

<b>Policy Name:</b>	<b>Spevigo (spesolimab)</b>	<b>Policy#:</b>	<b>3180P</b>
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### Purpose of the Policy

The purpose of this policy is to define coverage criteria for Spevigo (spesolimab).

### Statement of the Policy

Health Alliance Medical Plans will approve the use of Spevigo (spesolimab) under the specialty medical benefit if the following criteria are met.

### Criteria

- 1. Coverage Criteria for Generalized Pustular Psoriasis (GPP) Flares (Spevigo intravenous formulation)**
  - 1.1 Diagnosis of generalized pustular psoriasis (GPP)
  - 1.2 Patient is currently experiencing a GPP flare of moderate to severe intensity as defined by the following:
    - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score 2-3 (moderate to severe)
    - GPPPGA pustulation subscore  $\geq 2$  (mild to severe)
    - Presence of fresh pustules (new appearance or worsening of pustules)
    - $\geq 5\%$  body surface area covered with erythema or pustules
  - 1.3 Age 12 years or older and weighing at least 40kg
  - 1.4 Prescribed by or in consultation with a dermatologist (skin doctor)
  - 1.5 In patients with non-disabling disease; previous trial and failure, contraindication or intolerance to one systemic therapy (such as cyclosporine, methotrexate, acitretin, isotretinoin, systemic glucocorticoid or mycophenolate)
- 2. Coverage Criteria for Generalized Pustular Psoriasis (GPP) (Spevigo subcutaneous formulation)**
  - 2.1 Diagnosis of generalized pustular psoriasis (GPP) as defined by both of the following:
    - Primary, sterile, macroscopically visible pustules on non-acral skin (excluding cases where pustulation is restricted to psoriatic plaques)
    - Disease is relapsing ( $>1$  episode) or persistent ( $>3$  months)
  - 2.2 Subcutaneous formulation will not be used to treat GPP flare
  - 2.3 Age 12 years or older and weighing at least 40kg
  - 2.4 Prescribed by or in consultation with a dermatologist (skin doctor)
- 3. Exclusion Criteria**
  - 3.1 Concomitant use with any other immunomodulator biologics for psoriasis
  - 3.2 Patient is experiencing life-threatening flare or intensive care
  - 3.3 Patient with active tuberculosis or other clinically significant active infection
- 4. Approval Period**
  - 4.1 Intravenous formulation: 6 months (2 infusions)
    - Maximum lifetime 2 visits based on FDA approved dosing
  - 4.2 Subcutaneous formulation:
    - Initial: 12 months
    - Reauthorization: 12 months with documented positive clinical response to therapy (e.g., reduction in number of flares)

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

## References

1. Spevigo (spesolimab) [prescribing information]. Ridgefield, Connecticut: Boehringer Ingelheim Pharmaceuticals Inc; March 2024.
2. Bachelez H, Choon SE, Marrakchi S, et al. Trial of spesolimab for generalized pustular psoriasis. *N Engl J Med*. 2021;385(26):2431-2440.
3. Choon SE, et al. Clinical course and characteristics of generalized pustular psoriasis. *Am J Clin Dermatol*. 2022;23(Suppl 1):21–29.
4. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology (JAAD)–National Psoriasis Foundation (NPF) guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol*. 2020 Jun;82(6):1445-1486.
5. Kearns DG, Chat VS, Zang PD, et al. Review of treatments for generalized pustular psoriasis. *J Dermatolog Treat* 2021; 32:492.
6. Morita A, Strober B, Burden AD, et al. Efficacy and safety of subcutaneous spesolimab for the prevention of generalised pustular psoriasis flares (Effisayil 2): an international, multicentre, randomised, placebo-controlled trial. *Lancet*. 2023 Oct 28;402(10412):1541-1551.

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