Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drug

Spevigo® (Spesolimab-sbzo)

Effective: April 1, 2023

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

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 Unify* – OneCare Plan (a dual-eligible product); Fax 617-673-0956
*The MNG applies to Tufts Health Unify 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

Approval of Spevigo 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.

Food and Drug Administration (FDA) Approved Indications:

Spevigo® (spesolimab-sbzo) is monoclonal antibody that blocks the activation of the interleukin -36 receptor (IL-36R), a protein that promotes inflammation in generalized pustular psoriasis (GPP) and the key part of signaling treat adults experiencing life-threatening flare ups of GPP

Clinical Guideline Coverage Criteria

The Plan may cover Spevigo (Spesolimab-sbzo) when all the following clinical criteria is met:

1. The Member has a diagnosis of Generalized Pustular Psoriasis

AND

2. The Member is experiencing a flare of moderate to severe intensity with a Generalized Pustular Psoriasis Physician Global Assessment (GPPGA)* total score of ≥ 3

OR

3. The Member is experiencing a flare of moderate to severe intensity with a GPPGA* pustulation sub score of ≥ 2 points that is accompanied by new or worsening pustules and erythema and pustules which affect ≥ 5% of body surface area (BSA)

AND

4. The Member is at least 18 years of age.

AND

5. The requested medication has been prescribed by a dermatologist or recommended in consultation with a dermatologist

*__NOTE:__ The GPPPGA score is adapted from the Physician Global Assessment, a tool physicians use to assess psoriatic lesions. The GPPPGA is used to assess the severity of pustules, scaling, and erythema, using a 5-point scale ranging from 0 to 4, with higher score indicating greater disease severity.

Limitations

- Spevigo will only be approved for an FDA-approved indication. All other uses are considered experimental or investigational.
- Authorization will be limited to 2 doses of Spevigo

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

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

References:

1. IPD Analytics; Rx insights New Drug Review Spevigo; accessed December 14,2022
2. Journal Of American Academy of Dermatology; accessed December 14,2022 Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies - Journal of the American Academy of Dermatology (jaad.org)
3. Spevigo (Spesolimab-sbzo) [package insert].Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc. September 2022. accessed December 14,2022 at GPP Treatment - FDA Approved | Spevigo® (spesolimab-sbzo) Injection for intravenous use (boehringer-ingelheim.com)
4. Clinical trial data last updated March 9,2022 accessed December 16/2022 Effisayil™ 1: A Study to Test Spesolimab (BI 655130) in Patients With a Flare-up of a Skin Disease Called Generalized Pustular Psoriasis - Full Text View - ClinicalTrials.gov
5. Boehringer Ingelheim press release September 1,2022 accessed December 16,2022 FDA approves the first treatment option for generalized pustular psoriasis flares in adults | boehringer-ingelheim.us
6. UpToDate accessed December 16,2022,pevigo Spesolimab: Drug information - UpToDate
7. Menter A, et al. Joint American Academy of Dermatology - National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. JAAD. 2020 June;82(6):P1445-1486.
8. 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.
9. Menter A, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. JAAD. 2019 Feb;80(4):P1029-1027.
10. Bachelez H, et al. Trial of spesolimab for generalized pustular psoriasis. N Engl J Med. 2021;385(26):2431–2440.
11. Krueger J, et al. Treatment options and goals for patients with generalized pustular psoriasis. Am J Clin Dermatol. 2022;23(Suppl 1):51–64.
12. Zheng M, et al. The prevalence and disease characteristics of generalized pustular psoriasis. Am J Clin Dermatol. 2022;23(1):5–12

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.

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 guidelines 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.