Spevigo®
(spesolimab-sbzo) injection

Patient Access Support Kit:

SPEVIGO SC for patients not experiencing a GPP flare

GPP, generalized pustular psoriasis; SC, subcutaneous.

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 (88 lb).

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. 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.

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

Please contact me if you have any questions.

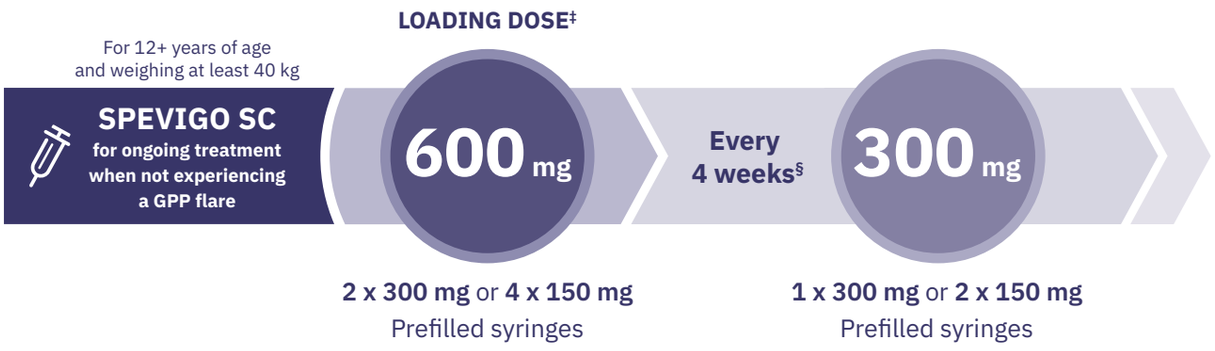
Name	
Title	
Email	
Phone	

LEO

Spevigo® treats both phases of GPP, flare and chronic, with two dosing options[1]

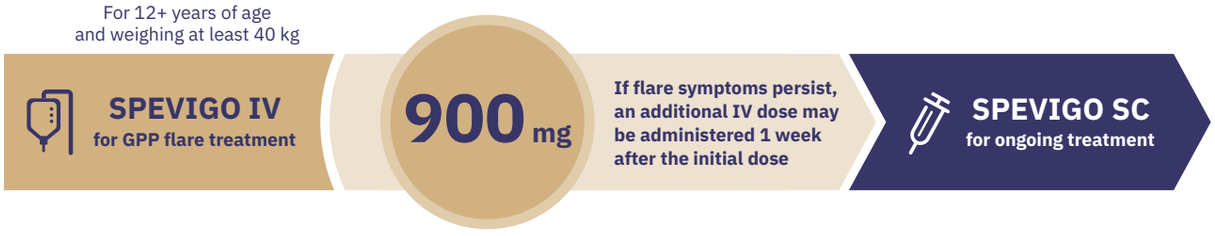
Prior to initial treatment with the IV or SC formulations of SPEVIGO, evaluate patient for tuberculosis infection (TB),* and complete all age-appropriate vaccinations.†

SPEVIGO SC for patients not experiencing a GPP flare



‡When initiating or reinitiating SPEVIGO SC 4 weeks after receiving SPEVIGO IV, no SC loading dose is required.

SPEVIGO IV for patients experiencing a GPP flare



2 x 450 mg/7.5 mL vials
Administered over 90 minutes

Four weeks after treatment with SPEVIGO IV, initiate or reinitiate SPEVIGO SC at a dose of 300 mg administered every 4 weeks. An SC loading dose is not required following treatment of a GPP flare with SPEVIGO IV.

Monitor patients for hypersensitivity reactions, such as DRESS and for signs and symptoms of active TB infection.
SPEVIGO SC 300-mg prefilled syringe: Patients may self-administer if the healthcare professional determines that it is appropriate.§
SPEVIGO SC 150-mg prefilled syringe: Loading dose to be administered by a healthcare professional. For subsequent 300-mg doses, patients may self-administer if the healthcare professional determines that it is appropriate.§

*SPEVIGO initiation is not recommended 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.

†Avoid the use of live vaccines in patients during and for at least 16 weeks after treatment with SPEVIGO.

§If the healthcare professional determines that it is appropriate, a patient 12 years of age or older may self-inject or the caregiver may administer SPEVIGO SC after proper training in subcutaneous injection technique. SPEVIGO should be administered under the supervision of an adult in pediatric patients 12 years of age or older.

DRESS, drug reaction with eosinophilia and systemic symptoms; GPP, generalized pustular psoriasis; IV, intravenous infusion; SC, subcutaneous.

Reference: 1. SPEVIGO (spesolimab-sbzo) injection. Prescribing information. LEO Pharma Inc; 2026.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

Spevigo® (spesolimab-sbzo) injection

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

This brochure is intended to support providers who are treating patients who are not experiencing a GPP flare with the subcutaneous formulation of Spevigo®.

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GPPPGA Scoring

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- **5. Patient Narrative**

Sample Medicare Forms

Codes

Important Safety Information (ISI)

Click or scan for editable Word documents.

GPP, generalized pustular psoriasis; GPPPGA, Generalized Pustular Psoriasis Physician Global Assessment; PA, prior authorization.

IMPORTANT SAFETY INFORMATION (cont'd)
WARNINGS AND PRECAUTIONS (cont'd)

- **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.

Spevigo® (spesolimab-sbzo) injection

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

Dosing scenarios leading to subcutaneous therapy for patients not experiencing a GPP flare

Treatment course may start with IV infusion

SPEVIGO IV 900-mg infusion for treatment of flares

Loading dose is not required following treatment with SPEVIGO IV within 4 weeks

SPEVIGO SC
Ongoing doses: 300 mg every 4 weeks

Loading dose is required after 4 weeks

SPEVIGO SC
Loading dose: 600 mg is required

Ongoing doses: 300 mg every 4 weeks

Submit the Enrollment Form to give your patient access to the SPEVIGO patient support they are eligible for:



Spevigo® (spesolimab-sbzo) injection

SPEVIGO Patient Support Program

Fax: 855-237-0134
Phone: 833-SPEVIGO (833-773-8446)
Email: Programs@SpevigoPatientSupport.com

Instructions: All fields required unless otherwise noted. Complete entire form and **fax pages 1-3** to **855-237-0134**.
For assistance call 833-SPEVIGO, Monday-Friday 8:00 AM – 8:00 PM ET.

1 Patient Information (to be completed by Patient/Legal Guardian)
For patients under the age of 18 years, this must be completed by the Legal Guardian over the age of 18 years, and all contact information must align to the Legal Guardian.

Patient First Name | MI | Patient Last Name | Patient Date of Birth | Gender: M F Not Specified
If Patient is under the age of 18: Legal Guardian First Name | Legal Guardian Last Name | Legal Guardian Date of Birth
Street Address | City | State | ZIP Code
Home Phone | Cell Phone | Email Address
Preferred contact: Home Phone Cell Phone | Preferred language if not English:
Best time to contact: Morning Afternoon Evening | YES, I am comfortable with the Program leaving my personal and health information on my voicemail.
Alternate Contact/Caregiver First and Last Name (Optional) | Alternate Contact/Caregiver Relationship to Patient (Optional)
Alternate Contact/Caregiver Email Address (Optional) | Alternate Contact/Caregiver Phone Number (Optional) | OK to discuss my condition, participation in the Program, and related services with my Alternate Contact/Caregiver.

