



## MVP Health Care Medical Policy

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### Medicare Part B: Spesolimab

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| <b>Type of Policy:</b>      | <b>Drug Therapy</b> |
| <b>Prior Approval Date:</b> | <b>11/01/2023</b>   |
| <b>Approval Date:</b>       | <b>04/01/2024</b>   |
| <b>Effective Date:</b>      | <b>06/01/2024</b>   |
| <b>Related Policies:</b>    | <b>N/A</b>          |

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

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### Drugs Requiring Prior Authorization under the medical benefit

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

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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) flares in adults. 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. Members should be screened for immunologic and infectious disease prior to initiating therapy and avoid the use of live vaccines when treated with spesolimab.

### Indications/Criteria

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 **AND**
- Chart notes are provided documenting all of the following:
  - 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 approval** for a **current flare** will be for two doses within 3 months

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

- Member has not received two doses of Spevigo for treatment of the current flare **AND**
- 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 **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.

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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
- More than two (2) doses per current flare
- Prescribed for an indication outside of the FDA approved package labeling

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## References

1. Spesolimab. Clinical Pharmacology. Revision date September 03, 2022. Accessed on May 4, 2023.
2. Spevigo (spesolimab-sbzo) injection, for intravenous use. Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. Revised September 2022.
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 About 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/>