Medical Drug Clinical Criteria

Subject:	Spevigo (spesolimab-sbzo)		
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Overview

This document addresses the use of Spevigo (spesolimab-sbzo). Spevigo 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 approved for the treatment of generalized pustular psoriasis (GPP) and is the first FDA-cleared treatment for this disease.

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 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.

Clinical Criteria

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.

Spevigo (spesolimab-sbzo) Vials for Intravenous Use

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 lease 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.

Requests for an additional 900 mg dose [2 additional vials] of Spevigo (spesolimab-sbzo) one week after the initial dose for treatment of the same GPP flare may be approved if the following criteria are met:

I. 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**
II. Second infusion will take place no sooner than one week after the initial infusion.

Requests for Spevigo (spesolimab-sbzo) vials for intravenous use 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.

Approval Duration: 1 week per infusion

Spevigo (spesolimab-sbzo) Prefilled Syringes for Subcutaneous Use

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.

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

I. Individual has been receiving and is maintained on a stable dose of Spevigo prefilled syringes for subcutaneous use; **AND**
II. 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).

Requests for Spevigo (spesolimab-sbzo) prefilled syringes for subcutaneous use 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, 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.

Initial and Continuation Approval Duration: 1 year

Quantity Limits

Spevigo (spesolimab-sbzo) Vials for Intravenous Use Quantity Limit

Drug	Limit
Spevigo (spesolimab-sbzo) 450mg/7.5 mL vial	2 vials [1 carton] per year*^
Override Criteria	
*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: I. 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** II. Second infusion will take place no sooner than one week after the initial infusion. ^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.	

Spevigo (spesolimab-sbzo) Prefilled Syringes for Subcutaneous Use Quantity Limit

Drug	Limit
Spevigo (spesolimab-sbzo) 150 mg/mL prefilled syringe	2 prefilled syringes [1 carton] per 28 days*
Override Criteria	
*For initiation of therapy, may approve up to 2 (two) additional prefilled syringes [1 additional carton] in the first 28 days of treatment.	

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J1747	Injection, spesolimab-sbzo, 1 mg [Spevigo]

ICD-10 Diagnosis

L40.1	Generalized pustular psoriasis

Document History

Revised: 05/17/2024
Document History:

- 05/17/2024 – Select Review: Add clinical criteria and quantity limit for new subcutaneous formulation; update age criteria for vial formulation per label. Coding Reviewed: No changes.
- 11/17/2023 – Annual Review: Wording and formatting updates. Coding Reviewed: No changes.
- 11/18/2022 – Annual Review: No changes. Coding Reviewed: No changes. Effective 4/1/2023 Added HCPCS J1747. Added ICD-10-CM L40.1. Removed HCPCS J3490, J3590, C9399.
- 09/07/2022 – Select Review: Create new clinical criteria document for Spevigo. Coding Reviewed: Added J3490, J3590, C9399. All diagnoses pend.

References

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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.