# Medical Policy

**Healthcare Services Department**

| Policy Name | Policy Number | Scope |
|---|---|---|
| **Spesolimab-sbzo (Spevigo®)** | MP-RX-FP-140-24 | ☒ MMM MA ☒ MMM Multihealth |

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

## Service Description

This document addresses the use of *Spesolimab-sbzo (Spevigo®),* an interleukin-36 receptor antagonist, approved by the Food and Drug Administration (FDA) for the treatment of generalized pustular psoriasis flares in adults and pediatric patients 12 years of age and older and weighing at least 40 kg.

**Background Information**

Spesolimab is a humanized, selective antibody that blocks the activation of the interleukin-36 receptor, a signaling pathway in the immune system involved in a number of autoimmune diseases. It is the first FDA-cleared treatment for generalized pustular psoriasis (GPP).

Generalized pustular psoriasis (GPP) is a potentially life-threatening neutrophilic skin disease that is clinically distinct from plaque psoriasis. A preceding history of plaque psoriasis may or may not be present in individuals presenting with GPP. It is characterized by the development of widespread eruption of pustules and erythematous plaques which may be accompanied by fever, malaise, and/or extracutaneous manifestations including arthritis. The European Rare and Severe Psoriasis Expert Network (ERASPEN) define consensus diagnosis criteria as the following:

Primary, sterile, macroscopically visible pustules on non-acral skin (excluding cases where pustulation is restricted to psoriatic plaques):

- With or without systemic inflammation
- With or without plaque-type psoriasis
- Either relapsing (>1 episode) or persistent (>3 months

Within dermatology, acral skin relates to that of the distal extremities such as ears, fingers, toes, nose, etc. The clinical course of GPP can be relapsing with recurrent flares, or persistent with intermittent flares. There is a lack of high-quality data on efficacy of various treatments for GPP, but may include adjunctive topical therapy, phototherapy, and/or conventional immunosuppressants such as acitretin, cyclosporine or methotrexate. Certain biologics approved for treatment of psoriasis have been used, but data is lacking.

Spevigo targets one of the underlying immunologic signaling pathways of the disease by blocking the IL-36 receptor. The intravenous formulation of Spevigo is used for the treatment of acute GPP flares. In a phase 2 trial, individuals randomized to one 900 mg IV infusion of spesolimab (n=35) or placebo (n=18) were treated when presenting with a moderate to severe GPP flare defined as a Generalized Pustular Psoriasis Physician Global

| Policy Name | Policy Number | Scope |
|---|---|---|
| **Spesolimab-sbzo (Spevigo®)** | MP-RX-FP-140-24 | ☒ MMM MA ☒ MMM Multihealth |

Assessment (GPPGA) score of at least 3, GPPGA pustular subscore of at least 2, and 5% of body surface area (BSA) with erythema and the presence of pustules. At the end of week 1, 54% of individuals in the spesolimab group and 6% of those in the placebo group had a GPPGA pustulation subscore of 0 (no visible pustules) (Bachelez 2021). The subcutaneous formulation of Spevigo is used as maintenance treatment for individuals that are not currently experiencing GPP flare. In a phase 2 trial, individuals randomized to a 600 mg subcutaneous loading dose followed by 300 mg subcutaneous Spevigo every 4 weeks (n=30) versus placebo (n=31) experienced less GPP flares up to 48 weeks of treatment (10% vs 52% experiencing at least one GPP flare, respectively) (Morita 2023). Individuals treated with subcutaneous Spevigo may receive intravenous Spevigo treatment for GPP flare and resume subcutaneous therapy at least four weeks after treatment of flare.

