Harvard Pilgrim Health Care | TUFTS Health Plan

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

Effective: January 1, 2026

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

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ 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

Food and Drug Administration - Approved Indications

Spevigo (spesolimab-sbzo) is an interleukin-36 receptor antagonist 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 **one (1)** of the following:
    a. At least two (2) generalized pustular psoriasis flares
    b. The condition has persisted for more than three months

AND

3. Documentation of **one (1)** of the following:
    a. Patient is at least 18 years of age or older
    b. Both of the following:
        i. Patient is 12 to 17 years of age
        ii. Patient weighs at least 40 kg

AND

4. Prescribed by a dermatologist

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been receiving the requested medication for at least six (6) months

AND

2. Documented diagnosis of generalized pustular psoriasis

AND

3. Documentation of **one (1)** of the following:
    a. Patient is at least 18 years of age or older
    b. Both of the following:
        i. Patient is 12 to 17 years of age
        ii. Patient weighs at least 40 kg

AND

4. Prescribed by a dermatologist

AND

5. Submission of medical charts documenting the patient experienced a beneficial clinical response defined as reduction in GPP flares or prolonging time between flares from baseline

AND

6. Submission of medical charts documenting that compared to baseline, the patient has experienced an improvement in at least one symptom of generalized pustular psoriasis such as erythema, pain, itching, or pustules

AND

7. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Limitations

- Initial approval will be authorized for six (6) months. Reauthorization will be provided in 12-month intervals.
- A Member who has received less than six (6) months of therapy or who is restarting therapy with the requested drug is reviewed under Initial Authorization 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. May 2025.

Approval And Revision History

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

- January 10, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T)
- 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 9/1/24).
- September 9, 2025: No clinical changes. Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage and replace Tufts Health Unify with Tufts Health OneCare on the Medical Necessity Guideline template.

- October 14, 2025: Implementation of Commercial products only Medical Necessity Guideline. Added coverage criteria to prevent duplicative targeted immunomodulator therapy. Modified age requirements and Reauthorization Criteria (eff 1/1/26).

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

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.