Please indicate if you are interested in receiving any of the additional resources below.
If prescribed for subcutaneous use: Sharps disposal container | Insulated travel bag
YES, I agree to receive periodic messages from LEO Pharma and its affiliates, business partners, agents and service providers ("Partners") supporting the Program via calls and text messages at the cell phone number provided above. I understand calls or texts may be autodialed or prerecorded, are not a condition of purchase, and that messaging or data rates may apply.
SPEVIGO Copay Program: By checking this box, I confirm I have commercial insurance and am not currently enrolled in any federal, state, or other government funded medical or prescription benefit programs. I have read and agree to the SPEVIGO Copay Program Terms and Conditions (See Section 10).
YES, I would like to receive periodic communications via email or mail to learn more about other services, products, or special opportunities that LEO Pharma or its Partners believe may be of interest to me.
Patient Assistance Program (PAP) – See Section 8 on page 3 for Patient Consent: SPEVIGO Patient Assistance Program

Patient/Legal Guardian Signature
SIGN HERE | Patient/Legal Guardian Signature (Required) | Date
My signature above affirms that I have read, understand and agree to the Patient Authorization in Section 9, page 4, and that I have received a prescription for SPEVIGO.
Scan or click to learn more about **SPEVIGO.**

Sections 2-7 must be completed by a healthcare professional.

2 Patient Insurance Information (Required)
Please include copies (front and back) of the patient's medical and pharmacy insurance card(s).
If no cards are available, other forms such as the Patient Demographic Form are acceptable.
Check all that apply: Primary Medical | Secondary Medical | Pharmacy | Patient is Uninsured

3 Prescriber Information
First Name | Last Name | State Medical License | NPI
Facility Name | Phone | Fax
Street Address | City | State | ZIP Code | HCP Specialty
Office Contact Name | Office Contact Phone (Direct Ext.) | Office Contact Email Address
Tax ID

Please see full Important Safety Information on page 6 and accompanying Prescribing Information, Medication Guide, and Instruction for use.

PAGE 1 OF 6

1. Download and complete pages 1-3 of the Enrollment Form
2. Attach a copy of the patient's insurance card (front and back)
3. **Fax to 1-855-237-0134**

Click or scan.

Or patients can enroll online here:

Click or scan.

GPP, generalized pustular psoriasis; IV, intravenous; SC, subcutaneous.

IMPORTANT SAFETY INFORMATION (cont'd)
WARNINGS AND PRECAUTIONS (cont'd)

- **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® (spesolimab-sbzo) injection

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

Spevigo® Patient Support Program offers comprehensive patient services



SPEVIGO Copay Program*

Help your eligible patients save.

Commercially insured patients may pay as little as $0 through the SPEVIGO Copay Program.



SPEVIGO Bridge Program†

Helps patients start therapy when coverage is delayed by 7 or more days (SPEVIGO SC only). The SPEVIGO Bridge Program may provide a limited supply of SPEVIGO for subcutaneous use for free to eligible, commercial patients who are experiencing a coverage delay or denial.



SPEVIGO Patient Assistance Program (PAP)‡

Eligible patients experiencing financial hardship with limited or no prescription coverage may be able to receive SPEVIGO through the SPEVIGO Patient Assistance Program.

For full Terms, Conditions, and Eligibility Rules, scan this QR code

*Eligible, commercially insured patients enrolled in the program may pay as little as $0 per fill. Government-insured patients (ie, Medicare, Medicaid, TRICARE, etc.) and cash-paying patients are not eligible for the Copay Program.

†The patient must have insurance that covers specialty medications; uninsured or cash-paying patients are not eligible. The patient must experience one of the following: 1) a documented delay of seven (7) calendar days or more in securing insurance coverage determination at the submission of the prior authorization or due to the patient switching insurance plans (ie, the actual submission of a prior authorization, etc.); 2) a documented denial of insurance coverage or due to the patient switching insurance plans that is based on a prior authorization request for which an appeal of the coverage denial, on behalf of the patient, has been submitted or will be submitted within thirty (30) days of such denial; or 3) a documented lapse of coverage due to insurance plan changes for which an appeal or other procedural effort to regain coverage is pending.

‡Eligible, uninsured or underinsured patients who meet eligibility requirements for PAP.



SPEVIGO (IV) 450-mL vials can typically be delivered within 24 hours

(Time from product shipment to site of infusion upon approval and confirmation of in-network site.)

Spevigo®
(spesolimab-sbzo) injection

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

The Spevigo® support team is here to support you and your patient at every step along the way

Patient Support Team (call **833-SPEVIGO / 833-773-8446**)

Your Rare Disease Sales Consultant or Key Account Executive can provide resources and help connect you with the Patient Support Team.



Clinical Nurse Educator

Whether the patient is starting with SPEVIGO IV or SC, the Clinical Nurse Educator (CNE) will engage with the patient through a welcome call. During that call, the CNE provides disease state education and helps to set expectations.*

For patients transitioning from SPEVIGO IV to SPEVIGO SC, the CNE can offer virtual injection education and reminders about the importance of continued treatment.



Patient Navigator

The Patient Navigator supports patients throughout their treatment journey.

The Navigator is the main point of contact for you, your patients, and your staff.

The Navigator can provide benefits explanation, treatment center information, and regular follow-ups to encourage injection persistency.



Field Reimbursement Manager

The Field Reimbursement Manager works with HCP offices to help overcome prior authorization challenges, product affordability concerns, and access issues.

The SPEVIGO Patient Support team can help locate infusion sites, coordinate appointments, and follow up with patients.

The CNE can help prepare the patient for their infusion appointment and provide post-infusion follow-up and continued treatment education.

The Navigator will confirm infusion center appointments.

Confirms coverage.

They may also be able to help coordinate travel to and from the infusion center.

*Clinical Nurse Educators cannot give medical treatment or advice.

Spevigo® (spesolimab-sbzo) injection

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

Checklist for infusion center referrals

Depending on the infusion site of care and your patient's payer requirements, you may need to provide some or all of the following information to initiate the infusion process for Spevigo® IV:

- [ ] The SPEVIGO Patient Support Program Enrollment form
- [ ] Order set/infusion center specific order set (if available)
- [ ] Insurance information (copy of front and back of insurance card)
- [ ] Recent chart notes, including decision for treatment
- [ ] Documentation of severity of flare including erythema, pustulation, scaling and body surface area (BSA) percentage
- [ ] Current or previous medications/biologics for GPP (if applicable)
- [ ] Current medications
- [ ] Any known allergies
- [ ] Evaluate for tuberculosis

The infusion site of care or patient's payer may also require additional information not listed above.

Please contact your FRM for any questions.

FRM, Field Reimbursement Manager; GPP, generalized pustular psoriasis; IV, intravenous.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

- **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.

Spevigo® (spesolimab-sbzo) injection

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

Common PA criteria for Spevigo® SC

SPEVIGO SC is typically covered under the pharmacy benefit, but may be covered under medical. Patients transitioning from IV to SC will require a new PA for SC coverage.