*Generalized Pustular Psoriasis Physician Global Assessment*

| Score | Erythema | Pustules | Scaling |
|---|---|---|---|
| **0 (clear)** | Normal or post-inflammatory hyperpigmentation | No visible pustules | No scaling or crusting |
| **1 (almost clear)** | Faint, diffuse pink or slight red | Low density occasional small discrete pustules (noncoalescent) | Superficial focal scaling or crusting restricted to periphery of lesions |
| **2 (mild)** | Light red | Moderate density grouped discrete small pustules (noncoalescent) | Predominantly fine scaling or crusting |
| **3 (moderate)** | Bright red | High density pustules with some coalescence | Moderate scaling or crusting covering most or all lesions |
| **4 (severe)** | Deep fiery red | Very high-density pustules with pustular lakes | Severe scaling or crusting covering most or all lesions |

*Composite mean score = (erythema + pustules + scaling)/3; total GPPGA score given is 0 if mean = 0 for all three components, 1 if mean 0 to <1.5, 2 if mean 1.5 to <2.5, 3 if mean 2.5 to <3.5, 4 if mean ≥3.5.

**Approved Indications**

A. Treatment of generalized pustular psoriasis flares (GPP).

**Other Uses**

i. None.

| Policy Name | Policy Number | Scope |
|---|---|---|
| **Spesolimab-sbzo (Spevigo®)** | MP-RX-FP-140-24 | ☒ MMM MA ☒ MMM Multihealth |

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

| HCPCS | Description |
|---|---|
| J1747 | Injection, spesolimab-sbzo, 1 mg [Spevigo] |

| ICD-10 | Description |
|---|---|
| L40.1 | Generalized pustular psoriasis |

## Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

### *Spesolimab-sbzo (Spevigo®) vial for IV use*

**A. Criteria For Initial Approval** *(Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

Requests for one initial 900 mg dose [2 vials] of Spevigo (spesolimab-sbzo) at the beginning of each Generalized Pustular Psoriasis (GPP) flare may be approved if the following criteria are met:

i. Individual is 12 years of age or older weighing at least 40 kg; **AND**
ii. Individual has a diagnosis of Generalized Pustular Psoriasis (GPP), as verified by (Bachelez 2021):
    A. The presence of primary, sterile, macroscopically visible pustules on non-acral skin; **AND**
    B. Pustulation that is *NOT* restricted to psoriatic plaques (i.e. occurs outside of psoriatic plaques); **AND**
iii. Individual is currently presenting with an acute flare of GPP of moderate to severe intensity, as defined by (Bachelez 2021):
    A. Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) score of at least 3; **AND**
    B. GPPGA pustulation sub score of at least 2 (i.e. moderate to very high-density pustules); **AND**

C. Presence of fresh pustules (new appearance or worsening of pustules); **AND**
D. At least 5% of Body Surface area (BSA) covered with erythema and the presence of pustules; **AND**

iv. If individual has previously received Spevigo treatment for a prior GPP flare*, individual achieved clinical response, as defined as achieving a GPPGA score of 0 or 1, to previous treatment but is now experiencing a new flare (Bachelez 2021).

*Treatment for a prior flare may include up to two 900 mg infusions of Spevigo separated by 1 week.

**B. Criteria For Continuation of Therapy**

i. MMM considers requests for an additional 900 mg dose [2 additional vials] of Spesolimab-sbzo (Spevigo®) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) if the request is made one week after the initial dose for treatment of the same GPP flare and if the following criteria are met:
ii. Individual is still experiencing persistent symptoms of an acute flare of GPP of moderate to severe intensity, as defined by (Bachelez 2021):
A. Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) score of at least 2; **AND**
B. GPPGA pustulation sub score of at least 2 (i.e. moderate to very high-density pustules); **AND**
iii. Second infusion will take place no sooner than one week after the initial infusion.

