Spevigo®
(spesolimab-sbzo) injection

Patient Access Support Kit:

SPEVIGO IV Infusion for patients experiencing a GPP flare

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.

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 IV for patients experiencing a GPP flare

For 12+ years of age and weighing at least 40 kg

SPEVIGO IV for GPP flare treatment

900 mg

If flare symptoms persist, an additional IV dose may be administered 1 week after the initial dose

SPEVIGO SC for ongoing treatment

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.

SPEVIGO SC for patients not experiencing a GPP flare

For 12+ years of age and weighing at least 40 kg

SPEVIGO SC for ongoing treatment when not experiencing a GPP flare

LOADING DOSE‡

600 mg

2 x 300 mg or **4 x 150 mg**
Prefilled syringes

Every 4 weeks§

300 mg

1 x 300 mg or **2 x 150 mg**
Prefilled syringes

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

Monitor patients for hypersensitivity reactions, such as DRESS or 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 using Spevigo® IV to treat patients with GPP flares

Table of contents

Initiation

GPPPGA Scoring

Resources that may help support health plan outcomes

1. Sample Expedited/Urgent Use Letter
2. Sample PA Appeal Letter
3. Sample Letter of Medical Necessity
4. Sample Appeal of a Claims Denial

Sample Medicare Claim Forms

Codes

Important Safety Information (ISI)

Click or scan for editable Word documents.

GPP, generalized pustular psoriasis; GPPPGA, Generalized Pustular Psoriasis Physician Global Assessment; IV, intravenous; 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.

For patients experiencing a GPP flare, consider their entire journey and enroll them in the Spevigo® Patient Support Program at the start

Treatment course is variable after the initial dose

SPEVIGO IV infusion

Additional IV infusion
7 days post initial infusion

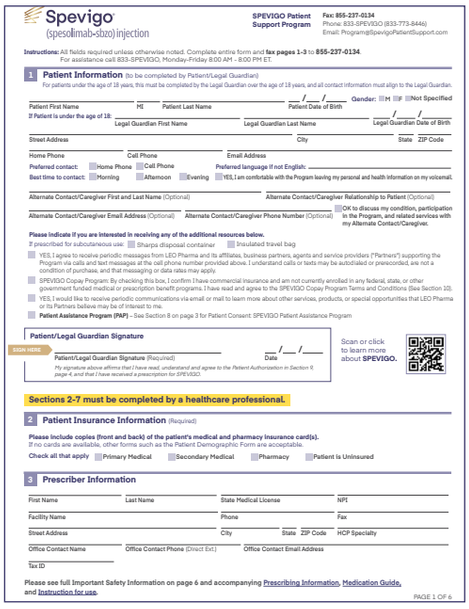
or

SPEVIGO SC
If more than 4 weeks, loading dose (600 mg) will be required.

Ongoing doses:
300 mg every 4 weeks

or no additional treatment

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: ProgramatSpevigoPatientSupport.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‡

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

Scan or click for full Terms, Conditions, and Eligibility Rules

*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 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 reinforce 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.

HCP, healthcare professional; SC, subcutaneous.

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 payor may also require additional information not listed above.

Please contact your FRM for any questions.

IMPORTANT SAFETY INFORMATION (cont'd)
WARNINGS AND PRECAUTIONS (cont'd)
Hypersensitivity and Infusion-Related Reactions, (cont'd):

- 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.

Spevigo® (spesolimab-sbzo) injection

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

Spevigo® IV is usually covered under the medical benefit

Typical criteria for prior authorizations for SPEVIGO IV

Usual formulary criteria is 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
- Indication: Treatment of GPP when patient is experiencing a flare. ICD-10 code: L40.1 Generalized Pustular Psoriasis (GPP)
- Negative tuberculosis (TB) test within the past 12 months
- A GPPPGA score of at least 3 (moderate); plans may also require a pustulation subscore of at least 2 (mild)
- Chart notes or medical record documentation of the presence of fresh pustules (new appearance or worsening of pustules) and affected area[3]
- ≥5% of body surface area covered with erythema and presence of pustules
- Prescribed by a dermatologist or in consultation with a dermatologist[4,5]
- Will not be used concomitantly with another biologic for the treatment of GPP

Additional criteria that may be required

- Chart notes or medical record documentation of all criteria
- May require trial and failure of methotrexate, cyclosporine, acitretin[2]
- May require trial and failure of another dermatologic biologic, such as infliximab, adalimumab, or secukinumab[6]
- Additional diagnostic criteria (eg, genetic test results, laboratory results, biopsy results)[3]
- May require justification for administration in a hospital or hospital outpatient setting[3]

Quantity limit

- Initial approval: up to two 900-mg doses
- Subsequent approvals may be treated as initial approvals

*GPPPGA, Generalized Pustular Psoriasis Physician Global Assessment; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification.

