Mass General Brigham
Health Plan

Spevigo SC (spesolimab-sbzo)
Effective 01/01/2026

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview
Spevigo (spesolimab-sbzo) is an interleukin-36 receptor 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 kilograms.

The subcutaneous formulations is approved for the treatment of GPP when not experiencing a flare.

Coverage Guidelines
Authorization may be granted for members who are new to the plan within the last 90 days currently receiving treatment with the 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, and documentation is provided:

Spevigo SC:
1. The member has a diagnosis of generalized pustular psoriasis (GPP)
2. The member has a Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of 0 or 1
3. The member is 12 years of age or older
4. The member weighs at least 40 kilograms
5. The requested medication is prescribed by or in consultation with a dermatology specialist
6. The member is NOT experiencing a flare of GPP

Continuation of Therapy
Reauthorization may be granted when the following criteria are met:

1. Documentation of positive response to therapy with Spevigo

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months
2. The following quantity limitations apply on the pharmacy benefit:

Drug Name and Dosage Form	Quantity Limitations
Spevigo SC prefilled syringe	4 syringes per 28 days

References

1. Bachelez H, Choon SE, Marrakchi S, et al. Trial of Spesolimab for Generalized Pustular Psoriasis. *N Engl J Med*. 2021;385(26):2431-2440.
2. Choon SE, Navarini AA, Pinter A. Clinical Course and Characteristics of Generalized Pustular Psoriasis. Am J Clin Dermatol. 2022 Jan;23(Suppl 1):21-29.
3. Fujita H, Gooderham M, Romiti R. Diagnosis of Generalized Pustular Psoriasis. *Am J Clin Dermatol*. 2022;23(Suppl 1):31-38.
4. Ly K, Beck KM, Smith MP, Thibodeaux Q, Bhutani T. Diagnosis and screening of patients with generalized pustular psoriasis. *Psoriasis (Auckl)*. 2019;9:37-42.
5. Morita A, Strober B, Burden AD, et al. Efficacy and safety of subcutaneous spesolimab for the prevention of generalized pustular psoriasis flares (Effisayil 2): an international, multicentre, randomized, placebo-controlled trial. *Lancet*. 2023;402:1542-1551.
6. Navarini AA, Burden AD, Capon F, et al. European consensus statement on phenotypes of pustular psoriasis. *J Eur Acad Dermatol Venereol*. 2017;31(11):1792-1799.
7. Spevigo [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; March 2024.
8. Zheng M, Jullien D, Eyerich K. The Prevalence and Disease Characteristics of Generalized Pustular Psoriasis. *Am J Clin Dermatol*. 2022;23(Suppl 1):5-12.

Review History

01/11/2023 – Created and Reviewed for January P&T. Effective 03/01/2023
08/14/2024 – Reviewed for August P&T. Added Spevigo SC to the policy for treatment of GPP. Updated criteria for Spevigo IV. Updated approvable age for Spevigo IV to 12 years of age and added minimum weight of 40 kg to align with updated FDA package labeling. Differentiated diagnosis requirements for GPP vs for GPP flare. Removed IL36RN, CARD14, and AP1S3 gene mutations from criteria. Updated Spevigo IV reauthorization criteria to require documentation that an additional dose for GPP flare is required. Removed TB screening requirement. Clarified step therapy language to indicate member must be new to the plan within the past 90 days. Effective 11/1/2024.
10/08/2025 - Reviewed at October P&T. Updated policy to reflect that it only applies to the SC formulation. Removed the IV from the policy. Updated policy to indicate it no longer applies to the medical benefit. Effective 01/01/2026.