Usual criteria are aligned with SPEVIGO Prescribing Information and inclusion criteria for its clinical trials[1,2]	• Age: 12 years of age and older • Weight: At least 88 lbs/40 kg • Negative TB test within the past 12 months • Patient is not experiencing a GPP flare • A GPPPGA total score of 0 or 1 • Prescribed by a dermatologist or in consultation with a dermatologist[3] • Will not be used concomitantly with another biologic
Additional criteria that some plans may require	• History of at least two flares of moderate-to-severe intensity • Trial of prior systemic therapy for prevention of GPP with continued flares either during treatment or following dose reduction • Chart notes or medical record documentation of all criteria • May require trial and failure of preferred drugs[2] • May require that SPEVIGO not be administered in a hospital outpatient setting[3]
Reauthorization	• Some payers may require annual reauthorization for ongoing therapy; others may require reauthorization as often as every 6 months[3]

GPP, generalized pustular psoriasis; GPPPGA, Generalized Pustular Psoriasis Physician Global Assessment; PA, prior authorization; SC, subcutaneous.

References: 1. SPEVIGO (spesolimab-sbzo) injection. Prescribing information. LEO Pharma Inc; 2026. **2.** Spevigo® policy. Blue Cross Blue Shield Blue Care Network of Michigan. June 11, 2026. Accessed August 25, 2026. https://www.bcbsm.com/amslibs/content/dam/public/mpr/mprsearch/pdf/2167376.pdf **3.** Spevigo® prior authorization policy. Cigna Healthcare. May 13, 2026. Accessed August 25, 2026. https://static.cigna.com/assets/chcp/pdf/coveragePolicies/cnf/cnf_856_coveragepositioncriteria_inflammatory_conditions_spevigo_subcutaneous_pa.pdf

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

- The most common adverse reactions with SPEVIGO when experiencing a flare include asthenia and fatigue, headache, nausea, pruritus and prurigo, infusion site hematoma and bruising, and urinary tract infection.

Spevigo® (spesolimab-sbzo) injection

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

This checklist can help ensure that your prior authorization requests for Spevigo® SC are complete

- ☐ **Health plan may request that you use the PA forms they have available on their website**
- ☐ **Clearly specify the formulation: SPEVIGO SC or SPEVIGO IV**
- ☐ **Provide images of the patient's medical and pharmacy prescription cards** (Front and back)
- ☐ **Indicate the individual provider ID number**
  vs the group practice/facility provider ID number on the prescription form;
  provide the name of the administering facility and its NPI, if different from the prescriber's
- ☐ **Provide complete documentation of all requested criteria**
  A common reason for delays and denials
- ☐ **Confirm diagnosis of GPP as distinct from plaque psoriasis**
- ☐ **Include GPP severity score**
  (See GPPPGA scoring tool on next page.) For SC, a GPPPGA score of 0 or 1
- ☐ **Include chart notes or medical records documenting** the treatment history (if applicable) and date of diagnosis
- ☐ **Submit a Letter of Medical Necessity** along with chart notes to support the prior authorization request. Establish that the GPP diagnosis is distinct from psoriasis
- ☐ **Document that any requirement for step therapy** has been met or explain why that requirement is not appropriate for the patient. Most step-therapy criteria require the use of off-label systemic therapies or biologics, which have limited or no support for GPP[1]
- ☐ **Provide correct coding information:**
  Diagnosis code: **L40.1** Generalized pustular psoriasis
  HCPCS code: **J1747** Spesolimab-sbzo, 1 mg
  Modifier: Add **JB** to indicate SC administration
- ☐ **Site of care:** Some plans may limit sites of care affiliated with hospitals
- ☐ **Follow up:** Confirm receipt of documentation for all PA submissions and ask the plan whether additional information is needed.
  Your SPEVIGO Patient Navigator or FRM can assist you

FRM, Field Reimbursement Manager; GPP, generalized pustular psoriasis; GPPPGA, Generalized Pustular Psoriasis Physician Global Assessment; HCPCS, Healthcare Common Procedure Coding System; IV, intravenous; NPI, National Provider Identifier; PA, prior authorization; SC, subcutaneous.

Reference: 1. 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.

Spevigo® (spesolimab-sbzo) injection

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

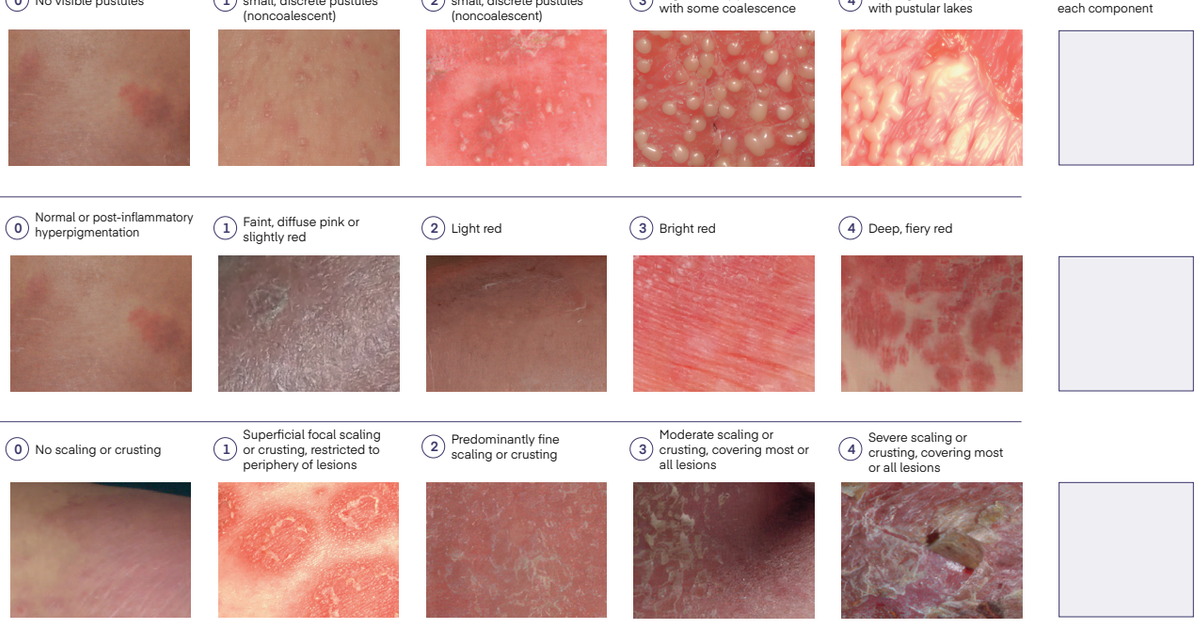
Most PA criteria for Spevigo® SC require an assessment using the Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) Tool*

To determine your patient's total GPPPGA score[1]

- Assess the severity of pustules, erythema, and scaling
- Apply a subscore to each individual component and calculate the average

Patient _____ Date _____

	Clear†	Almost clear†	Mild	Moderate	Severe	
Pustules subscore	0 No visible pustules	1 Low-density, occasional, small, discrete pustules (noncoalescent)	2 Moderate-density, grouped, small, discrete pustules (noncoalescent)	3 High-density pustules with some coalescence	4 very high-density pustules with pustular lakes	Enter subscore for each component
Erythema subscore	0 Normal or post-inflammatory hyperpigmentation	1 Faint, diffuse pink or slightly red	2 Light red	3 Bright red	4 Deep, fiery red	
Scaling/Crusting subscore	0 No scaling or crusting	1 Superficial focal scaling or crusting, restricted to periphery of lesions	2 Predominantly fine scaling or crusting	3 Moderate scaling or crusting, covering most or all lesions	4 Severe scaling or crusting, covering most or all lesions	



Enter mean value

$$\text{Mean of 3 subscores} = \frac{\text{pustules} + \text{erythema} + \text{scaling}}{3} = \boxed{}$$

In a SPEVIGO clinical trial, GPP flare was defined as[2]



The GPPPGA total score ranges from 0 (clear) to 4 (severe) and is determined by averaging the subscores of pustules, erythema, and scaling. These components are graded separately. The average is calculated: 0† (0 for all 3 components), 1† (average is >0 to <1.5), 2 (average is 1.5 to <2.5), 3 (average is 2.5 to <3.5), or 4 (average is ≥3.5).[1]

*The GPPPGA score is adapted from the Physician Global Assessment, a tool that physicians use to evaluate disease severity. This tool utilizes a 5-point scale, ranging from 0 to 4, to evaluate the severity of pustules, scaling, and erythema, with higher scores indicating greater disease severity.[1] This score may also be required by certain insurance companies as part of the prior authorization process.