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 1, 2026. https://www.bcbsm.com/amslibs/content/dam/public/mpr/mprsearch/pdf/2167376.pdf **3.** Spesolimab-sbzo (Spevigo). Clinical policy bulletins; Medical clinical policy bulletins. April 2, 2026. Accessed August 1, 2026. https://www.aetna.com/cpb/medical/data/1000_1099/1013.html **4.** Prior Authorization policy: Spevigo. Cigna Healthcare. May 13, 2026. Accessed August 1, 2026. https://static.cigna.com/assets/chcp/pdf/coveragePolicies/cnf/cnf_856_coveragepositioncriteria_inflammatory_conditions_spevigo_subcutaneous_pa.pdf **5.** Spesolimab-sbzo (Spevigo). April 3, 2024. BlueSheld California. Accessed August 1, 2026. https://www.blueshieldca.com/content/dam/bsca/en/provider/docs/2024/March/PRV_MP_Spesolimab-sbzo_Spevigo_MCAL.pdf **6.** Spesolimab-sbzo (Spevigo) Updated prior authorization criteria. Kaiser Permanente. March 31, 2025. Accessed August 1, 2026. https://wa-provider.kaiserpermanente.org/static/pdf/provider/communications/letters/20250331-spevigo-criteria.pdf

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Hypersensitivity and Infusion-Related Reactions, (cont'd):

- 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.

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

- [ ] **Health plan may request that you use the PA forms they have available on their website**
- [ ] **Clearly specify the formulation: SPEVIGO IV or SPEVIGO SC**
- [ ] **Clearly specify if your request is "Expedited/Urgent"** meaning that a delay in authorization could seriously jeopardize the patient's life or overall health
- [ ] **Provide images of the patient's medical and pharmacy prescription cards** (Front and back)
- [ ] **Indicate the individual provider ID number**
  versus 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.
- [ ] **Include GPP severity score**
  (See GPPPGA scoring tool on next page.) For IV, a GPPPGA score of at least 3 (moderate); a pustulation sub-score of at least 2 (mild) may also be required
- [ ] **Include chart notes or medical records documenting** the disease severity, treatment history (if applicable), date of diagnosis, and presence of fresh pustules (new appearance or worsening of pustules) and affected area. Include hospital admission or emergency department notes, if applicable
- [ ] **Consider including a photo** of the affected area, labeled "Clinical photograph taken [date], showing primary sterile pustules on erythematous nonplaque skin, consistent with active GPP flare."*
- [ ] **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
- [ ] **Provide correct coding information:**
  Diagnosis code: **L40.1** Generalized pustular psoriasis
  HCPCS code: **J1747** Spesolimab-sbzo, 1 mg **Modifier:** Add **JA** to indicate IV administration
- [ ] **Site of care:** Some plans may limit the site of administration to non-hospital settings or request an explanation for why that setting is required
- [ ] **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.

Spevigo® (spesolimab-sbzo) injection

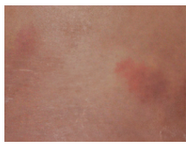
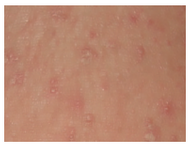
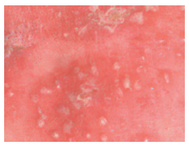
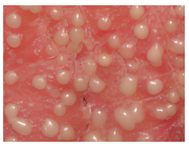
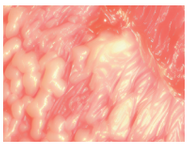
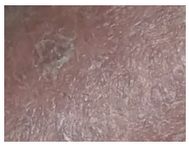
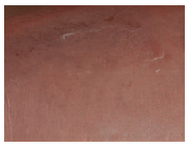
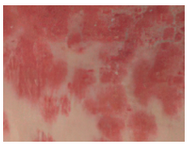
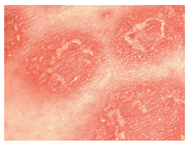
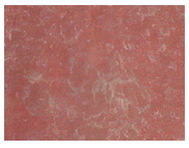
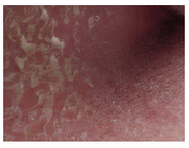
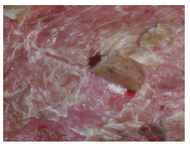
Please see Important Safety Information throughout and accompanying full Prescribing Information.

Most PA criteria for Spevigo® (spesolimab-sbzo) injection IV 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

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

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

TOTAL ≥3 A GPPPGA total score of ≥3 + The presence of fresh pustules + SUBSCORE ≥2 A GPPPGA pustulation subscore of ≥2 + 5% or greater body surface area (BSA) affected

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, patient must be afebrile in addition to the skin presentation requirements.[3]

Reference: 1. Burden AD, Bachelez H, Choon SE, et al. The Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) 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

All images © 2026 LEO Pharma Inc. All rights reserved.

Spevigo® (spesolimab-sbzo) injection

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

Sample letter templates

An opportunity to change outcomes

1. Expedited/Urgent Use Letter
2. PA Appeal Letter
3. Letter of Medical Necessity
4. Appeal of a Claims Denial

Click or scan for editable Word documents.

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.

