Clinical Policy: Spesolimab-sbzo (Spevigo)

Reference Number: CP.PHAR.606
Effective Date: 03.01.23
Last Review Date: 05.25
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Spesolimab-sbzo (Spevigo®) is an interleukin-36 receptor antagonist.

FDA Approved Indication(s)

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.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Spevigo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Generalized Pustular Psoriasis (must meet all)**:**

1. Diagnosis of GPP;
2. Prescribed by or in consultation with a dermatologist;
3. Age ≥ 12 years;
4. If request is for intravenous (IV) formulation, member is currently having a GPP flare of moderate-to-severe intensity (*see Appendix D*);
5. If request is for subcutaneous (SC) formulation, both of the following (a and b):
   a. Member has had history of at least two GPP flares of moderate-to-severe intensity (*see Appendix D*);
   b. Spevigo is prescribed for prevention of GPP flares;
6. For age 12 to 17 years: Documentation that member weighs ≥ 40 kg at time of request;
7. Failure of a ≥ 3 consecutive month trial of one of the following at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated: methotrexate, cyclosporine, acitretin; †
   †For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395
8. Spevigo is not prescribed concurrently with biological disease-modifying antirheumatic drug or Janus kinase inhibitors (*see Section III: Diagnosis/Indications for which coverage is NOT authorized*);
9. Dose does not exceed one of the following (a, b, or c):
   a. IV: 900 mg one time, followed by an optional second 900 mg dose 1 week later if flare symptoms persist;

b. SC: 600 mg once, followed by maintenance dose of 300 mg every 4 weeks;
c. Both of the following (i and ii):
   i. Initial dose (IV): 900 mg one time;
   ii. Maintenance dose (SC): 300 mg administered 4 weeks after the IV dose and every 4 weeks thereafter.

Approval duration:
IV formulation – 1 month
SC formulation –
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Generalized Pustular Psoriasis (must meet all)**:**
1. If request is for IV formulation: Re-authorization is not permitted. Members must meet the initial approval criteria;
2. If request is for SC formulation, member meets all of the following (a, b, c, d, and e):
   a. Member meets one of the following (i or ii):
      i. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
      ii. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
   b. Member is responding positively to therapy (e.g., increased time to flare onset, decrease in number of flares);
   c. For age 12 to 17 years: Documentation that member weighs ≥ 40 kg at time of request;

d. Spevigo is not prescribed concurrently with biological disease-modifying antirheumatic drug or Janus kinase inhibitors (*see Section III: Diagnosis/Indications for which coverage is NOT authorized*);
e. If request is for a dose increase, new dose does not exceed 300 mg every 4 weeks.

Approval duration:
IV formulation – Not applicable
SC formulation –
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

B. Combination use with biological disease-modifying antirheumatic drugs (bDMARDs) or potent immunosuppressants, including but not limited to any tumor necrosis factor (TNF) antagonists [e.g., Cimzia®, Enbrel®, Humira® and its biosimilars, Remicade® and its biosimilars, Simponi®], interleukin agents [e.g., Actemra® (IL-6RA) and its biosimilars, Arcalyst® (IL-1 blocker), Bimzelx® (IL-17A and F antagonist), Cosentyx® (IL-17A inhibitor), Ilaris® (IL-1 blocker), Ilumya™ (IL-23 inhibitor), Kevzara® (IL-6RA), Kineret® (IL-1RA), Omvoh™ (IL-23 antagonist), Siliq™ (IL-17RA), Skyrizi™ (IL-23 inhibitor), Spevigo® (IL-36 antagonist), Stelara® (IL-12/23 inhibitor) and its biosimilars, Taltz® (IL-17A inhibitor), Tremfya® (IL-23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Cibinqo™, Olumiant™, Rinvoq™, Xeljanz®/Xeljanz® XR,], anti-CD20 monoclonal antibodies [Rituxan® and its biosimilars], selective co-stimulation modulators [Orencia®], integrin receptor antagonists [Entyvio®], tyrosine kinase 2 inhibitors [Sotyktu™], and sphingosine 1-phosphate receptor modulator [Velsipity™] because of the additive

immunosuppression, increased risk of neutropenia, as well as increased risk of serious infections.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

bDMARD: biological disease-modifying antirheumatic drug
DRESS: drug reaction with eosinophilia or systemic symptoms
FDA: Food and Drug Administration
GPP: generalized pustular psoriasis
GPPPGA: Generalized Pustular Psoriasis Physician Global Assessment
IV: intravenous
SC: subcutaneous

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
acitretin (Soriatane®)*	0.5 – 1 mg/kg PO QD	1 mg/kg/day
cyclosporine (Sandimmune®, Neoral®)*	2.5 – 5 mg/kg PO QD	5 mg/kg/day
methotrexate (Rheumatrex®)*	15 – 25 mg/week IM or SC	30 mg/week