†To receive a score of 0 or 1, the patient must be afebrile in addition to the skin presentation requirements.[3]

References: 1. Burden AD, Bachelez H, Choon SE, et al. The Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) score: online assessment and validation study of a specific measure of GPP disease activity. *Br J Dermatol.* 2023;189(1):138-140. doi:10.1093/bjd/ljad071 **2.** SPEVIGO (spesolimab-sbzo) injection. Prescribing information. LEO Pharma Inc; 2026. **3.** Gwillim EC, Nichols AJ. Spesolimab for generalized pustular psoriasis: a review of two key clinical trials supporting initial US regulatory approval. *Front Immunol.* 2024;15:1359481. doi:10.3389/fimmu.2024.1359481

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Spevigo® (spesolimab-sbzo) injection

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

Sample letter templates

Resources that may help support health plan outcomes

1. PA Denial Appeal Letter
2. Step-Edit Appeal Letter
3. Letter of Medical Necessity
4. Formulary Exception Letter
5. Patient Narrative

Click or scan for editable Word documents.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS (cont'd)

The most common adverse reactions with SPEVIGO when not experiencing a flare include injection site reaction, urinary tract infection, arthralgia, and pruritus.

Spevigo® (spesolimab-sbzo) injection

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

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

Prior Authorization Denial Appeal Letter: SPEVIGO SC

If a prior authorization (PA) request for SPEVIGO SC has been denied, you can submit an appeal. Keep in mind that the individual reviewing your appeal letter may not be the same person who denied the prior authorization request. It is therefore important to include comprehensive information in the appeal, even if that information was included with the initial PA. If you use the sample letter template on the following page, submit it on your practice letterhead. Keep in mind that some plans will require that appeals be submitted using their own form.

Core Information:

- Restate the reason for the denial, which must be provided to you if a prior authorization request is denied. Include the denial reference number and the date of the denial
- 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
- It is essential that the submission be complete. It must address and provide documentation for each of the criteria listed in the plan's prior authorization and step edit requirements. An incomplete submission is a common reason for denials
- If you use the sample letter template on the next page, that template includes fields for criteria required by most plans, but it's important to verify individual plan requirements
- If you are submitting an appeal using a form provided by the health plan, it should be accompanied by a letter of medical necessity
- When a plan issues a denial, it will describe their process for appealing their decision. There may be two levels of internal appeal prior to an external appeal. You may also request a peer-to-peer review
- 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
- 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 generalized pustular psoriasis (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[4]
- Some plans may require your patient's signature in addition to your own

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.

Click or scan for editable Word documents.

*Verify billing codes before submitting.

HCPCS, Healthcare Common Procedural Coding System;
ICD-10, International Classification of Diseases, 10th Revision;
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

Spevigo® (spesolimab-sbzo) injection

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

1 **Sample**

PA Denial Appeal Letter

[Date]
[Health Plan]
[Address]

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

RE: **Appeal of denial for 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 #].

My request for prior authorization was denied because [insert reason given in the letter]. I have reviewed the denial letter and maintain that SPEVIGO SC is the appropriate treatment for this patient because [insert your rationale].

Dosage regimen requested:

[OPTION 1 (Loading dose is not required)]: We are appealing the denial in order to initiate therapy with SPEVIGO 300 mg SC every 4 weeks in accordance with the product label.[1] This patient received an IV infusion of SPEVIGO on [date]. May be self-injected or administered by HCP1 (HCPCS J1747-JB).

[OPTION 2 (Loading dose is required)]: We are appealing the denial to initiate therapy with a loading dose of SPEVIGO 600 mg SC followed by SPEVIGO 300 mg SC 4 weeks later and every 4 weeks thereafter. May be self-injected or administered by HCP[1]*(HCPCS J1747-JB).

Generalized pustular psoriasis (GPP) is a chronic condition.[2] SPEVIGO is FDA-approved maintenance therapy for patients who are not experiencing a flare. GPP flares can be unpredictable and life-threatening.[1-3]

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
- Confirm patient is not experiencing a flare (GPPPGA score of 0 or 1[1]): ( ) 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 (required by some plans[4])
- Patient is not receiving other biologics for treatment of GPP

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.)

The [enclosed] prescribing information supports the use of SPEVIGO for the treatment of GPP.[1] In the Effisayil® 2 trial, SPEVIGO SC reduced the relative risk of GPP flares by 84% vs placebo over 48 weeks (primary endpoint).[1,3] In addition, the National Psoriasis Foundation advocates for timely support of FDA-approved treatments for GPP.[5]

I would appreciate your prompt review and approval. 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. SPEVIGO (spesolimab-sbzo) injection. Prescribing information. LEO Pharma Inc; 2026.
2. Elewski B, et al. *J Psoriasis Psoriatic Arthritis*. 2025;10(2):58-66. doi:10.1177/24755303251318976
3. Morita A, et al. *Lancet*. 2023;402(10412):1541-1551. doi:10.1016/S0140-6736(23)01378-8
4. Data on file. MMIT (July 22, 2026). LEO Pharma Inc; 2026.
5. Armstrong AW, et al. *J Am Acad Dermatol*. 2024;90(4):727-730. doi:10.1016/j.jaad.2023.09.080

Spevigo® (spesolimab-sbzo) injection

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

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

Appeal of Step-Edit Requirement: SPEVIGO SC

Some plans may require the off-label trial of a generic systemic agent or a preferred biologic[1] based on the inclusion of these agents in guidelines for plaque psoriasis. However, the evidence for their efficacy in generalized pustular psoriasis (GPP) is limited, and they are not indicated to target the IL-36 pathway, which is the central driver of pathogenesis in GPP.[2] If you consider the requirement unwarranted for your patient, you can appeal. The sample template on the following page may help you organize support for the appeal.

SPEVIGO is FDA-approved for GPP. That approval was based on two randomized clinical trials.[3]
In Puig et al, the evidence for SPEVIGO was rated **A** (Strong research-based evidence).[2]

- The evidence supporting the use of generic systemic agents, such as acitretin, cyclosporine, and methotrexate, is based on small, retrospective trials without a placebo arm and without the use of a standardized scoring tool. Their level of evidence supporting their use for GPP was assessed as **C** (Limited evidence) or **D** (No evidence)[2]
- The evidence supporting the use of infliximab was assessed as **C**[2]
- The evidence supporting the use of other biologics for GPP, such as secukinumab, guselkumab, or ustekinumab, was rated **C** or **D**[2]

Level of evidence is not a measure of efficacy. There are no head-to-head trials of SPEVIGO vs the agents mentioned. If you use the sample letter template on the following page, submit it on your practice letterhead.