Suggestions and checklist for submission

Expedited / Urgent Prior Authorization Letter

Most payers, whether regulated by CMS, individual states, or ERISA, have provided similar guidance for use of urgent or expedited authorization requests.[1,2] By specifying "Expedited/Urgent," you are certifying that the plan's standard review time may seriously jeopardize the life or health of the patient.[3] While response times differ by plan type, CMS-impacted plans, such as Medicare Advantage plans and Medicaid plans, must respond to expedited/urgent requests within 72 hours and to standard requests within 7 days.[1] State-regulated and ERISA-regulated plans may have a similar or shorter timeframe.[2]

Important:

- Some plans require that appeals be submitted using their own form, in which case, there should be a check box on the form to specify "Expedited/Urgent" request
- When submitting an urgent/expedited request, it is essential that the submission be complete — it must address and provide documentation for each of the criteria specified in their prior authorization and step edit requirements. An incomplete submission is likely to be denied
- When using a form provided by the plan, it should be accompanied by a Letter of Medical Necessity. If you use the letter template on the next page, that template includes fields that should address the criteria required by most plans, but be sure to consult individual plan requirements. Your letter should be submitted on the letterhead of your practice
- As part of the submission, you should explicitly certify that a delay due to the standard review times may seriously jeopardize the life or health of the patient
- **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] Including statements of support from the 2023 National Psoriasis Foundation Consensus Statement,[5] which are included in the letter template, may be helpful

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.

CMS, Centers for Medicare & Medicaid Services; ERISA, Employee Retirement Income Security Act.

References: 1. CMS Finalizes rule to expand access to health information and improve the prior authorization process. CMS.gov. January 17, 2024. Accessed July 10, 2026. www.cms.gov/newsroom/press-releases/cms-finalizes-rule-expand-access-health-information-improve-prior-authorization-process **2.** Cornell Law School Legal Information Institute. 29 CFR § 2590.715-2719 – Internal claims and appeals and external review processes. Accessed July 16, 2026. https://www.law.cornell.edu/cfr/text/29/2590.715-2719 **3.** Important Molina provider news: prior authorization requests—urgent vs. non-urgent. Molinahealthcare.com. Accessed July 10, 2026. https://www.molinahealthcare.com/-/media/Molina/PublicWebsite/PDF/Providers/tx/medicaid/forms/04-25-MHTX-PROV-AUTH-URGENT-VS-NON-URGENT-508.ashx **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 **5.** Armstrong AW, Elston CA, Elewski BE, et al. Generalized pustular psoriasis: a consensus statement from the National Psoriasis Foundation. *J Am Acad Dermatol*. 2024;90(4):727-730. doi:10.1016/j.jaad.2023.09.080

Spevigo® (spesolimab-sbzo) injection

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

1 **Sample**

Expedited / Urgent Prior Authorization Letter

[Date]
[Medical Director]
[Health Plan]
[Address]

[Patient Name]
[Member ID Number, Group Number]
[DOB]

RE: **EXPEDITED/URGENT authorization for Spevigo® (spesolimab-sbzo) vials for IV use**
(ICD-10 L40.1, HCPCS J1747-JA)

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 [name of the hospital system.]

My patient is currently an [inpatient] [outpatient] experiencing a generalized pustular psoriasis (GPP) flare (ICD-10 L40.1). A delay in authorization of the requested service could seriously jeopardize the patient's life or overall health. Date of onset: [date]. GPP is a rare condition characterized by painful pustules, along with systemic symptoms such as fever.[1,2] Disease flares are unpredictable and can progress into life-threatening complications, including cardiorespiratory failure, renal failure, hepatic failure, and/or sepsis.[1,3] SPEVIGO is FDA-approved for the treatment of GPP.[1]

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

- Age (≥12 years) _____ Weight (at least 88 lbs / 40 kg): _____
- GPPPGA score (≥3)[4]: _____ Pustulation subscore (≥2), where required: _____
- % BSA with erythema and fresh pustules (≥5%)[2]: _____
- Negative TB test within the past 12 months: ( ) Yes ( ) No
- Presence of primary, sterile, macroscopically visible pustules on erythematous base, not arising within psoriatic plaques[2]: ( ) Yes ( ) No
- [Photo of affected area, if appropriate]
- Systemic symptoms (if applicable): [Describe]
- Lab abnormalities (if applicable): [Describe]
- Prior therapies (if applicable): [List agents, with dates and reasons for discontinuation]

Dose requested: 1 dose of 900 mg by IV infusion (two 450-mg/7.5-mL vials); authorization for a second dose one week after the initial dose if flare symptoms persist.[4] (HCPCS J1747-JA)

Site of service: ☐ Hospital-affiliated outpatient or infusion center (IC) ☐ Non-hospital-affiliated IC ☐ Group practice ☐ Home infusion ☐ Other _____ (If hospital-affiliated, provide justification.)

