


# PHYSICIAN OFFICE (CMS-1500) SPEVIGO Subcutaneous Injection

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

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

<input type="checkbox"/> PICA		PICA <input type="checkbox"/>	
1. MEDICARE <input type="checkbox"/> MEDICAID <input type="checkbox"/> TRICARE <input type="checkbox"/> CHAMPVA <input type="checkbox"/> GROUP HEALTH PLAN <input type="checkbox"/> FECA BLK (LUNG) <input type="checkbox"/> OTHER <input type="checkbox"/>		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 <input type="checkbox"/> F <input type="checkbox"/>	
5. PATIENT'S ADDRESS (No., Street)		6. PATIENT RELATIONSHIP TO INSURED Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>	
CITY STATE		7. INSURED'S ADDRESS (No., Street)	
ZIP CODE TELEPHONE (Include Area Code)		8. RESERVED FOR NUCC USE CITY STATE	
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)		10. IS PATIENT'S CONDITION RELATED TO:	
a. OTHER INSURED'S POLICY OR GROUP NUMBER		a. EMPLOYMENT? (Current or Previous) YES <input type="checkbox"/> NO <input type="checkbox"/>	
b. RESERVED FOR NUCC USE		b. AUTO ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/> PLACE (State)	
c. RESERVED FOR NUCC USE		c. OTHER ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/>	
d. INSURANCE PLAN NAME OR PROGRAM NAME		10d. CLAIM CODES (Designated by NUCC)	
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.		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 _____ DATE _____		SIGNED _____ DATE _____	
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL		15. OTHER DATE MM DD YY QUAL	
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE		18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY	
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) NDC, drug name (branded & generic), unit of measure, cost		20. OUTSIDE LAB? YES <input type="checkbox"/> NO <input type="checkbox"/> \$ CHARGES	
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY. Relate A-L to service line below (24E) ICD-10 Code		22. RESUBMISSION CODE ORIGINAL REF. NO	
A. _____ B. _____ C. _____ D. _____		23. PRIOR AUTHORIZATION NUMBER	
E. _____ F. _____ G. _____ H. _____			
I. _____ J. _____ K. _____ L. _____			
24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY		F. \$ CHARGES	
B. PLACE OF SERVICE		G. DAYS OR UNITS	
C. EMG		H. PSOT Party Plan	
D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CRT/HCPCS MODIFIER		I. ID. QUAL	
E. DIAGNOSIS POINTER		J. RENDERING PROVIDER ID. #	
1		A	
2		A	
3		A	
4		A	
5		A	
6		A	
25. FEDERAL TAX I.D. NUMBER SSN EIN		26. PATIENT'S ACCOUNT NO.	
27. ACCEPT ASSIGNMENT? (For gov't claims, see back) YES <input type="checkbox"/> NO <input type="checkbox"/>		28. TOTAL CHARGE \$ XXX \$	
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)		32. SERVICE FACILITY LOCATION INFORMATION	
SIGNED _____ DATE _____		33. BILLING PROVIDER INFO & PH# ( )	
a. NPI		a. NPI	
b. NPI		b. NPI	

**Box 21:**  
ICD-10 Code:  
L40.1

**Box 24B:**  
Place of Service Code

**Box 24D:**  
CPT-HCPCS Codes:  
J1747  
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

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED CMB-0938-1197 FORM 1500 (02-12)

\*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.

## INDICATION

SPEVIGO is indicated for the treatment of generalized pustular psoriasis (GPP) in adults and pediatric patients 12 years of age and older and weighing at least 40 kg.

## IMPORTANT SAFETY INFORMATION

### CONTRAINDICATIONS

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

### WARNINGS AND PRECAUTIONS

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

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

### Hypersensitivity and Infusion-Related Reactions:

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

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

### ADVERSE REACTIONS

#### Intravenous SPEVIGO for Treatment of GPP Flare

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

#### Specific Adverse Reactions

- **Infections:** The most frequent adverse reactions that occurred in subjects treated with intravenous SPEVIGO were infections. During the 1-week placebo-controlled period in Study Effisayil-1, infections were reported in 14% of subjects treated with SPEVIGO compared with 6% of subjects treated with placebo. Serious infection (UTI) was reported in 1 subject (3%) in the SPEVIGO group and no subjects in the placebo group. Infections observed through Week 1 in Study Effisayil-1 in subjects treated with SPEVIGO were mild (29%) to moderate (71%).
- **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.

## IMPORTANT SAFETY INFORMATION (Cont'd)

### ADVERSE REACTIONS (Cont'd)

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

### Clinical Development of Spesolimab-sbzo

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

## SPECIFIC POPULATIONS

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

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

 **Spevigo**<sup>®</sup>  
(spesolimab-sbzo) injection



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

April 2026 MAT-93646



## Approval Signatures

**Name:** Spevigo SC Sample CMS 1500 Form  
**Id:** MAT-93646  
**Version:** 1  
**Status:** Approved  
**Product:** Spevigo®  
**Form:**  
**Strength:**  
**Region/Country:** United States  
**Target Audience:** Healthcare Professionals (HCPs)  
**Description:** Spevigo SC Sample CMS 1500 Form (BLA transfer); includes ISI. Updated LEO Version. Update to PC-US-139054.

Document Approvals	
Zafar Toor	Regulatory - 17-Apr-2026 00:41:47 GMT+0000