Core information:

- In your appeal letter, restate the reason given for the denial
- Provide your rationale for initiating treatment with SPEVIGO
- 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
- 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[4]: ICD-10 L40.1
  — HCPCS code and modifier[5,6]: J1747-JB
- It is essential that the submission be complete. 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[7]

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.

Click or scan for editable Word documents.

*Verify billing codes before submitting.

HCPCS, Healthcare Common Procedural Coding System;
ICD-10, International Classification of Diseases, 10th Revision; IL, interleukin;
SC, subcutaneous.

References: 1. Data on file. MMIT (July 22, 2026). LEO Pharma Inc; 2026. **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.** SPEVIGO (spesolimab-sbzo) injection. Prescribing information. LEO Pharma Inc; 2026. **4.** 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 **5.** 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 **6.** Modifiers. Noridian Healthcare Solutions. Updated July 6, 2026. Accessed July 9, 2026. https://med.noridianmedicare.com/web/jfb/topics/modifiers **7.** 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

Spevigo® (spesolimab-sbzo) injection

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

2 Sample

Step-Edit Appeal Letter

Date]
[Health Plan]
[Address]

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

RE: **Appeal of requirement for step therapy prior to 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 #].

My request for prior authorization was denied because of a required trial of [insert drug name given in the letter]. I have reviewed the denial letter and maintain that initiating SPEVIGO SC without the trial of an off-label agent is medically necessary. SPEVIGO SC is FDA-approved maintenance therapy for patients who are not experiencing a flare. Flares can be unpredictable and life-threatening.[1,2]

[OPTION 1: SYSTEMICS] The requirement for the use of a systemic, [such as acitretin, cyclosporine, or methotrexate], may be based on guidelines for plaque psoriasis, which do not reflect current evidence specific to GPP. In a comprehensive review of agents that have been used to treat GPP, the level of evidence for the use of these agents in GPP has been assessed as **C** (Limited research-based evidence] or **D** (no evidence) (Puig et al., 2024).[3] Initiating SPEVIGO SC without the trial of an off-label systemic is medically necessary because [insert your rationale].

[OPTION 2: INFLIXIMAB] The requirement for the use of infliximab may be based on guidelines for plaque psoriasis, which do not reflect current evidence specific to GPP. In a comprehensive review of agents that have been used to treat GPP, the level of evidence supporting infliximab has been assessed as **C** (Limited research-based evidence) (Puig et al., 2024).[3] Initiating SPEVIGO SC without the trial of an off-label biologic is medically necessary because [insert your rationale].

[OPTION 3: REQUIREMENT FOR USE OF PREFERRED BIOLOGICS] The requirement for the use of [name of preferred biologic] may be based on guidelines for plaque psoriasis, which do not reflect current evidence specific to GPP. In a comprehensive review of agents that have been used to treat GPP, the level of evidence for biologics, such as secukinumab, guselkumab, and ustekinumab, was assessed as **C** (Limited research-based evidence] or **D** (No evidence) (Puig et al., 2024).[3] Initiating SPEVIGO SC without the trial of an off-label biologic is medically necessary because [insert your rationale].

Dosage regimen requested:

[If loading dose is not required: We are appealing the denial in order to initiate therapy with SPEVIGO 300 mg SC every 4 weeks in accordance with the product label.[3] This patient received an IV infusion of SPEVIGO on [date]. SPEVIGO SC may be self-injected or administered by HCP[3] (HCPCS J1747-JB).]

[If loading dose is required: We are appealing the denial to initiate therapy with 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[3]* (HCPCS J1747-JB).]

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
- Confirm patient is not experiencing a flare (GPPPGA score of 0 or 1[3]): ( ) 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
- Patient is not receiving other biologics for treatment of GPP

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.)

The [enclosed] prescribing information supports the use of SPEVIGO for the treatment of GPP.[3] In the Effisayil® 2 trial, SPEVIGO SC reduced the relative risk of GPP flares by 84% vs placebo over 48 weeks (primary endpoint).[3,4] In addition, the National Psoriasis Foundation advocates for timely support of FDA-approved treatments for GPP.[5]

I would appreciate your prompt review and approval. 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, et al. J *Psoriasis Psoriatic Arthritis*. 2025;10(2):58-66. doi:10.1177/24755303251318976 **2.** SPEVIGO (spesolimab-sbzo) injection. Prescribing information. LEO Pharma Inc; 2026. **3.** Puig L, et al. *Dermatol Ther (Heidelb)*. 2024;14(9):2331-2378. doi:10.1007/s13555-024-01230-z **4.** Morita A, et al. *Lancet*. 2023;402(10412):1541-1551. doi:10.1016/S0140-6736(23)01378-8 **5.** Armstrong AW, et al. *J Am Acad Dermatol*. 2024;90(4):727-730. doi:10.1016/j.jaad.2023.09.080

Spevigo® (spesolimab-sbzo) injection

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

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.

Click or scan for editable Word documents.

*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

Spevigo® (spesolimab-sbzo) injection

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

3 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 #]. I am affiliated with the [name of the hospital system.]

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 (primary 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 outpatien ☐ 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, et al. *J Psoriasis Psoriatic Arthritis*. 2025;10(2):58-66. doi:10.1177/24755303251318976 **2.** Puig L, et al. *Dermatol Ther (Heidelb)*. 2024;14(9):2331-2378. doi:10.1007/s13555-024-01230-z **3.** Morita A, et al. *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, et al. *J Am Acad Dermatol*. 2024;90(4):727-730. doi:10.1016/j.jaad.2023.09.080

Spevigo® (spesolimab-sbzo) injection

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

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

Formulary Exception Letter: SPEVIGO SC

This type of letter can be used when SPEVIGO SC is not covered on a formulary or if it has an NDC block. While plans may provide forms on their website that can be used to apply for an exception, the template on the following page can provide a comprehensive framework to support the request.

If you use the sample letter template, submit it on your practice letterhead.

Core information:

- If this request is in response to a denial, restate the reason for the denial, which must be provided to you if a prior authorization request is denied. Include the denial reference number and the date of the denial. Be sure to address all reasons given for the denial. An incomplete submission is a common reason for denials
- **Keep in mind that, unless the reviewer has a background in rare dermatologic conditions, he or she may not be familiar with generalized pustular psoriasis (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)[1]
- The sample letter template provides a structure for documenting that the patient meets the eligibility criteria provided in the product label
- 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
- 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[2]: ICD-10 L40.1
  — HCPCS code and modifier[3,4]: J1747-JB
- Provide chart notes or medical records as supporting documentation
- Some plans may require your patient's signature in addition to your own

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.

Click or scan for editable Word documents.

*Verify billing codes before submitting.

HCPCS, Healthcare Common Procedural Coding System; ICD-10, International Classification of Diseases, 10th Revision; NDC, National Drug Code; SC, subcutaneous.