The [enclosed] prescribing information supports the use of SPEVIGO for the treatment of GPP flares in this patient. 54% of patients on SPEVIGO in the Effisayil® 1 trial achieved rapid and complete pustular clearance at week 1.[4,5]

This expedited request is further supported by the 2023 National Psoriasis Foundation Consensus Statement, which notes that SPEVIGO is the first FDA-approved "*treatment that is highly effective in the treatment of GPP flares in adults,*" stating that, "*Timely access to approved therapies is critical to reducing morbidity and mortality in patients presenting with GPP.*" [6]

I attest that, in my clinical judgment, this request meets the criteria for expedited/urgent review as described above. 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]

References: 1. Elewski B, et al. *J Psoriasis Psoriatic Arthritis*. 2025;10(2):58-66. doi:10.1177/24755303251318976 **2.** Bachelez H, et al. *N Engl J Med*. 2021;385(26):2431-2440. doi:10.1056/NEJMoa2111563 **3.** Crowley JJ, et al. *Postgrad Med*. 2021;133(3):330-334. doi:10.1080/00325481.2020.1831315 **4.** SPEVIGO (spesolimab-sbzo) injection. Prescribing information. LEO Pharma Inc; 2026. **5.** Elewski BE, et al. *J Am Acad Dermatol*. 2023;89(1):36-44. doi:10.1016/j.jaad.2023.02.040 **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) injection:

Prior Authorization Denial Appeal Letter: SPEVIGO IV

If a prior authorization (PA) request for SPEVIGO IV 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 letter template on the following page, submit it on your practice letterhead. Some plans 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
- It is essential that the submission be complete. It must address and provide documentation for each of the criteria listed in the prior authorization and step edit requirements. An incomplete submission is a common reason for denials
- If you are submitting an appeal using a form provided by the health plan, it should be accompanied by a Letter of Medical Necessity
- If you use the sample letter template on the next page, that template includes fields that encompass the criteria required by most plans, but it's important to verify individual plan requirements
- When a plan issues a denial, it will describe their process for appealing their decision. There may be 2 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 IV:
  - — Diagnosis code[1]: ICD-10 L40.1
  - — HCPCS code and modifier[2,3]: J1747-JA
- 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] Including statements of support from the 2023 National Psoriasis Foundation Consensus Statement,[5] which are included in the letter template, may be helpful
- 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.

HCPCS, Healthcare Common Procedural Coding System; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; IV, intravenous.

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 **5.** Armstrong AW, Elston CA, Elewski BE, et al. Generalized pustular psoriasis: a consensus statement from the National Psoriasis Foundation. *J Am Acad Dermatol*. 2024;90(4):727-730. doi:10.1016/j.jaad.2023.09.080

Spevigo® (spesolimab-sbzo) injection

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

2 Sample

PA Denial Appeal Letter

[Date]
[Medical Director]
[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) vials for IV use** (ICD-10 L40.1, HCPCS J1747-JA)

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 [name of the hospital system.]

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

[If this is an appeal of a 2nd or 3rd denial, include a copy of the letter, restate the reason given for the denial, and describe why SPEVIGO IV is the appropriate treatment.]

My patient is currently experiencing a generalized pustular psoriasis (GPP) flare (ICD-10 L40.1). Date of onset: [date]. GPP is a rare condition characterized by painful pustules, along with systemic symptoms such as fever.[1,2] SPEVIGO is an FDA-approved medication for the treatment of GPP flares.[1]

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

- Age (≥12 years) _____ Weight (at least 88 lbs / 40 kg): _____
- GPPPGA score[3] (≥3): _____ Pustulation subscore (≥2) where required: _____
- % BSA with erythema and fresh pustules (≥5%)[2]: _____
- Negative TB test within the past 12 months: ( ) Yes ( ) No
- Presence of primary, sterile, macroscopically visible pustules on erythematous base, not arising within psoriatic plaques[2]: ( ) Yes ( ) No
- [Photo of affected area, if appropriate]
- Systemic symptoms (if applicable): [Describe]
- Lab abnormalities (if applicable): [Describe]
- Prior therapies (if applicable): [List agents, with dates and reasons for discontinuation]

Dose requested: 1 dose of 900 mg by IV infusion (two 450-mg/7.5-mL vials); authorization for a second dose one week after the initial dose if flare symptoms persist.[3] (HCPCS J1747-JA)

Site of service: ☐ Hospital-affiliated outpatient or infusion center (IC) ☐ Non-hospital-affiliated IC ☐ Group practice ☐ Home infusion ☐ Other _____ (If hospital-affiliated, provide justification.)

The [enclosed] prescribing information supports the use of SPEVIGO for the treatment of GPP flares in this patient. 54% of patients on SPEVIGO in the Effisayil® 1 trial achieved rapid and complete pustular clearance at week 1.[3,4]

This appeal is further supported by the 2023 National Psoriasis Foundation Consensus Statement, which notes that, "*GPP is a life-threatening disease that needs to be treated as quickly as possible*." It further states that SPEVIGO is the first FDA-approved "*treatment that is highly effective in the treatment of GPP flares in adults*," emphasizing that, "*Timely access to approved therapies is critical to reducing morbidity and mortality in patients presenting with 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]

References: 1. Elewski B, et al. *J Psoriasis Psoriatic Arthritis*. 2025;10(2):58-66. doi:10.1177/24755303251318976 **2.** Bachelez H, et al. *N Engl J Med*. 2021;385(26):2431-2440.doi:10.1056/NEJMoa2111563 **3.** SPEVIGO (spesolimab-sbzo) injection. Prescribing information. LEO Pharma Inc; 2026. **4.** Elewski BE, et al. *J Am Acad Dermatol*. 2023;89(1):36-44. doi:10.1016/j.jaad.2023.02.040 **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) injection

Letter of Medical Necessity: SPEVIGO IV

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

Core information:

