Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

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

Generalized Pustular Psoriasis (GPP) is a distinct skin disease that commonly occur in middle aged adults between 40 and 60 years of age. It is more common in women than men. GPP is a rare, heterogenous and potentially life-threatening neutrophilic skin disease which is clinically different from plaque psoriasis. GPP is caused by neutrophils accumulating in the skin resulting in painful sterile pustules all over the body. If left untreated, can be life threatening due to complications such as sepsis and multisystem organ failure. This chronic, systemic disease has a substantial quality of life impact for patients and increased healthcare burden. It is estimated that 1 out of every 10,000 people in US have GPP.

GPP is a rare, debilitating, systemic skin disease with life-threatening potential. 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.

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 are 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

None

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

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)

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.