Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drug
Spevigo® (spesolimab-sbzo)

Effective: January 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Public Plans Products

☒ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual-eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Generalized Pustular Psoriasis (GPP) is a rare, heterogenous and potentially life-threatening neutrophilic skin disease which is clinically different from plaque psoriasis. The disease is caused by neutrophils accumulating in the skin resulting in painful sterile pustules all over the body. If left untreated, GPP can be life threatening due to complications such as sepsis and multisystem organ failure. There are currently no widely accepted standard diagnosis criteria for GPP; however, the European Rare and Severe Psoriasis Expert Network (ERASPEN) consensus criteria can be used. ERASPEN states that GPP should only be diagnosed when the condition has relapsed at least once or when it persists for more than three months. GPP flares can erupt suddenly, escalate quickly, and require emergency care. GPP flares are characterized by a widespread eruption of pustules, erythema, and scaling and may occur with or without systemic inflammation. Short-term treatment goals for a GPP flare are to gain rapid control of pustules, improve other skin symptoms, and reduce systemic inflammation to prevent potential complications. Long-term treatment goals include prevention of new flares or disease worsening and improving patients' quality of life. Prior to the approval of Spevigo (spesolimab-sbzo), no Food and Drug Administration-approved treatments for GPP exist.

Approval of Spevigo for GPP flare is based on the 12-week, Phase 2 Effisayil-1 trial in 53 patients experiencing a moderate- to severe-intensity GPP flare. After one week, 54% of Spevigo-treated patients treated showed no visible pustules compared to 6% of placebo-treated patients. Per the Food and Drug Administration-approved package labeling, if GPP flare symptoms persist, an additional dose may be administered one week after the initial dose.

Approval of Spevigo for the treatment of GPP was based on results from the 48-week Effisayil-2 trial in which patients at least 12 years of age with a history of GPP who were treated with Spevigo, the risk of GPP flares was reduced by 84% compared to placebo.

Food and Drug Administration - Approved Indications

Spevigo (spesolimab-sbzo) is indicated for the treatment of generalized pustular psoriasis in adults and pediatric patients 12 years of age and older and weighting at least 40 kg.

Clinical Guideline Coverage Criteria

The plan may authorize Spevigo when **ALL** the following clinical criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of generalized pustular psoriasis

AND

2. Documentation of both of the following:
   a. Patient is at least 12 years of age or older
   b. Patient weighs at least 40 kg

AND

3. Prescribed by a dermatologist

Reauthorization Criteria

1. Documented diagnosis of generalized pustular psoriasis

AND

2. Documentation of both of the following:
    a. Patient is at least 12 years of age or older
    b. Patient weighs at least 40 kg

AND

3. Prescribed by a dermatologist

AND

4. Documentation the patient has experienced a therapeutic response as defined by a decrease in GPP flares

Limitations

- Initial approval of Spevigo will be authorized for six (6) months. Reauthorization of Spevigo will be provided in 12-month intervals.
- Members new to the plan stable on Spevigo should be reviewed against reauthorization criteria.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J1747	Injection, spesolimab-sbzo, 1 mg

References

1. Bachelez H, et al. Trial of spesolimab for generalized pustular psoriasis. N Engl J Med. 2021;385(26):2431–40.
2. Menter A, et al. Joint American Academy of Dermatology – National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020 June;82(6): 1445-86.
3. Menter A, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019 Apr;80(4):1029-72.
4. Navarini AA, et al. European consensus statement on phenotypes of pustular psoriasis. J Eur Acad Dermatol Venerol. 2017 June;31(11):1792-99.
5. Robinson A, et al. Treatment of pustular psoriasis: from the Medical Board of the National Psoriasis Foundation. J Am Acad Dermatol. 2012 Aug;67(2):279-88.
6. Spevigo (spesolimab-sbzo) [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc. March 2024.

Approval And Revision History

January 10, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T)

December 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

Subsequent endorsement date(s) and changes made:

- August 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024.
- November 2023: Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- January 9, 2024: Removed the Limitations Spevigo will only be approved for an FDA-approved indication. All other uses are considered experimental or investigational. Minor wording changes. Administrative update to clarify duration of authorizations by updating the Limitation to be Authorizations for Spevigo will be limited to two (2) doses and provided in one-month intervals (effective 2/1/2024).
- August 13, 2024: Updated coverage criteria to address expanded indication in treatment of GPP (eff 10/1/24).
- September 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 10/1/24).
- June 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template
- December 9, 2025: No changes (eff 1/1/26)
- December 2025: Joint Medical Policy and Health Care Services UM Committee review (effective 1/1/26)

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug

Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.