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

Effective: February 1, 2024

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

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
☐ 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 flares in adults.

Clinical Guideline Coverage Criteria

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

1. Documented diagnosis of generalized pustular psoriasis

AND

2. Documentation the patient is experiencing a flare of moderate to severe intensity as defined by **one (1)** of the following:
    a. Generalized Pustular Psoriasis Physician Global Assessment total score of at least 3
    b. All of the following:
        i. Generalized Pustular Psoriasis Physician Global Assessment pustulation subscore of at least 2
        ii. New or worsening pustules
        iii. Erythema and presence of pustules covering at least 5% of body surface area

AND

3. Patient is at least 18 years of age

AND

4. Prescribed by or in consultation with a dermatologist

Limitations

- Authorizations for Spevigo will be limited to two (2) doses and provided in one-month intervals.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

None

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. 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.
5. Spevigo (spesolimab-sbzo) [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc. September 2022.

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).

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.