

**Targeted Immunomodulators**  
**Spevigo (spesolimab-sbzo)**  
**Effective 11/01/2024**

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Medical and Specialty Medications</b>		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
<b>Contact Information</b>	<b>Non-Specialty Medications</b>		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
<b>Notes</b>	Spevigo (spesolimab-sbzo) is also available on the pharmacy benefit. Please see the <a href="#">MassHealth Drug List</a> for coverage and criteria.		

### Overview

Spevigo (spesolimab-sbzo) is an interleukin-36 receptor antagonist indicated for the treatment of generalized pustular psoriasis (GPP) flares in adults.

### Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

### OR

Authorization may be granted for members when all the following criteria are met:

1. Diagnosis of Generalized Pustular Psoriasis (GPP)
2. **ONE** of the following:
  - a. Member is  $\geq 18$  years of age
  - b. **BOTH** of the following:
    - i. Member is  $\geq 12$  years of age
    - ii. Member's current weight is  $\geq 40$  kg
3. For Spevigo (spesolimab-sbzo) **prefilled syringe**, **ONE** of the following:
  - a. Inadequate response or adverse reaction to ONE, or contraindication to ALL of the following:
    - i. Enbrel (etanercept)
    - ii. Humira (adalimumab)
    - iii. infliximab
    - iv. Stelara (ustekinumab)
    - v. Taltz (ixekizumab)
  - b. Documentation of positive response to treatment for an acute pustular psoriasis flare using Spevigo vial (spesolimab-sbzo)
4. Appropriate dosing

## Continuation of Therapy

*For subcutaneous Spevigo in maintenance therapy in members not experiencing an acute GPP flare:*  
Resubmission by prescriber will infer a positive response to therapy.

## Limitations

1. Initial approvals
  - a. For intravenous Spevigo in management of acute GPP flares: up to 2 doses to be given within 1 month
  - b. For subcutaneous Spevigo in maintenance of GPP remission: 6 months
2. Reauthorizations
  - a. For intravenous Spevigo in management of acute GPP flares: if a member has only received one dose, a second dose may be approved as long as the two doses are administered at least a week apart. Maximum lifetime dose has not been established. Additional doses beyond 2 doses will be reviewed on a case-by-case basis.
  - b. For subcutaneous Spevigo in maintenance therapy in members not experiencing an acute GPP flare: 12 months

## References

1. Spevigo® [package insert]. Ridgefield (CT): Boehringer Ingelheim Pharmaceuticals, Inc.; 2022 Jun.
2. FDA Approves Spevigo for Treatment of Generalized Pustular Psoriasis Flares in Adults [press release on the internet]. PharmacyTimes; 2022 Sep 12 [cited 2022 Sep 17]. Available from: <https://www.pharmacytimes.com/view/fda-approves-spevigo-for-treatment-of-generalized-pustular-psoriasis-flares-in-adults>.

## Review History

Reviewed and created for P&T. Matched MH UPPL criteria to be in compliance with Masshealth unified formulary requirements. Effective 4/1/23.

10/9/24 – Reviewed and updated for P&T. Pharmacy criteria for Spevigo vial and syringe will be available on MHDL, while medical criteria will be managed on the MGBHP website. Added maintenance therapy for GPP per labeling. Added pediatric dosing following FDA approval. Effective 11/1/24

