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 an urgent or expedited authorization request.[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 similar or shorter timeframes.[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 the only agent 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.

Letter templates are available from your LEO Pharma Field Reimbursement Manager or the SPEVIGO website.

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

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

Spevigo® (spesolimab-sbzo) injection

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) IV** (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 the — 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 currently the only FDA-approved medication 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 authorization 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,"* specifically 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, 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**. Bachelez H, Choon S-E, Marrakchi S, et al; Effisayil 1 Trial Investigators. Trial of spesolimab for generalized pustular psoriasis. *N Engl J Med*. 2021;385(26):2431-2440. doi:10.1056/NEJMoa2111563 **3**. Crowley JJ, Pariser DM, Yamauchi PS. A brief guide to pustular psoriasis for primary care providers. *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, Lebwohl MG, Anadkat MJ, et al. Rapid and sustained improvements in generalized pustular psoriasis physician global assessment scores with spesolimab for treatment of generalized pustular psoriasis flares in the randomized, placebo-controlled Effisayil 1 study. *J Am Acad Dermatol*. 2023;89(1):36-44. doi:10.1016/j.jaad.2023.02.040 **6**. 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

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 ≥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.

Please see Prescribing Information for SPEVIGO, including Medication Guide and Instructions for Use.

IMPORTANT SAFETY INFORMATION, 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.

Please see Prescribing Information for SPEVIGO, including Medication Guide and Instructions for Use.

The information herein is for educational purposes and does not constitute legal advice. When completing a prior authorization request or an appeal, it is the responsibility of the health care provider to ensure adherence to the payer's requirements. Payers' public and nonpublic requirements may change, and LEO Pharma undertakes no obligation to provide updated information with respect to such requirements. Under no circumstances should any product or ancillary supplies that are received free of charge be billed to any third-party payer. LEO Pharma cannot and will not guarantee coverage, and nothing herein shall be construed to create such a guarantee.

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August 2026 | MAT-97259