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.** 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 **3.** 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 **4.** Modifiers. Noridian Healthcare Solutions. Updated July 6, 2026. Accessed July 9, 2026. https://med.noridianmedicare.com/web/jfb/topics/modifiers

Spevigo® (spesolimab-sbzo) injection

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

4 Sample

Formulary Exception Request Letter

[Date]
[Health Plan]
[Address]

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

RE: **Formulary Exception Request for Spevigo® (spesolimab-sbzo) for subcutaneous injection**
(ICD-10 L40.1, HCPCS J1747-JB)

To whom it may concern:

My name is [HCP name], [board-certified in specialty, NPI #]. I am writing as the treating physician of [patient name] to request a formulary exception for SPEVIGO SC, which is currently not covered on the formulary of my patient's plan.

Generalized pustular psoriasis (GPP) is a rare, systemic, 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 (primary endpoint).[2,3]

I'd like to bring to your attention a few additional points:

- GPP is recognized as clinically, genetically, and phenotypically distinct from plaque psoriasis. In GPP, the IL-36 pathway plays a central pathogenetic role. Systemic agents, such as acitretin, cyclosporine, and methotrexate, and IL-17/IL-23 biologics that have been included in guidelines for plaque psoriasis, have limited evidence for their use in GPP[4]
- SPEVIGO is FDA-approved to treat GPP[1]
- In a recent comprehensive review of agents used to treat GPP, support for systemics and biologics was assessed as level **C** (Limited research-based evidence) or **D** (No evidence). SPEVIGO is supported by two randomized, controlled trials and was assessed as level **A** (Strong research-based evidence)[4]

SPEVIGO SC is the appropriate treatment for this patient because [insert your rationale].

I have included documentation of the following, consistent with the label requirements for SPEVIGO SC:

- Age (≥12 years) ____ Weight (at least 88 lbs/40 kg): ____
- Patient has been diagnosed with GPP: ( ) Yes ( ) No
- Confirm patient is not experiencing a flare (GPPPGA score of 0 or 1[3]): ( ) 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
- 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.[3] This patient received an IV infusion of SPEVIGO on [date]. May be self-injected or administered by HCP[3] (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. May be self-injected or administered by HCP[3] (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.[2] The [enclosed] prescribing information supports the use of SPEVIGO for the treatment of GPP.[3] SPEVIGO is FDA-approved to treat GPP.[1]

I request that you make SPEVIGO available to my patient. 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, et al. *J Psoriasis Psoriatic Arthritis*. 2025;10(2):58-66. doi:10.1177/24755303251318976 **2.** Morita A, et al. *Lancet*. 2023;402(10412):1541-1551. doi:10.1016/S0140-6736(23)01378-8 **3.** SPEVIGO (spesolimab-sbzo) injection. Prescribing information. LEO Pharma Inc; 2026. **4.** Puig L, et al. *Dermatol Ther (Heidelb)*. 2024;14(9):2331-2378. doi:10.1007/s13555-024-01230-z

Spevigo® (spesolimab-sbzo) injection

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

Patient Narrative: SPEVIGO SC

Consider asking your patient to prepare a letter to the insurer to support the appeal. For SPEVIGO SC, it should describe the impact of generalized pustular psoriasis (GPP) on the patient's life while the patient is not experiencing a flare.

Keep in mind that, unless the reviewer for the appeal has a background in rare dermatologic conditions, he or she may not be familiar with GPP, its severity, and its impact on patients' quality of life — even when they are not experiencing a flare. 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).[1,2]

You can provide your patient with the template on the following page, or simply provide this list of topic suggestions to help get them started.

A patient's letter can support your appeal for the insurer's approval of SPEVIGO SC, which has been shown to reduce the risk of flares due to generalized pustular psoriasis (GPP). Their letter may help health plan reviewers get a better understanding of how GPP impacts your patient's life.

Here are some examples of questions the patient may want to discuss in the letter.

- How long has the patient had GPP? When was the last time the patient experienced a flare? How severe was it?
- What treatments did the patient have?
- Examples of how GPP has affected the patient's life or limited activities?
- Any impact on the patient's ability to sleep?
- Any impact on the patient's mental health?

The patient should be sure to include::

- The name of his or her health plan
- The group number
- The patient's address, date of birth, and phone number

Click or scan for editable Word documents.

HCP, healthcare professional; SC, subcutaneous.

Reference: 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

Spevigo® (spesolimab-sbzo) injection

5 Sample

Patient Letter

[Date]
[Health Plan]
[Address]

[Patient Name]
[Member ID Number, Group Number]
[Date of Birth]

RE: **Request for approval of Spevigo® (spesolimab-sbzo) for subcutaneous injection**

To whom it may concern:

My doctor, [enter name of doctor], has diagnosed me with generalized pustular psoriasis (GPP), a rare, chronic condition, and recommended that I take SPEVIGO SC, which has been shown to reduce the risk of flares.

I was initially diagnosed with GPP after experiencing flares about [how long ago]. While GPP flares are painful, I would like to describe how GPP affects my life even when I'm not experiencing a flare, and why the approval of SPEVIGO SC is so important to me:

[Here are a few areas you can consider including if they are relevant to your experience.]

- [Describe the symptoms of GPP that you experience]
- [Describe how they impact your ability to perform daily activities]
- [Describe how those symptoms affect your ability to work]
- [Describe how those symptoms affect your ability to sleep]

[Include this portion on previous treatments, if relevant]

Treatments that I have tried to control the condition are:

- [First treatment for GPP and why you stopped taking it]
- [Second treatment for GPP and why you stopped taking it]

In conclusion, my doctor has confirmed a diagnosis of GPP. [Include a brief summary of the impact GPP has had on your life.] I'd be grateful if you would cover SPEVIGO SC as requested by my doctor, who can be reached at [insert doctor's phone #].