- 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 IV:
  - — Diagnosis code[1]: ICD-10 L40.1
  - — HCPCS code and modifier[2,3]: J1747-JA
- Provide comprehensive support for the diagnosis. Clearly establish the generalized pustular psoriasis (GPP) diagnosis as distinct from psoriasis
- Document that all requirements for prior authorization and step therapy have been met, or explain why they are not appropriate for the patient

Suggestions:

- Confirm the specific criteria required by the plan. While the requirements of most plans are consistent with the SPEVIGO Prescribing Information, some are more restrictive
- It is essential that the submission be complete — it should address and provide documentation for each of the criteria specified in the plan's prior authorization and step edit requirements. Incomplete submissions are a common reason for denials
- If requesting an expedited approval, clearly label "EXPEDITED/URGENT REQUEST"
- 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
- Include hospital admission or emergency department notes, if applicable
- **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.[4] Including statements of support from the 2023 National Psoriasis Foundation Consensus Statement,[5] which are included in the letter template, may be helpful

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.

HCPCS, Healthcare Common Procedural Coding System; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; IV, intravenous; NPI, National Provider Identifier.

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 **5.** Armstrong AW, Elston CA, Elewski BE, et al. Generalized pustular psoriasis: a consensus statement from the National Psoriasis Foundation. *J Am Acad Dermatol*. 2024;90(4):727-730. doi:10.1016/j.jaad.2023.09.080

Spevigo® (spesolimab-sbzo) injection

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

3 Sample

Letter of Medical Necessity

[Date]
[Medical Director]
[Health Plan]
[Address]

[Patient Name]
[Member ID Number, Group Number]
[DOB]

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

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 [name of the hospital system.]

In my clinical judgment, SPEVIGO IV is the appropriate therapy for this patient, who is currently experiencing a generalized pustular psoriasis (GPP) flare (ICD-10 L40.1). Date of onset: [date]. GPP is a rare, potentially life-threatening condition characterized by painful pustules, along with systemic symptoms such as fever.[1,2] SPEVIGO is an FDA-approved medication for the treatment of GPP flares.[1]

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

- Age (≥12 years) _____ Weight (at least 88 lbs / 40 kg): _____
- GPPPGA score3 (≥3): _____ Pustulation subscore (≥2) where required: _____
- % BSA with erythema and fresh pustules (≥5%)[2]: _____
- Negative TB test within the past 12 months: ( ) Yes ( ) No
- Presence of primary, sterile, macroscopically visible pustules on erythematous base, not arising within psoriatic plaques[2]:
  ( ) Yes ( ) No
- [Photo of affected area, if appropriate]
- Systemic symptoms (if applicable): [Describe]
- Lab abnormalities (if applicable): [Describe]
- Prior therapies (if applicable): [List agents, with dates and reasons for discontinuation]
- Other support for GPP diagnosis: [Describe]

Dose requested: 1 dose of 900 mg by IV infusion (two 450-mg/7.5-mL vials); authorization for a second dose one week after the initial dose if flare symptoms persist.[3] (HCPCS J1747-JA)

Site of service: ☐ Hospital-affiliated outpatient or infusion center (IC) ☐ Non-hospital-affiliated IC ☐ Group practice ☐ Home infusion ☐ Other _____ (If hospital-affiliated, provide justification.)

This statement of medical necessity is further supported by the 2023 National Psoriasis Foundation Consensus Statement, which notes that, "*GPP is a life-threatening disease that needs to be treated as quickly as possible.*" It further states that SPEVIGO is the first FDA-approved "*treatment that is highly effective in the treatment of GPP flares in adults*," emphasizing that, "*Timely access to approved therapies is critical to reducing morbidity and mortality in patients presenting with GPP.*" [4]

In conclusion, [patient name] has a confirmed diagnosis of GPP flares with an unpredictable clinical course associated with numerous complications. 54% of patients on SPEVIGO in the Effisayil® 1 trial achieved rapid and complete pustular clearance at week 1.[3,5]

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]

References: 1. Elewski B, et al. *J Psoriasis Psoriatic Arthritis*. 2025;10(2):58-66. doi:10.1177/24755303251318976 **2.** Bachelez H, et al. *N Engl J Med*. 2021;385(26):2431-2440. doi:10.1056/NEJMoa2111563 **3.** SPEVIGO (spesolimab-sbzo) injection. Prescribing information. LEO Pharma Inc; 2026. **4.** Armstrong AW, et al. *J Am Acad Dermatol*. 2024;90(4):727-730. doi:10.1016/j.jaad.2023.09.080. **5.** Elewski BE, et al. *J Am Acad Dermatol*. 2023;89(1):36-44. doi:10.1016/j.jaad.2023.02.040

Spevigo® (spesolimab-sbzo) injection

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

Appeal of a Claims Denial

Consider using this letter if reimbursement for a claim is underpaid or denied. If using the templated letter on the next page, submit the letter on your letterhead.

