

Medical Policy:

Spevigo (spesolimab-sbzo), Intravenous Infusion

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.367	January 4, 2024	November 10, 2022

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Spevigo, an interleukin-36 receptor antagonist is indicated for the treatment of generalized pustular psoriasis flares in adults.

Length of Authorization

1 month (30 days)

Dosing Limits [Medical Benefit]

Approve the following dosing regimens (A, B, and C):

- A. Approve 900 mg per dose administered by intravenous (IV) infusion; **AND**
- B. If a second dose is administered, 7 days elapse between the doses; **AND**
- C. If this a new flare, at least 12 weeks have elapsed since the last dose of Spevigo.

Max Units (per dose and over time) [HCPCS Unit]:

- 900 mg (2 vials) on day 1 and 8

Guideline

I. Initial Criteria

- Generalized Pustular Psoriasis.** Approve for up to two doses if the patient meets **ALL** of the following criteria (A, B, C, and D):
 - Patient is ≥ 18 years of age; **AND**
 - Patient is experiencing a flare of moderate-to-severe intensity and meets all of the following (i, ii, iii, and iv)
 - Patient has Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of ≥ 3 points; **AND**
Note: The Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score ranges from 0 [clear skin] to 4 [severe disease].
 - Patient has a GPPGA pustulation subscore of ≥ 2 points; **AND**
 - Patient has new or worsening pustules; **AND**
 - Patient has erythema and pustules which affects $\geq 5\%$ of body surface area; **AND**
 - The medication is prescribed by or in consultation with a dermatologist; **AND**
 - If patient has already received Spevigo, patient meets both of the following criteria (i and ii):
 - Patient has not already received two doses of Spevigo for treatment of the current flare; **AND**
 - If this is a new flare, at least 12 weeks have elapsed since the last dose of Spevigo

Limitations/Exclusions

- Patient is not on concurrent treatment with a TNF-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast, tofacitinib, baricitinib, upadacitinib, etc.); **AND**
- Patient will not use concomitantly with systemic immunosuppressants (e.g., retinoids, cyclosporine, methotrexate, etc.) or other topical agents (e.g., corticosteroids, calcipotriene, tacrolimus, etc.); **AND**
- Patient does not have plaque psoriasis; **AND**
- Coverage may not be renewed

Applicable Procedure Codes

Code	Description
J1747	Injection, spesolimab-sbzo, 1mg

Applicable NDCs

Code	Description
00597-0035-10	Spevigo (spesolimab-sbzo) 60mg/mL (7.5mL vial)

ICD-10 Diagnoses

Code	Description
L40.1	Generalized pustular psoriasis

Revision History

Company(ies)	DATE	REVISION
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EmblemHealth & ConnectiCare	1/4/2024	Annual Review: Added Limitations and Exclusions, moved previous renewal criteria into initial criteria.
EmblemHealth & ConnectiCare	5/3/2023	Annual Review: Removed code J3590, add code J1747
EmblemHealth & ConnectiCare	11/10/2022	New Policy

References

1. Spevigo® intravenous infusion [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; September 2022.