Medical Policy:

Spevigo (spesolimab-sbzo), Intravenous Infusion and Subcutaneous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.367	February 13, 2025	November 10, 2022

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

Coverage will be provided for one Loading Dose:

Intravenous: Coverage will be provided for two doses (900mg each) and may not be renewed

Subcutaneous: Coverage will be provided for 1 loading dose of 600mg SC (four 150mg injections) x 1 dose only

Dosing Limits [Medical Benefit]

Approve the following IV dosing regimens- Treatment of GPP Flare (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.

Approve the following SC dosing regimen- Treatment of GPP When Not Experiencing a Flare:

A. 600 mg (four 150 mg injections) as a loading dose at week 0

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

- IV: 900 mg (2 vials) on day 1 and 8
- SC: 600mg (four 150 mg injections) on day 0

Guideline

I. Initial Criteria

Intravenous Loading dose:

1. **Generalized Pustular Psoriasis.** Approve for up to two doses if the patient meets **ALL** of the following criteria (A, B, C, and D):
   A. Patient is ≥ 12 years of age and weighs at least 40kg (88 lbs); **AND**
   B. Patient is experiencing a flare of moderate-to-severe intensity and meets **ONE** of the following (i **OR** ii):
      i. Patient is NOT currently receiving Spevigo Subcutaneous and meets ALL of the following a, b, c, **AND** d):
         a. 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].
         b. Patient has a GPPGA pustulation subscore of ≥ 2 points; **AND**
         c. Patient has new or worsening pustules; **AND**
         d. Patient has erythema and pustules which affects ≥ 5% of body surface area; **OR**
      ii. Patient IS currently receiving Spevigo subcutaneous and meets **BOTH** of the following (a and b):
         a. Patient has had an increase in Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of ≥ 2 points; **AND**
         b. Patient has Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) pustulation subscore of ≥ 2 points; **AND**
   C. The medication is prescribed by or in consultation with a dermatologist; **AND**
   D. If patient has already received Spevigo, patient meets both of the following criteria (i and ii):
      i. Patient has not already received two doses of Spevigo for treatment of the current flare; **AND**
      ii. If this is a new flare, at least 12 weeks have elapsed since the last dose of Spevigo

Subcutaneous Loading Dose:

2. **Generalized Pustular Psoriasis.**
   A. Patient is ≥ 12 years of age; **AND**
   B. Patient weighs ≥ 40 kilograms (kg); **AND**
   C. Patient has history of at least two generalized pustular psoriasis flares of moderate-to-severe intensity in the past; **AND**
   D. Patient has a Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of 0 or 1; **AND**
   E. Patient meets ONE of the following (i or ii):
      i. Patient meets BOTH of the following (a and b):
         a. Patient has had a 4-month trial of least one treatment for generalized pustular psoriasis; **AND**
            Note: Examples of treatment include methotrexate, acitretin, cyclosporine, or biologics.
         b. Patient has had a history of flaring while on treatment or with dose reduction or discontinuation of treatment; **OR**
      ii. Patient has tried at least one treatment for generalized pustular psoriasis but was unable to tolerate a 4-month trial; **AND**
   F. The medication is prescribed by or in consultation with a dermatologist.

Limitations/Exclusions

Intravenous:

1. 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.) for the treatment of generalized pustular psoriasis; **AND**
3. Patient does not have plaque psoriasis; **AND**
4. Coverage may not be renewed

Subcutaneous:

1. Concomitant use with Another Biologic or Disease-Modifying Antirheumatic Drugs (DMARD) Prescribed for Treatment of Generalized Pustular Psoriasis; **AND**
2. Plaque Psoriasis

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)
00597-0620-xx	Spevigo 150 mg/mL two-pack single-dose pre-filled syringe for subcutaneous use

ICD-10 Diagnoses

Code	Description
L40.1	Generalized pustular psoriasis

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/13/2025	Annual Review: Intravenous Loading dose: Generalized Pustular Psoriasis. Added: "Patient is NOT currently receiving Spevigo Subcutaneous and meets ALL of the following a, b ,c, AND d):" to the current criteria Added: "Patient IS currently receiving Spevigo subcutaneous and meets BOTH of the following (a and b): Patient has had an increase in Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of ≥ 2 points; AND Patient has Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) pustulation subscore of ≥ 2 points; AND" as an alternative pathway. Renewal Criteria: Intravenous: Added:" for the treatment of generalized pustular psoriasis" to the following statement: "_ 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.) for the treatment of generalized pustular psoriasis" Removed: " 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"

EmblemHealth & ConnectiCare	6/28/2024	Revision: Updated Policy name to include Subcutaneous. Updated length of authorization and dosing limits; added all subcutaneous criteria and exclusions.
EmblemHealth & ConnectiCare	3/25/2024	Annual Review: updated age range to include 12 years and older and weigh at least 40kg (88 lbs)
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.