Medical Necessity Guidelines
Medical Benefit Drug

Spevigo® (spesolimab-sbzo)

Effective: February 1, 2024

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

Applies to:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956
☒ CarePartners of Connecticut Medicare Advantage PPO plans, 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. 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

Approval of Spevigo (spesolimab-sbzo) for GPP 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.

Food and Drug Administration - Approved Indications

Spevigo (spesolimab-sbzo) is an interleukin-36 receptor antagonist indicated for the treatment of GPP flares in adults.

Clinical Guideline Coverage Criteria

The plan may authorize Spevigo when all the following clinical criteria is 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

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

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:

- 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).

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.