Common reasons for denials[1]:

- **Treatment is deemed not medically necessary or documentation is incomplete:** Provide your rationale; consider quoting from the 2023 National Psoriasis Foundation Consensus Statement[2]
- **Prior authorization was not obtained or improperly documented:** Consider disputing with the authorization number, or, if emergent, why it qualifies as an emergency service
- **Incorrect units:** Check billed units with NDC quantity (J1747 is billed per 1 mg; 900-mg dose = 900 units)
- **Incomplete claim information, such as incorrect or missing codes:**
  - Diagnosis code[3]: ICD-10 L40.1
  - HCPCS code and modifier[4,5]: J1747-JA

Reminder:

- Pay attention to timelines for appeal, which should be provided on the EOB

Click or scan for editable Word documents.

EOB, explanation of benefits; 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. Real reasons behind claim denials in medical billing. OneMed Billing. Updated February 24, 2026. Accessed July 10, 2026. https://www.onemedbilling.com/blog-details/claim-denials-in-medical-billing **2.** Armstrong AW, Elston CA, Elewski BE, et al. Generalized pustular psoriasis: a consensus statement from the National Psoriasis Foundation. *J Am Acad Dermatol.* 2024;90(4):727-730. doi:10.1016/j.jaad.2023.09.080 **3.** 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 **4.** 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 **5.** 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**

Appeal of a Claims Denial

[Date]
[Medical Director]
[Health Plan]
[Address]

[Patient Name]
[Member ID Number, Group Number]
[DOB]
[Date of Service]

RE: **APPEAL OF [DENIED/UNDERPAID] CLAIM: Spevigo® (spesolimab-sbzo) vials for IV use**
(ICD-10 L40.1, HCPCS J1747-JA)
[Claim number from the EOB or remittance advice]

To whom it may concern:

I am writing to request reconsideration of coverage for SPEVIGO IV, which was administered on [date of service]. Reimbursement was [denied] [underpaid] because [state reason given in denial letter — quote exact description].

Dose administered: [# of doses] of 900 mg by IV infusion (two 450-mg/7.5-mL vials (HCPCS J1747-JA)

Billed amount: [enter amount] **Paid amount**: [enter amount]

Provider identification: [Billing provider name, NPI, Tax ID]
[Administering facility name (if different), NPI]
Contact name:_____ Phone:_____ Fax:_____

[Describe why the denial is incorrect.]

If prior authorization (PA) was approved:
Date PA was approved _____ PA # issued by the plan _____
Authorized dose and number of doses _____
Confirmation that the drug was administered as authorized _____

The following criteria were met at the time of service:

- ☐ GPP diagnosis (ICD-10 L40.1) ☐ Age (≥12 years) ☐ Weight (at least 88 lbs/40 kg)
- ☐ GPPPGA score (≥3) ☐ Pustulation subscore (≥2) (where required)
- ☐ % BSA with erythema and fresh pustules (≥5%): _____
- ☐ Negative TB test within the past 12 months
- ☐ Presence of primary, sterile, macroscopically visible pustules on erythematous base, not arising within psoriatic plaques
- ☐ Systemic symptoms (if applicable): [Describe]
- ☐ Lab abnormalities (if applicable): [Describe]

Site of service: ☐ Hospital-affiliated outpatient or infusion center (IC) ☐ Non-hospital-affiliated IC ☐ Group practice ☐ Home infusion ☐ Other _____ (If hospital-affiliated, provide justification.)

Coding and billing documentation: ☐ HCPCS J1747-JA: Injection, spesolimab-sbzo, 1 mg, 900 units ☐ A second dose one week after the initial dose ☐ Revenue code provided, if applicable: _____

Generalized pustular psoriasis (GPP) is a rare, potentially life-threatening condition characterized by painful pustules, along with systemic symptoms such as fever.[1,2] SPEVIGO is FDA-approved for the treatment of GPP flares.[1] The [enclosed] prescribing information supports the use of SPEVIGO for the treatment of GPP flares in this patient. 54% of patients on SPEVIGO in the Effisayil® 1 trial achieved rapid and complete pustular clearance at week 1.[3,4]

According to the 2023 National Psoriasis Foundation Consensus Statement, "*GPP is a life-threatening disease that needs to be treated as quickly as possible.*" It further states that SPEVIGO is the first FDA-approved "*treatment that is highly effective in the treatment of GPP flares in adults,*" emphasizing that, "*Timely access to approved therapies is critical to reducing morbidity and mortality in patients presenting with GPP.*" [5]

We request that [plan name] reverse the denial of claim [number] and remit payment of [amount].