Sincerely,

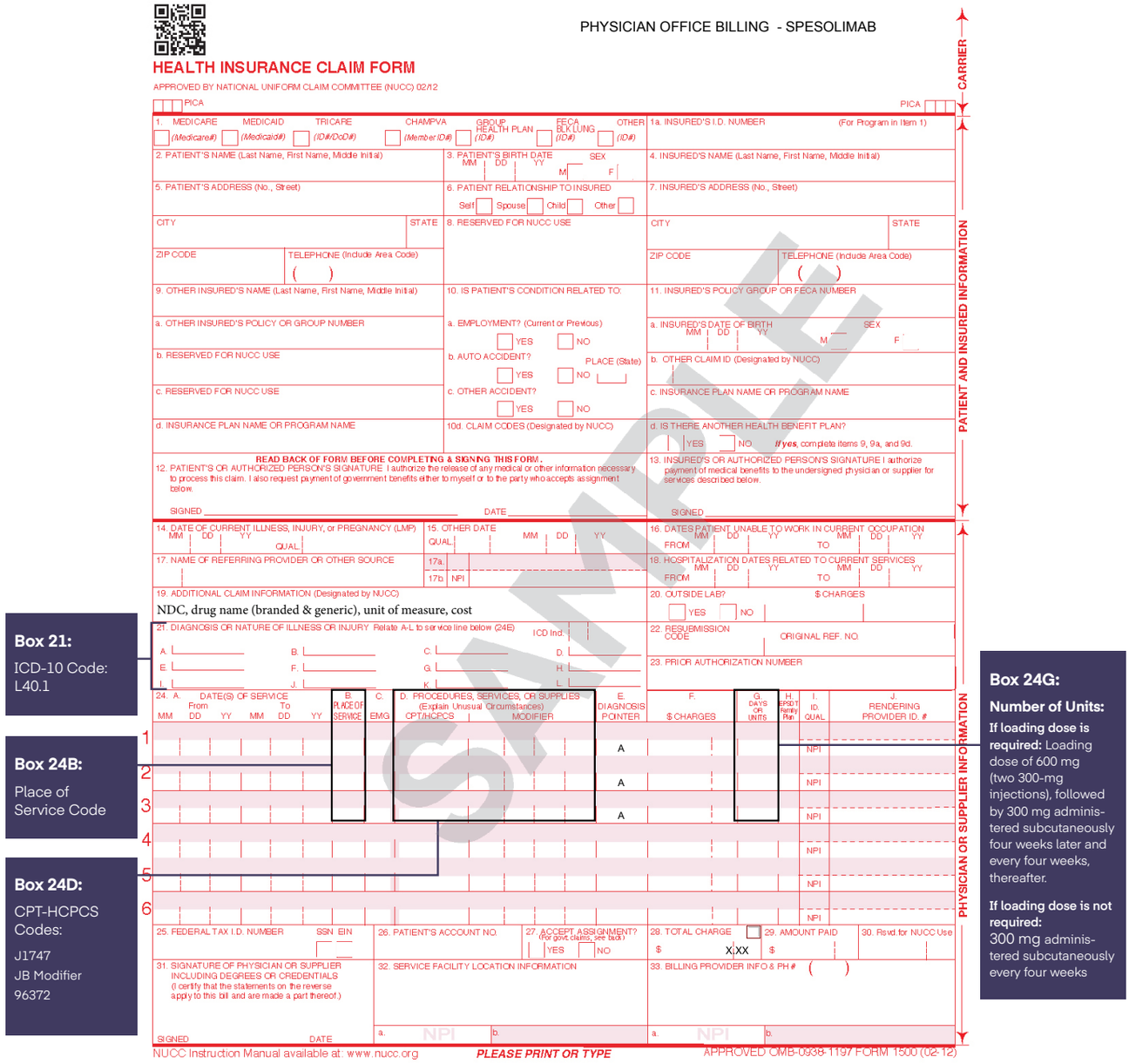
[Your name, signature, and contact information]

Spevigo® (spesolimab-sbzo) injection

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

For use when Spevigo® SC is administered in the physician's office (CMS-1500) Sample form — for educational purposes only

SPEVIGO and the associated services provided in a physician office are billed on the CMS-1500 claim form or its electronic equivalent. A sample CMS-1500 claim form for billing SPEVIGO is provided below.*


PHYSICIAN OFFICE BILLING - SPESOLIMAB

HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code) ( )

ZIP CODE TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? PLACE (State) YES NO

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO If yes, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO MM DD YY

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO MM DD YY

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

NDC, drug name (branded & generic), unit of measure, cost

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. B. C. D. E. F. G. H. I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1						A				NPI	
2						A				NPI	
3						A				NPI	
4										NPI	
5										NPI	
6										NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $ X,XX

29. AMOUNT PAID $

30. Rsvd. for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

SAMPLE

Box 21:
ICD-10 Code:
L40.1

Box 24B:
Place of Service Code

Box 24D:
CPT-HCPCS Codes:
J1747
JB Modifier
96372

Box 24G:
Number of Units:
If loading dose is required: Loading dose of 600 mg (two 300-mg injections), followed by 300 mg administered subcutaneously four weeks later and every four weeks, thereafter.

If loading dose is not required:
300 mg administered subcutaneously every four weeks

*LEO Pharma provides this material for informational purposes only. This material is not an affirmative instruction as to the appropriate code(s) and modifier(s) to use for a particular service, supply, procedure, or treatment. Physicians and providers are responsible for determining and submitting appropriate codes, modifiers, and claims for all services they render and for determining that those services were reasonable and necessary. Actual codes and/or modifiers used are done so at the sole discretion of the treating physician or facility. You should contact your local payer for the most recent and specific coding and coverage guidelines, and reimbursement applicable to you. LEO Pharma makes no guarantee regarding medical benefit coverage or reimbursement from any payer. Information included in this material was obtained from third-party sources and is accurate as of the time of its publication but is subject to change without notice.

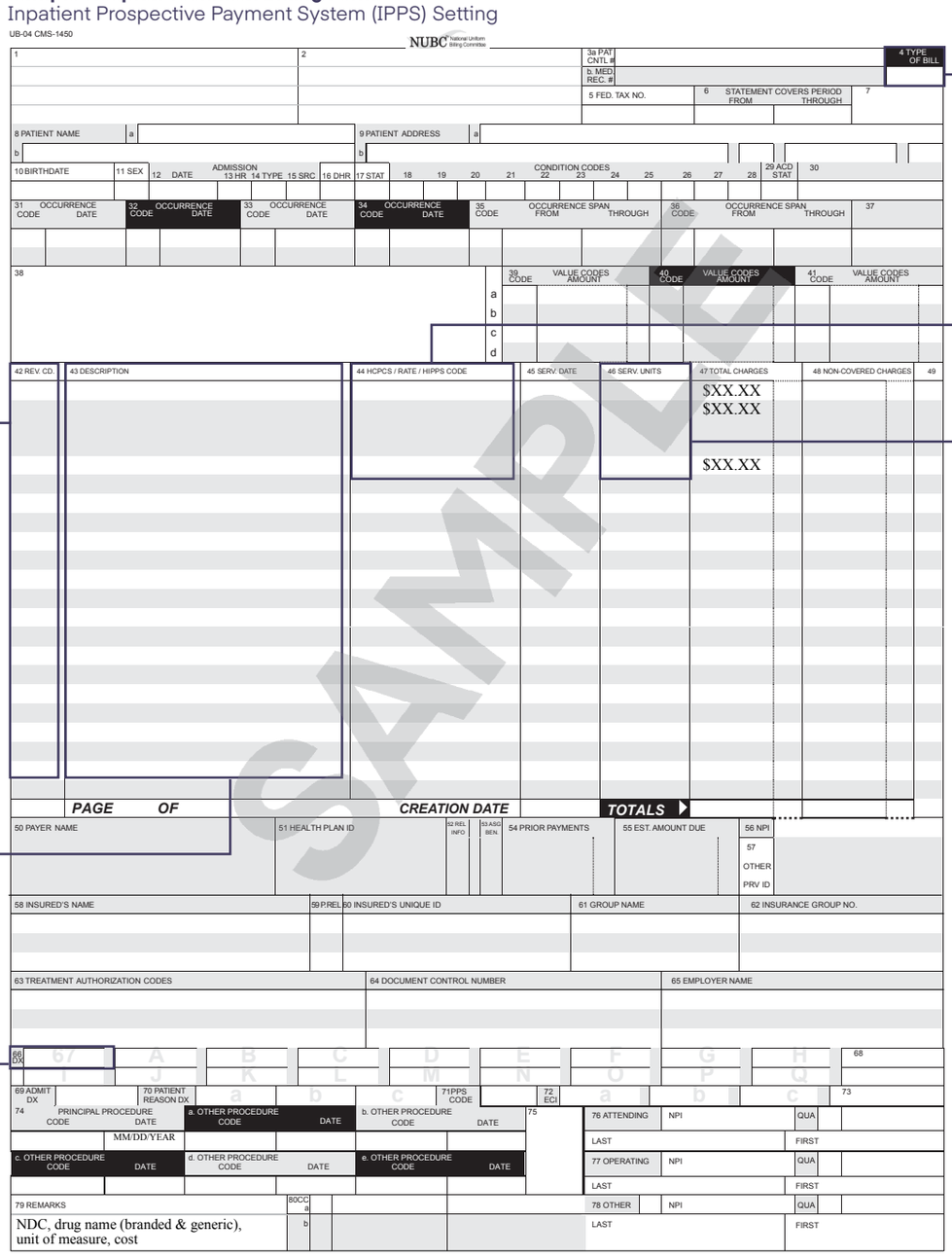
Spevigo® (spesolimab-sbzo) injection

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

For use when Spevigo® SC is administered in a hospital outpatient setting (CMS-1450) Sample form — for educational purposes only

