Spevigo (spesolimab-sbzo)
PAM – 085

Iowa Medicaid Program	Prior Authorization	**Effective Date**	04/01/2023
Revision Number	2	**Last Reviewed**	10/17/2025
Reviewed By	Medicaid Medical Director	**Next Review**	10/16/2026
Approved By	Medicaid Clinical Advisory Committee	**Approved Date**	10/18/2024

Overview

Medication: [1]	spesolimab-sbzo
Brand Name:	Spevigo®
Pharmacologic Category:	Immunological agent; interleukin blocker; interleukin-36 receptor antagonist
FDA-Approved Indication(s):	Treatment of generalized pustular psoriasis (GPP) in adults and pediatric patients 12 years of age and older and weighing at least 40 kg

How Supplied:	• Prefilled syringes (for subcutaneous use)
	  ○ Carton containing one single-dose 300 mg/2 mL prefilled syringe
	  ○ Carton containing two single-dose 300 mg/2 mL prefilled syringes
	  ○ Carton containing two single-dose 150 mg/mL prefilled syringes
	• Single-dose vials (for intravenous use)
	  ○ Carton containing two single-dose 450 mg/7.5 mL (60 mg/mL) vials

Dosage and Administration:

Subcutaneous (SC) formulation (for treatment of GPP when not experiencing a flare)

- 600 mg loading dose, followed by 300 mg 4 weeks later and every 4 weeks thereafter.
- If patient receives IV Spevigo® for treatment of a GPP flare, may initiate (or reinitiate) SC Spevigo® for treatment of GPP at a dose of 300 mg administered every 4 weeks (a loading dose is not required following treatment of a GPP flare with IV Spevigo®).

Administration

- When using the 150 mg/mL prefilled syringe: *If required, the 600 mg loading dose is to be administered by a healthcare professional.* For subsequent 300 mg doses, 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 after proper training in subcutaneous injection technique. In pediatric patients 12 years of age and older, administer under the supervision of an adult.
- When using the 300 mg/2 mL prefilled syringe: 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 after proper training in subcutaneous injection technique. In pediatric patients 12 years of age and older, administer under the supervision of an adult.

Intravenous (IV) formulation (for treatment of GPP flare)

- Single 900 mg dose administered via IV infusion.
- If GPP flare symptoms persist, an additional IV 900 mg dose may be administered one week after the initial dose.
- To be administered only by a healthcare professional in a healthcare setting.

Benefit Category:	Medical

Testing and Procedures Prior to Treatment Initiation
Risk of Tuberculosis • Evaluate patients for active or latent tuberculosis (TB) infection. 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. • Monitor patients for signs and symptoms of active TB during and after Spevigo® treatment. Risk of 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.

Descriptive Narrative

Psoriasis is a common skin disorder characterized by the development of erythematous, scaling plaques on the skin and a wide spectrum of clinical presentations. The most common presentation of psoriasis is chronic plaque psoriasis, which manifests as well-defined, inflammatory, red, scaling plaques on the skin. Pustular psoriasis is a less common subtype of psoriasis that presents as an acute, subacute, or chronic pustular eruption. Pustular psoriasis primarily affects adults but can also occur in children.[2]

Generalized Pustular Psoriasis (GPP) is a rare and potentially life-threatening form of psoriasis that can present at any age, but the median age is around 50. GPP is characterized by widespread areas of inflamed skin with pustules, and its severity can fluctuate, with periods of flare-ups followed by remission. Flares may be triggered by multiple factors, such as rapid withdrawal of systemic corticosteroids, infections, pregnancy, and even stress. The etiology of GPP is not fully understood, but emerging evidence implicates a multifactorial interplay of genetic, environmental, and immune dysregulation factors. Genetic predisposition, particularly mutations in genes such as IL36RN, highlights the crucial role of the IL-36 pathway in the pathogenesis of GPP.

Guidelines

A consensus statement was published by the International Psoriasis Council (IPC) in May 2024. A final definition was established for generalized pustular psoriasis (GPP):

> "Generalized Pustular Psoriasis is a systemic inflammatory disease characterized by cutaneous erythema and macroscopically visible sterile pustules."

The identified essential criterion established was:

> "Macroscopically visible sterile pustules on erythematous base and not restricted to the acral region or within psoriatic plaques."

Twenty-three consensus statements were approved and utilized to develop the proposed definitions and diagnostic criteria for GPP. [3]

Treatment/Management

Patients with generalized pustular psoriasis (GPP) flares may require hospitalization to ensure adequate hydration, bed rest, and prevention of excessive heat loss. [4]

Supportive Care

- Bland topical compresses and saline or oatmeal baths (help relieve discomfort and promote debridement of affected skin)
- Initiation of systemic therapy is recommended alongside supportive interventions for patients with a GPP flare

Systemic Therapy*

- **First Line**
  - Adults
    - Oral retinoids (acitretin, isotretinoin)
    - Methotrexate
    - Cyclosporine
    - Infliximab
    - Spesolimab (Spevigo®)
  - Pediatric Patients
    - Acitretin
    - Methotrexate
    - Cyclosporine
    - Etanercept
- **Second Line**
  - Etanercept
  - Adalimumab
  - Ustekinumab
  - Secukinumab
  - Topical treatments (particularly corticosteroids, calcipotriene, and tacrolimus for localized involvement of the palms and soles)

* In March 2024, the FDA granted an expanded indication for spesolimab to include adults and pediatric patients aged 12 years or older weighing at least 40 kg.