**C. Authorization Duration**

i. Initial Approval Duration: 1 week per infusion
ii. Reauthorization Approval Duration: 1 week per infusion

**D. Conditions Not Covered**

*Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):*

Requests for Spevigo (spesolimab-sbzo) may not be approved for the following:

i. Individual has plaque psoriasis without pustules or with pustules restricted to psoriatic plaques;
**OR**
ii. Tuberculosis, other active serious infections, or a history of recurrent infections;
**OR**
iii. If initiating therapy (not currently on spesolimab), individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention- recommended equivalent to evaluate for latent tuberculosis prior;
**OR**
iv. When the above criteria are not met and for all other indications.

| Policy Name | Policy Number | Scope |
|---|---|---|
| **Spesolimab-sbzo (Spevigo®)** | MP-RX-FP-140-24 | ☒ MMM MA ☒ MMM Multihealth |

## *Spesolimab-sbzo (Spevigo®) Prefilled Syringe for SC use*

**A. Criteria For Initial Approval** *(Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

Requests for Spevigo (spesolimab-sbzo) prefilled syringes for subcutaneous use may be approved if the following criteria are met:

i. Individual is 12 years of age or older weighing at least 40 kg; **AND**
ii. Individual has a diagnosis of Generalized Pustular Psoriasis (GPP), as verified by (Morita 2023):
    A. The presence of primary, sterile, macroscopically visible pustules on non-acral skin; **AND**
    B. Pustulation that is NOT restricted to psoriatic plaques (i.e. occurs outside of psoriatic plaques); **AND**
iii. Individual has a history of at least two GPP flares of moderate-to-severe intensity in the past (Morita 2023); **AND**
iv. Individual is not currently experiencing an acute flare of GPP; **AND**
v. If individual has previously received Spevigo intravenous infusion for treatment for a GPP flare; Spevigo prefilled syringes for subcutaneous use will be initiated no earlier than four weeks after the most recent infusion.

**B. Criteria For Continuation of Therapy**

i. MMM considers continuation requests for Spesolimab-sbzo (Spevigo®) prefilled syringes for subcutaneous use medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) if the following criteria are met:
    A. Individual has been receiving and is maintained on a stable dose of Spevigo prefilled syringes for subcutaneous use; **AND**
    B. There is clinically significant improvement or stabilization in clinical signs and symptoms of the disease (for example, a reduction in the frequency of GPP flares).

**C. Authorization Duration**

i. Initial Approval Duration: 1 year
ii. Reauthorization Approval Duration: 1 year

**D. Conditions Not Covered**

*Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):*

Requests for Spevigo (spesolimab-sbzo) may not be approved for the following:

i. Individual has plaque psoriasis without pustules or with pustules restricted to psoriatic plaques;

| Policy Name | Policy Number | Scope |
|---|---|---|
| **Spesolimab-sbzo (Spevigo®)** | MP-RX-FP-140-24 | ☒ MMM MA ☒ MMM Multihealth |

**OR**

ii. Tuberculosis, other active serious infections, or a history of recurrent infections;

**OR**

iii. If initiating therapy (not currently on spesolimab), individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention- recommended equivalent to evaluate for latent tuberculosis prior;

**OR**

iv. When the above criteria are not met and for all other indications.

## Limits or Restrictions

A. Therapeutic Alternatives

*The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.*

i. N/A

B. Quantity Limitations

*Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.*

**Spevigo (spesolimab-sbzo) Vials for IV Use**

| Drug | Recommended Dosing Schedule | Limit |
|---|---|---|
| Spesolimab-sbzo (Spevigo®) 450 mg/7.5 mL (60 mg/mL) SDV | 900 mg dose by intravenous infusion | 2 vials [1 carton] per year *^ |
| **Exceptions** | | |
| *Requests for 2 additional vials (1 additional carton) one week after the initial dose for treatment of the same GPP flare may be approved if the following criteria are met:<br>i. Individual is still experiencing persistent symptoms of an acute flare of GPP of moderate to severe intensity, as defined by (Bachelez 2021):<br>A. Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) score of at least 2; AND<br>B. GPPGA pustulation sub score of at least 2 (i.e. moderate to very high-density pustules); AND<br>ii. Second infusion will take place no sooner than one week after the initial infusion.<br>^May approve additional vial fills [2 vials, plus 2 additional vials one week later] per criteria above for each subsequent Generalized Pustular Psoriasis (GPP) flare.<br>• Live vaccines should be avoided during and for at least 16 weeks after treatment with Spevigo. | | |