Sincerely,

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

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

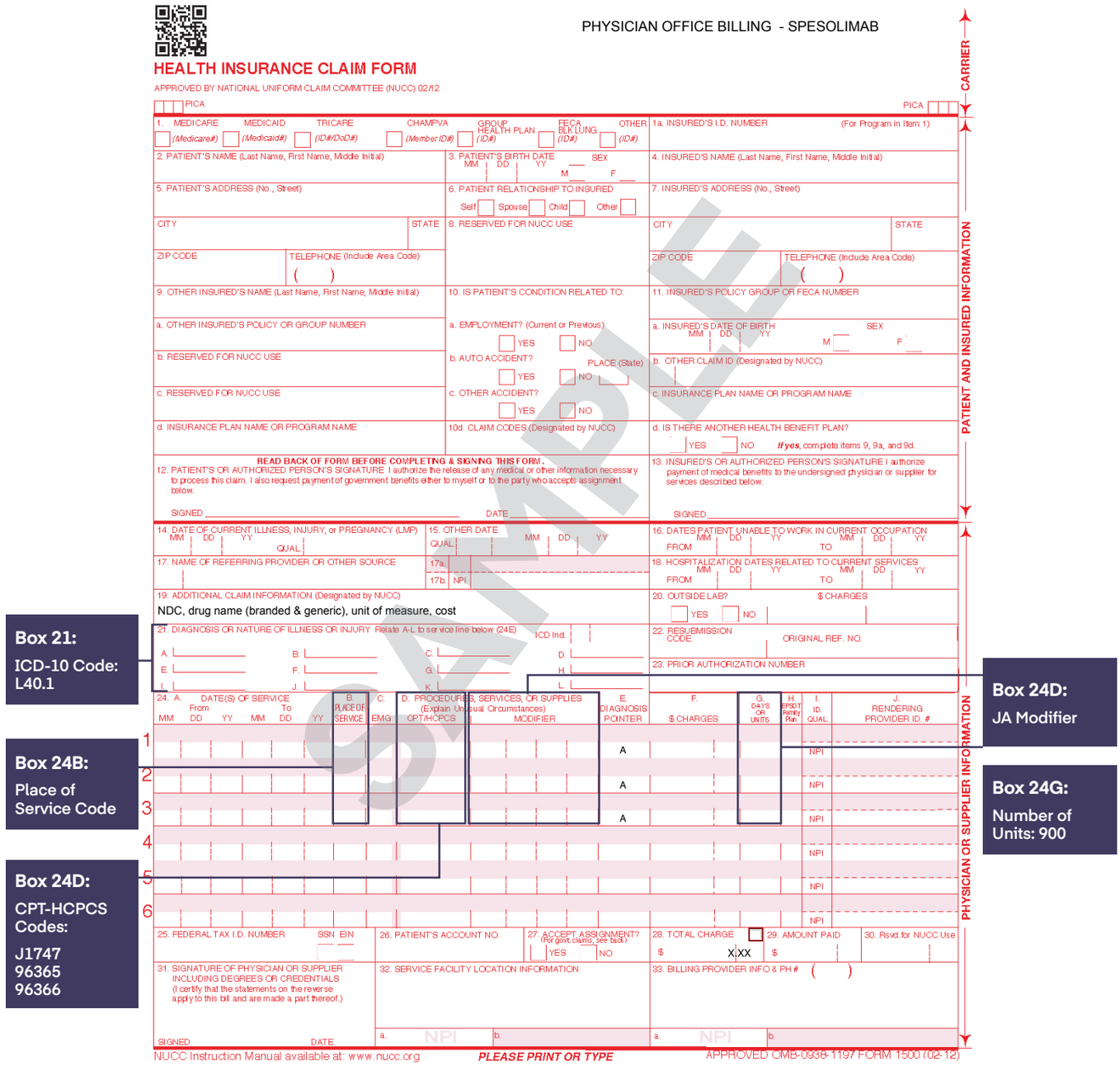
References: **1.** Elewski B, et al. *J Psoriasis Psoriatic Arthritis.* 2025;10(2):58-66. doi:10.1177/24755303251318976 **2.** Bachelez H, et al. *N Engl J Med.* 2021;385(26):2431-2440. doi:10.1056/NEJMoa2111563 **3.** SPEVIGO (spesolimab-sbzo) injection. Prescribing information. LEO Pharma Inc; 2026. **4.** Elewski BE, et al. *J Am Acad Dermatol.* 2023;89(1):36-44. doi:10.1016/j.jaad.2023.02.040 **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

For use when Spevigo® IV 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.*



*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 payor 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 payor. 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.