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Off-label*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): severe or life-threatening hypersensitivity to spesolimab-sbzo or any of the excipients in Spevigo, drug reaction with eosinophilia or systemic symptoms (DRESS)
- Boxed warning(s): none reported

Appendix D: General Information

- Initiating or reinitiating SC Spevigo after treatment of a GPP flare with IV Spevigo: Four weeks after treatment of GPP flare with IV Spevigo, initiate or reinitiate SC Spevigo for treatment of GPP at dose of 300 mg administered every 4 weeks. A SC loading dose is not required following treatment of a GPP flare with IV Spevigo.
- Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) classification on intensity of GPP:
  - GPPPGA relied on the clinical assessment of the GPP patient's skin presentation. The total score is calculated by taking the mean of the three sub-scores: 1) erythema; 2) pustules; and 3) scaling and crusting which were all assessed using a scale score 0 to 4 (0 = clear, 1 = almost clear, 2 = mild, 3 = moderate, 4 = severe).
  - The final GPPPGA score:
    - 0 (clear defined as no visible pustules): if scores for all three sub-scores are 0
    - 1 (almost clear defined as low-density occasional small discrete pustules [noncoalescent]): if $0 < \text{mean} < 1.5$
    - 2 (mild defined as moderate-density grouped discrete small pustules [noncoalescent]): if $1.5 \leq \text{mean} < 2.5$

- 3 (moderate defined as high-density pustules with some coalescence): if 2.5 ≤ mean < 3.5
- 4 (severe defined as very-high-density pustules with pustular lakes): if mean ≥ 3.5

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
GPP	**IV:** Treatment of GPP flare 900 mg IV infusion once; if flare symptoms persist additional 900 mg dose may be administered one week after initial dose **SC:** Treatment of GPP when not experiencing a flare Initial dose: 600 mg SC once Maintenance dose: 300 mg SC 4 weeks after initial dose and every 4 weeks thereafter	IV: 900 mg/infusion up to 2 doses SC: 300 mg every 4 weeks (after loading dose)

VI. Product Availability

- Single-dose vial for intravenous infusion: 450 mg/7.5 mL (60 mg/mL)
- Single-dose prefilled syringes: 150 mg/mL, 300 mg/2 mL (150 mg/mL)

VII. References

1. Spevigo Prescribing Information. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc.; May 2025. Available at: www.spevigo.com. Accessed June 17, 2025.
2. ClinicalTrials.gov. A Study to Test Whether BI 655130 (Spesolimab) Prevents Flare-ups in Patients with Generalized Pustular Psoriasis. Available at: https://classic.clinicaltrials.gov/ct2/show/NCT04399837. Accessed February 28, 2025.
3. Bachelez H, Choon S.E, Marrakchi S, et al. Trial of spesolimab for generalized pustular psoriasis. N Engl J Med 2021;385:2431-40. https://doi.org/10.1056/NEJMoa2111563.
4. Kruegar J, Puig Lluis, Diamant Thaç. Treatment options and goals for patients with generalized pustular psoriasis. Am J Clin Dermatol 23 (Suppl 1), 51–64 (2022). https://doi.org/10.1007/s40257-021-00658-9.
5. Spevigo Drug Monograph. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2025. Available at: https://www.clinicalkey.com/pharmacology/. Accessed June 17, 2025.
6. Fujita H, Terui T, Hayma K, et al. Japanese guidelines for the management and treatment of generalized pustular psoriasis: The new pathogenesis and treatment of GPP. J Dermatol 45: 1235-1270. https://doi.org/10.1111/1346-8138.14523.
7. Burden AD, Bachelez H, Choon SE, et al. The Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) score: online assessment and validation study of a specific measure of GPP disease activity. Br J Dermatol. 2023 Jul 7;189(1):138-140. doi: 10.1093/bjd/ljad071. PMID: 37075220.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J1747	Injection, spesolimab-sbzo, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	11.22.22	02.23
Added HCPCS code [J1747].	04.17.23	
1Q 2024 annual review: no significant changes; added Tofidence to section III.B; removed expired HCPCS codes for Spevigo [C9399, J3590]; references reviewed and updated.	11.02.23	02.24
2Q 2024 annual review: added Bimzelx, Zymfentra, Omvoh, Wezlana, Sotyktu, and Velsipity to section III.B; references reviewed and updated. RT4: added criteria for newly approved pediatric extension for patients 12 years of age and older weighing at least 40 kg; added newly approved subcutaneous formulation.	04.04.24	05.24
2Q 2025 annual review: no significant changes; updated section III.B with Spevigo and biosimilar verbiage; references reviewed and updated.	01.23.25	05.25
RT4: added new dosage form [300 mg/2 mL (150 mg/mL) single-dose prefilled syringe] to criteria; added step therapy bypass for IL HIM per IL HB 5395.	06.17.25	

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage

decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.