



## **MVP Health Care Medical Policy**

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### **Medicare Part B: Spesolimab**

**Type of Policy:** Drug Therapy  
**Prior Approval Date:** 04/01/2025  
**Approval Date:** 04/01/2026  
**Effective Date:** 06/01/2026  
**Related Policies:** N/A

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

**Refer to relevant CMS LCDs/NCDs/Policy Articles for most up to date Medicare Part B guidance if available.**

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### **Drugs Requiring Prior Authorization under the medical benefit**

J1747 injection, spesolimab-sbzo, 1mg (Spevigo)

J1747 injection, spesolimab-sbzo, 1mg (Spevigo) pre-filled syringes for subcutaneous injection

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### **Overview/Summary of Evidence**

Spesolimab is an interleukin-36 receptor (IL36R) antagonist indicated for the treatment of generalized pustular psoriasis (GPP) in adults and pediatric patients 12 years of age and older and weighing at least 40 kg. Intravenous (IV) Spesolimab is used for treatment of acute GPP flares, and subcutaneous (SC) Spesolimab is used for treatment of GPP when not experiencing a flare, including prevention of future flares. The IV dosage form is administered by intravenous infusion over 90 minutes and an additional infusion may be administered one week after the initial dose if symptoms persist or via subcutaneous injection. Members should be screened for immunological and infectious disease prior to initiating therapy including TB screening. Members avoid the use of live vaccines during treatment with spesolimab and for at least 16 weeks after treatment.

## Indications/Criteria

### **Generalized Pustular Psoriasis (GPP):**

Spesolimab may be considered for coverage when the following criteria are met:

- Member has a diagnosis of moderate to severe generalized pustular psoriasis  
**AND**
- Must be ordered by or with consult from a dermatologist or rheumatologist

### **IV Spevigo for GPP Flare:**

May be considered for coverage when all of the following criteria are met:

- Criteria for **Generalized Pustular Psoriasis (GPP)** above are met
- Chart notes are provided documenting all of the following:
  - Current acute GPP flare
    - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) score of at least 3- [GPPPGA scores range from 0 (clear) to 4 (severe)]
    - At least 5% of body surface area covered with erythema and presence of pustules
    - Current presence of fresh pustules (new or worsening)

**Initial IV Spevigo approval** for a **current flare** will be for **two doses within 3 months**

**Subsequent IV Spevigo approval** for a **new flare** will be considered when the following criteria is met:

- For a new flare, at least 12 weeks has passed since the last dose of Spevigo
- Medication is ordered by or with consult from a dermatologist or rheumatologist
- Chart notes are provided indicate previous use and clinical benefit from Spevigo
- **Subsequent approvals for a new flare will be for two doses within 3 months**

### **Subcutaneous Use After IV Spevigo for Treatment of GPP Flare:**

- Criteria for IV **Spevigo for GPP Flare** above are met
- 4 weeks have passed since treatment with loading dose of IV SPEVIGO

**Initial approval** for subcutaneous Spevigo will be **every 4 weeks for 12 months**

### **Subcutaneous Spevigo for Generalized pustular psoriasis (GPP) when *not experiencing a flare*:**

- Chart notes documenting the following:
  - Criteria for **Generalized Pustular Psoriasis (GPP)** above are met

- Member is not currently experiencing a flare
  - History of at least 2 moderate to severe GPP flares **OR**
  - History of flare during concomitant therapy **AND**
  - Clear or almost clear skin

**Initial approval** will be dosed every **4 weeks for 12 months**

**Subsequent approvals for subcutaneous use** when not experiencing a flare:

- Documentation indicating an overall beneficial clinical response
  - Low disease activity
  - Reduction in flares
  - Improvement in clinical signs and symptoms
  - **Approve for 12 months**

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## Exclusions

The use of spesolimab will not be covered for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Current administration of live vaccines

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## References

1. Spesolimab. Clinical Pharmacology. Revision date 10/23/2025. Accessed on 02/26/2026.
2. Spevigo (spesolimab-sbzo) injection, for subcutaneous or intravenous use. Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. Revised 10/2025.
3. Bachelez H, Choon SE, Marrakchi S, et al. Trial of spesolimab for generalized pustular psoriasis. *N Engl J Med*. 2021;385(26):2431-2440. doi:10.1056/NEJMoa2111563.
4. Effect of Spesolimab on Sustained Disease Control in Patients With Generalized Pustular Psoriasis: Post Hoc Analysis of the EFFISAYIL 2 Study. *Journal of the American Academy of Dermatology*. 2025. Gordon KB, Augustin M, Barker J, et al.
5. Pustular Psoriasis: Molecular Pathways and Effects of Spesolimab in Generalized Pustular Psoriasis. *The Journal of Allergy and Clinical Immunology*. 2022. Baum P, Visvanathan S, Garcet S, et al.

6. Spesolimab for Generalized Pustular Psoriasis: A Review of Two Key Clinical Trials Supporting Initial US Regulatory Approval. *Frontiers in Immunology*. 2024. Gwillim EC, Nichols AJ.