Criteria

Prior authorization is required.

Spevigo® is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of generalized pustular psoriasis (GPP); **AND**
2. Other pustular and skin conditions have been ruled out (e.g., primary erythrodermic psoriasis vulgaris, plaque psoriasis without pustules, plaque psoriasis with limited plaque pustules, etc.); **AND**
3. If member is receiving intravenous (IV) infusion of Spevigo®, must be experiencing a persistent GPP flare of moderate-to-severe intensity; **AND**
4. Member is 12 years of age or older (if 12 to 17 years of age, member must weigh at least 40 kg at time of request); **AND**
5. Spevigo® is not prescribed concurrently with biological disease-modifying antirheumatic agents or Janus kinase inhibitors; **AND**
6. Prescribed by, or in consultation with, a dermatologist; **AND**
7. Request meets one of the following (a, b, c, or d):
    a. Intravenous (IV) infusion: Dose does not exceed 900 mg one time, followed by an optional second 900 mg dose 1 week later if flare symptoms persist; or
    b. Subcutaneous (SC) injection: Dose does not exceed 600 mg once, followed by maintenance dose of 300 mg every 4 weeks; or
    c. Both of the following (i and ii):
        i. Initial dose (IV) does not exceed 900 mg one time (unless second dose is clinically warranted in the opinion of the prescribing provider); followed by,
        ii. Maintenance dose (SC) does not exceed 300 administered 4 weeks after the last IV dose and every 4 weeks thereafter; or
    d. Regimen is supported by clinical practice guidelines. Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Spevigo® is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; **AND**
2. Documentation of positive clinical response to therapy (e.g., increased time to flare onset, decrease in number of flares); **AND**
3. If member is 12 to 17 years of age, member weighs at least 40 kg; **AND**
4. Spevigo® is not prescribed concurrently with biological disease-modifying antirheumatic agents or Janus kinase inhibitors; **AND**
5. Prescribed by, or in consultation with, a dermatologist; **AND**
6. Request meets one of the following (a or b):
    a. Request is for the subcutaneous formulation, and dose does not exceed 300 mg every 4 weeks; or
    b. Regimen is supported by clinical practice guidelines. Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Approval Duration and Quantity Limits

	Initial Authorization and Request is for:		Subsequent Authorization(s)
	IV Formulation *	**SC Formulation only**	
Approval Duration	1 month (IV) + 6 months (SC)	6 months	(SC only) ** 12 months
Quantity Limits	**IV:** 900 mg 1 time, followed by an optional 900 mg dose 1 week later if flare symptoms persist **SC:** 300 mg every 4 weeks (beginning 4 weeks after member receives IV dose)	600 mg 1 time, followed by 300 mg every 4 weeks (assumes IV induction is not utilized)	300 mg every 4 weeks

* Initial IV authorization includes approval for a one-time intravenous (IV) dose of 900 mg, followed by a 6-month authorization of the subcutaneous (SC) formulation (300 mg every 4 weeks, beginning 4 weeks after the member receives the IV dose).

** Subsequent authorization applies to SC only. Repeating the IV formulation would require a new authorization to document presence of acute flare.

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
J1747	Injection, spesolimab-sbzo, 1 mg

ICD-10	Description
L40.1	Generalized pustular psoriasis

NDC (and contents per carton)	Form	Labeler	Dosage	Pkg Size	Pkg Qty	Units /Pkg
00597-0035-10 (two single-dose vials, 450 mg/7.5 mL each)	IV	Boehringer Ingelheim Pharmaceuticals, Inc.	1 mg	2	EA	900
00597-0620-20 (two single-dose prefilled syringes, 150 mg/mL each)	SC	Boehringer Ingelheim Pharmaceuticals, Inc.	1 mg	2	EA	300
00597-7705-41 (one single-dose prefilled syringe, 300 mg/2 mL)	SC	Boehringer Ingelheim Pharmaceuticals, Inc.	1 mg	1	EA	300
00597-7705-72 (two single-dose prefilled syringes, 300 mg/2 mL each)	SC	Boehringer Ingelheim Pharmaceuticals, Inc.	1 mg	2	EA	600

Compliance

1. Should conflict exist between the policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.

3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician-administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

[1] Spevigo prescribing information (05/2025). Boehringer Ingelheim Pharmaceuticals, Inc.: Ridgefield, CT. Available online: pro.boehringer-ingelheim.com/us/products/spevigo. Accessed August 13, 2025.

[2] Kalb RE. Pustular psoriasis: Pathogenesis, clinical manifestations, and diagnosis. Ofori AO, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed August 14, 2025.

[3] Choon SE, van de Kerkhof P, Gudjonsson JE, et al. International Consensus Definition and Diagnostic Criteria for Generalized Pustular Psoriasis From the International Psoriasis Council. *JAMA Dermatol.* 2024;160(7):758–768.

[4] Mirza HA, Saleh HM. Generalized Pustular Psoriasis. [Updated 2025 Aug 9]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan. Available from: www.ncbi.nlm.nih.gov/books/NBK493189.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
10/17/2025	CAC	Annual review. Updated Overview and Coding/Product Information sections with new 300 mg/2 mL prefilled syringe information. Moved Treatment/Management section into Guidelines section. Removed reference to number of vials/syringes used in criteria.	2
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
10/18/2024	CAC	Criteria implementation.	1
Signature William (Bill) Jagiello, DO			

CAC = Medicaid Clinical Advisory Committee