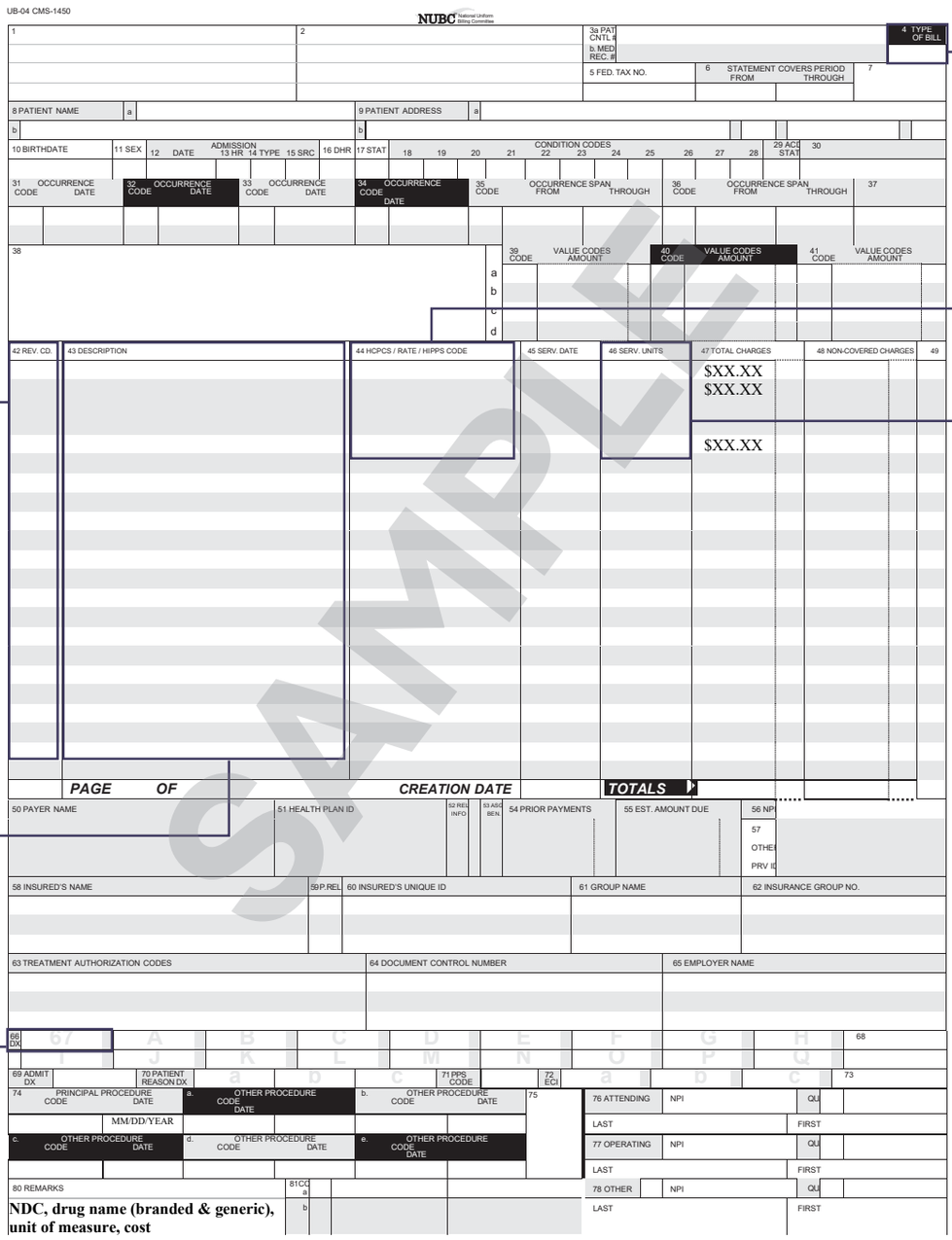
Spevigo®
(spesolimab-sbzo) injection

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

For use when Spevigo® IV is administered in an inpatient 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-04 claim form for billing SPEVIGO 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
96365
96366

Box 46:
Number of Units: 900

Box 42:
Revenue Codes
Enter appropriate revenue code for each line item:
0636
0260

Box 43:
Enter the description of the revenue code used:
- Spesolimab
- Intravenous infusion, for therapy, prophylaxis, or diagnosis; initial, up to 1 hour
- Each additional hour

Box 66:
ICD-10 Code:
L40.1

*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 payor 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 payor. 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.

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	Strength
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.

References: 1. National Center for Health Statistics – ICD-10-CM. Index to Diseases and Injuries. Accessed February 24, 2026. https://icd10cmtool.cdc.gov/?fy=FY2026&query=generalized%20pustular%20psoriasis **2.** CPT 2026 Professional Edition. American Medical Association. 4th Edition, Revised 2025. Chicago, ILL. **3.** Codify by AAPC. Drugs, administered by injection HCPCS Code range J0013-J7175. Accessed February 24, 2026. https://www.aapc.com/codes/hcpcs-codes-range/210/370 **4.** Noridian Healthcare Solutions. Modifiers. Accessed February 24, 2026. https://med.noridianmedicare.com/web/jfb/topics/modifiers **5.** Revenue codes. Accessed February 24, 2026. Noridian Healthcare Solutions. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

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

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	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 syringe

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; SC, subcutaneous.

References: 1. National Center for Health Statistics — ICD-10-CM. Accessed February 24, 2026. https://icd10cmtool.cdc.gov/?fy=FY2026&query=generalized%20pustular%20psoriasis **2.** *CPT 2026 Professional Edition.* American Medical Association. 4th Edition, Revised 2025;2026. **3.** Drugs, administered by injection HCPCS code range J0013-J7175. Codify by AAPC. Accessed February 24, 2026. https://www.aapc.com/codes/hcpcs-codes-range/210/370 **4.** Modifiers. Noridian Healthcare Solutions. Accessed February 24, 2026. https://med.noridianmedicare.com/web/jfb/topics/modifiers

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

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%).

Spevigo® (spesolimab-sbzo) injection

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

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

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

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

Hypersensitivity and Infusion-Related Reactions:

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

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

ADVERSE REACTIONS

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

Specific Adverse Reactions

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

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

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

Continued

Spevigo® (spesolimab-sbzo) injection

IMPORTANT SAFETY INFORMATION (Cont'd)
ADVERSE REACTIONS (Cont'd)

Clinical Development of Spesolimab-sbzo

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

SPECIFIC POPULATIONS

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

Spevigo® (spesolimab-sbzo) injection

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.

The LEO Pharma logo and Spevigo® are registered trademarks of LEO Pharma A/S.
Other trademarks are the property of their respective owners.
© 2026 LEO Pharma Inc. All rights reserved.

October 2026 MAT-99288