SPEVIGO and the associated services provided in an inpatient setting are billed on the UB-04 claim form or its electronic equivalent. A sample UB-40 claim form for billing SPEVIGO Subcutaneous is provided below.*

Sample Hospital Technical Billing Form:
Inpatient Prospective Payment System (IPPS) Setting



Box 4:
Place of Service

Box 44:
HCPS/CPT Code:
J1747
96372

Box 42:
Revenue Codes
Enter appropriate revenue code for each line item:
0636

Box 46:
Number of Units:
If loading dose is required: Loading dose of 600 mg (two 300-mg injections), followed by 300 mg administered subcutaneously four weeks later and every four weeks, thereafter

If loading dose is not required: 300 mg (two 150-mg injections) administered subcutaneously every four weeks

Box 43:
Enter the description of the revenue code used:
- The administration of a therapeutic, prophylactic or diagnostic drug by subcutaneous or intramuscular injections, and infusions

Box 66:
ICD-10 Code:
L40.1

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Spevigo® (spesolimab-sbzo) injection

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

Spevigo® IV Billing and Coding Guide

Coding for SPEVIGO IV*

Code Type	Code	Description
ICD-10-CM[1]	L40.1	Generalized pustular psoriasis
CPT®[2]	96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
	96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
HCPCS[3]	J1747	Injection, spesolimab-sbzo, 1 mg **Modifier:** Add **JA** to indicate IV administration[4]
Revenue Code[5]	0636 0260	Drugs requiring detailed coding IV therapy: General

These codes are not all-inclusive; appropriate codes can vary by patient, site of care, and payer. Correct coding is the responsibility of the provider submitting the claim for item or service.

Please check with the payer to verify codes and billing requirements. LEO Pharma does not make any representation or guarantee concerning reimbursement or coverage for any service or item.

How Supplied

NDC Code	NDC Descriptor	Dose
00597-0035-10	**1** carton containing **2** single-dose 450-mg/7.5-mL vials	900 mg per IV infusion

*The information provided by LEO Pharma regarding potential billing codes for SPEVIGO is for informational purposes only. It is not intended to constitute advice or be regarded as a substitute for advice. Providers should not rely upon the information as a basis for making any decisions, and LEO Pharma makes no representations or warranties about the completeness, accuracy, reliability, or suitability of the information.

CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedural Coding System; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; IV, intravenous; NDC, National Drug Code.

References: 1. Index to diseases and injuries: psoriasis. Centers for Disease Control and Prevention. National Center for Health Statistics – ICD-10-CM. Accessed August 25, 2026. https://icd10cmtool.cdc.gov/?fy=FY2026&query=generalized%20pustular%20psoriasis **2.** American Medical Association. *CPT 2026 Professional Edition.* 4th ed. American Medical Association; 2025. **3.** Codify by AAPC. Drugs, administered by injection HCPCS code range J0013-J7175. Accessed August 25, 2026. https://www.aapc.com/codes/hcpcs-codes-range/210/370 **4**. Modifiers. Noridian Healthcare Solutions. Updated July 6, 2026. Accessed February 24, 2026. https://med.noridianmedicare.com/web/jfb/topics/modifiers **5.** Revenue codes. Noridian Healthcare Solutions. Updated February 12, 2026. Accessed August 25, 2026. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes

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. 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.

Spevigo® (spesolimab-sbzo) injection

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

Spevigo® SC Billing and Coding Guide

Coding for SPEVIGO SC*

Code Type	Code	Description
ICD-10-CM[1]	L40.1	Generalized pustular psoriasis
CPT®[2]	96372	The administration of a therapeutic, prophylactic, or diagnostic drug by subcutaneous or intramuscular injections, and infusions
HCPCS[3]	J1747	Injection, spesolimab-sbzo, 1 mg **Modifier:** Add **JB** to indicate subcutaneous administration[4]

These codes are not all-inclusive; appropriate codes can vary by patient, site of care, and payer. Correct coding is the responsibility of the provider submitting the claim for item or service.

Please check with the payer to verify codes and billing requirements. LEO Pharma does not make any representation or guarantee concerning reimbursement or coverage for any service or item.

How Supplied

NDC Code	Dose/NDC Descriptor
00597-7705-72	**Loading dose: 1** carton with **2** single-dose, 300-mg/2-mL prefilled syringes
00597-7705-41	**Ongoing dose: 1** carton containing **1** single-dose, 300-mg/2-mL prefilled syringe
00597-0620-20	**Loading dose: 2** cartons with **2** single-dose, 150-mg/mL prefilled syringes **Ongoing dose: 1** carton containing **2** single-dose, 150-mg/mL prefilled syringes

SC dosing: If loading dose is required: Loading dose of 600 mg (four 150-mg injections), followed by 300 mg (two 150-mg injections) administered subcutaneously four weeks later, and every four weeks thereafter.
If loading dose is not required: 300 mg (two 150-mg injections) administered subcutaneously every four weeks

*The information provided by LEO Pharma regarding potential billing codes for SPEVIGO is for informational purposes only. It is not intended to constitute advice or be regarded as a substitute for advice. Providers should not rely upon the information as a basis for making any decisions, and LEO Pharma makes no representations or warranties about the completeness, accuracy, reliability, or suitability of the information.

CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedural Coding System; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; NDC, National Drug Classification; 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 August 25, 2026. https://icd10cmtool.cdc.gov/?fy=FY2026&query=generalized%20pustular%20psoriasis **2.** American Medical Association. *CPT 2026 Professional Edition.* 4th ed. American Medical Association; 2025. **3.** Drugs, administered by injection HCPCS code range J0013-J7175. Codify by AAPC. Accessed August 25, 2026. https://www.aapc.com/codes/hcpcs-codes-range/210/370 **4.** Modifiers. Noridian Healthcare Solutions. Updated July 6, 2026. Accessed August 25, 2026. https://med.noridianmedicare.com/web/jfb/topics/modifiers

IMPORTANT SAFETY INFORMATION (cont'd)

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.

Spevigo® (spesolimab-sbzo) injection

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IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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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.
- **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

- The most common adverse reactions with SPEVIGO when experiencing a flare include asthenia and fatigue, headache, nausea, pruritus and prurigo, infusion site hematoma and bruising, and urinary tract infection.
- The most common adverse reactions with SPEVIGO when not experiencing a flare include injection site reaction, urinary tract infection, arthralgia, and pruritus.

Spevigo® (spesolimab-sbzo) injection

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

For additional resources and enrollment forms, click or scan the QR code, or visit spevigohcp.com

Spevigo®
(spesolimab-sbzo) injection

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

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