



MVP Health Care Medical Policy

Medicare Part B: Spesolimab

Type of Policy:	Drug Therapy
Prior Approval Date:	04/01/2024
Approval Date:	04/01/2025
Effective Date:	06/01/2025
Related Policies:	N/A

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

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

Overview/Summary of Evidence

Spesolimab is an interleukin-36 receptor (IL36R) antagonist indicated for the treatment of generalized pustular psoriasis (GPP) flares in adults and pediatric patients 12 years of age and older and weighing at least 40 kg. It 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 immunologic and infectious disease prior to initiating therapy and 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

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 **AND**
- Chart notes are provided documenting all of the following:
 - Current GPP flare
 - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) score of at least 3- [GPPPGA scores range from 0 (clear) to 4 (severe)] **AND**
 - At least 5% of body surface area covered with erythema and presence of pustules **AND**
 - 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 **AND**
- Medication is ordered by or with consult from a dermatologist or rheumatologist **AND**
- 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 **Spevigo for GPP Flare** above are met **AND**
- 4 weeks have passed since treatment with 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 **AND**
 - 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
 - o Low disease activity
 - o Reduction in flares
 - o Improvement in clinical signs and symptoms
 - o **Approve for 12 months**

Exclusions

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

- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Systemic and/or topical therapy used concomitantly with Spevigo

References

1. Spesolimab. Clinical Pharmacology. Revision date 12/17/2024. Accessed on 03/2025.
2. Spevigo (spesolimab-sbzo) injection, for subcutaneous or intravenous use. Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. Revised 03/2024.
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. Shah M, Al Aboud DM, Crane JS, et al. Pustular Psoriasis. [Updated 2023 Aug 8]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK537002/>