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.

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.

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. 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 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

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pustules). Currently, spesolimab is also under investigation for the prevention of GPP flares and for the treatment of other neutrophilic skin disease including palmoplantar pustulosis (PPP) and hidradenitis suppurativa (HS).

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

Spevigo is approved by the FDA for the treatment of generalized pustular psoriasis flares in adults.

Other Uses

None.

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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

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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.

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

Spesolimab-sbzo (Spevigo®)

A. Criteria For Initial Approval

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 18 years of age or older; **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:

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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 for a new flare, 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

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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.

Drug	Recommended Dosing Schedule
Spesolimab-sbzo (Spevigo®)	900 mg dose by intravenous infusion
Exceptions	
• If flare symptoms persist, may administer an additional intravenous 900 mg dose one week after the initial dose	

Reference Information

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 11, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
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.

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Policy Inception	Elevance Health's Medical Policy adoption	N/A	6/28/2024

Revised: 01/29/2024