| Policy Name | Policy Number | Scope |
|---|---|---|
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**Spevigo (spesolimab-sbzo) Prefilled Syringe for SC Use**

| Drug | Recommended Dosing Schedule | Limit |
|---|---|---|
| Spesolimab-sbzo (Spevigo®) 150 mg/mL SD prefilled syringe | • Treatment of GPP when not experiencing a flare: loading dose of 600 mg sc (four 150 mg injections); followed by 300 mg (two 150 mg injections) sc 4 weeks later and every 4 weeks thereafter.<br>• SC use after IV Spevigo treatment of GPP flare: 300 mg (two 150 mg injections) sc 4 weeks later and every 4 weeks thereafter. A loading dose is not required. | 2 prefilled syringes [1 carton] per 28 days* |

| Exceptions |
|---|
| *For initiation of therapy, may approve up to 2 (two) additional prefilled syringes [1 additional carton] in the first 28 days of treatment.<br>• The 600 mg subcutaneous loading dose of Spevigo is to be administered by a healthcare professional. Subsequent doses of 300 mg may be self-administred if provider determines that is appropriate.<br>• Live vaccines should be avoided during and for at least 16 weeks after treatment with Spevigo. |

## Reference Information

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5. Navarini AA, Burden AD, Capon F, et al. European consensus statement on phenotypes of pustular psoriasis. J Eur Acad Dermatol Venereol 2017;31:1792-9.
6. Bachelez H, Choon SE, Marrakchi S, Burden AD, Tsai TF, Morita A, Navarini AA, Zheng M, Xu J, Turki H, Anadkat MJ, Rajeswari S, Hua H, Vulcu SD, Hall D, Tetzlaff K, Thoma C, Lebwohl MG; Effisayil 1 Trial Investigators. Trial of Spesolimab for Generalized Pustular Psoriasis. N Engl J Med. 2021 Dec 23;385(26):2431-2440. doi: 10.1056/NEJMoa2111563.
7. Choon SE, Lebwohl MG, Marrakchi S, Burden AD, Tsai TF, Morita A, Navarini AA, Zheng M, Xu J, Turki H, Rajeswari S, Deng H, Tetzlaff K, Thoma C, Bachelez H. Study protocol of the global Effisayil 1 Phase II, multicentre, randomised, double-blind, placebo- controlled trial of spesolimab in patients with generalized pustular psoriasis presenting with an acute flare. BMJ Open. 2021 Mar 30;11(3):e043666. doi: 10.1136/bmjopen-2020-043666.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

| Policy Name | Policy Number | Scope |
|---|---|---|
| **Spesolimab-sbzo (Spevigo®)** | MP-RX-FP-140-24 | ☒ MMM MA ☒ MMM Multihealth |



## Policy History

| Revision Type | Summary of Changes | P&T Approval Date | UM/CMPC Approval Date |
|---|---|---|---|
| Annual Review 11/20/2025 | Minimal Changes; Coding reviewed: No changes | 12/3/2025 | 12/11/2025 |
| Annual Review 12/26/2024 | Updated service description to add new indication for patients 12 years of age or older weighing at least 40kg. Add clinical criteria (initial and continuation requests criteria, conditions not covered and authorization duration) for the new subcutaneous formulation; updated age criteria for vial formulation per label. Updated quantity limit table to include dosage forms and strenghts; added new sc formulation dosage and quantity limits. Wording and formatting changes. Coding Reviewed: No changes. | 3/20/2025 | 4/2/2025 |
| Policy Inception 01/29/2024 | Elevance Health's Medical Policy adoption | N/A | 6/28/2024 |