(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  $\geq 1$  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**<sup>®</sup>  
(spesolimab-sbzo) injection



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# [Sample Appeal Letter: 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]

[Attention]

[Name of Health Plan]

[Health Plan Mailing Address]

[Patient Name]

[Patient Date of Birth]

[Patient ID#]

RE: Appeal for SPEVIGO® (spesolimab-sbzo) injection, for subcutaneous use

Dear Appeal Reviewer,

My name is [treating provider] and I am a [physician specialty]. I am writing to appeal the denial for SPEVIGO (spesolimab-sbzo) injection for the treatment of Generalized Pustular Psoriasis (GPP) when not experiencing a flare (SPEVIGO SC) on behalf of my patient [patient name]. I have enclosed the SPEVIGO SC prescribing information that supports the use of this therapy that was approved by the US Food and Drug Administration (FDA) on March 18, 2024 for the indication of GPP treatment in adults and children 12 years of age and older weighing at least 40 kg. The FDA's approval for SPEVIGO SC for the treatment of GPP when not experiencing a flare indication was based upon the safety and efficacy profile established in a randomized, double-blind, placebo-controlled study.

My patient's disease state, prior treatments and response to those treatments, as well as other underlying health issues, age, and additional factors that impact my treatment decision are:

[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.]

[Lab Values (if available):]

In conclusion, my patient, [patient name], has a confirmed diagnosis of GPP with an unpredictable clinical course associated with numerous complications. One of the treatment goals is to reduce the risk of future flares, which SPEVIGO SC demonstrated in Effisayil-2. I would appreciate your prompt review of this appeal and approval for this important therapy. Thank you for your time and reconsideration of my request for SPEVIGO SC.

Sincerely,

[Physician Signature]

[Enclosures include:]

- [• SPEVIGO SC prescribing information]
- [• SPEVIGO SC published clinical studies]
- [• Patient clinical/diagnostic records and related laboratory reports]
- [• Patient authorization and notice of release of information]

# APPEAL TIPS AND CHECKLIST

## Tips for Filing an Appeal of Treatment Denial

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

### IDENTIFY THE REASON FOR DENIAL

- Find out in writing why the authorization request has been denied. The reason should be in the denial letter from the patient's health plan or in the explanation of benefits letter. If you did not receive either of these, they can be obtained from the insurer

### DETERMINE THE APPEAL GUIDELINES

- Contact the insurer to find out the deadline for appealing, the number of appeals permitted (some plans only allow one), and the mailing address or fax number to which the appeal should be sent. Some insurers have short appeal periods—you may need to respond promptly. Also, inquire whether the appeal should be submitted by the patient or the HCP and proceed accordingly

### CONTACT THE REVIEW DEPARTMENT

- Many denial letters include a telephone number for the review department that physicians can call for further clarification. If a reviewer agrees with your rationale and approves treatment for the patient during the call, the appeal process is completed

### COMPOSE A WRITTEN APPEAL

- Most insurers require a written appeal from either the member or the healthcare provider. The insurer should tell you what is needed. A written appeal package includes an appeal letter and supporting documents

### PROVIDE ADDITIONAL SUPPORTING DOCUMENTATION<sup>a</sup>

- A patient's appeal package should include all relevant medical documentation—including clinical notes and related test results—to support your case for coverage. Any newly available information related to the patient's condition should be supplied as well

### CHECK PATIENT'S INSURER

- Do you know the type of insurance your patient has? Is the treatment a covered benefit? Are there state laws that may impact the treatment decision? Ask your patient to check his or her benefit plan to help determine whether the requested treatment is excluded. If it is, provide a written explanation as to why the plan should make an exception for your patient. Depending on the state where your practice is located, seeking an independent external review may be an option

### FOLLOW UP AS NEEDED

- Contact the patient's insurer if they have not responded within 30 to 60 days of receipt of the appeal package

### MAINTAIN COMPLETE RECORDS

- Retain a duplicate copy of all documentation submitted with the patient's appeal and record all subsequent communications made to the patient's insurer. Include the date and the name of the person contacted

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## APPEAL TIPS AND CHECKLIST (CONT'D)

### Documents for Filing a Response to Treatment Denial: An Appeal Checklist

If an insurer denies coverage of a prescribed treatment for your patient, the following is a sample checklist of materials you may need for an appeal package. Note that each appeal may need different information depending on the insurer and/or patient. Carefully review each denial and the insurer's requirements to determine what to include in a patient's appeal package.

#### COMMONLY REQUIRED DOCUMENTS INCLUDE<sup>a</sup>:

- Statement of medical necessity
- Patient authorization and notice of release of information
- Copy of the patient's health plan or prescription card (front and back)
- Denial information, including the patient's denial letter and/or explanation of benefits
- Letter of appeal
- Supporting documentation
  - SPEVIGO® (spesolimab) injection prescribing information
  - SPEVIGO injection published clinical studies
  - Patient clinical/diagnostic records and related laboratory reports

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