Corporate Medical Policy: Spesolimab-sbzo (Spevigo®) **"Notification"** **POLICY EFFECTIVE NOVEMBER 1, 2025**

Restricted Product(s):

- spesolimab-sbzo (Spevigo®) intravenous infusion and subcutaneous injection for administration by a healthcare professional

FDA Approved Use:

- For treatment of generalized pustular psoriasis (GPP) in adults and pediatric patients 12 years of age and older and weighing at least 40 kg

Criteria for Medical Necessity:

The restricted product(s) may be considered medically necessary when the following criteria are met:

1. The patient is 12 years of age or older and weighs at least 40 kg; **AND**
2. The patient has a diagnosis of generalized pustular psoriasis (GPP); **AND**
3. If the request is for intravenous administration, the patient is experiencing a moderate to severe flare of GPP; **AND**
    a. The patient has NOT received treatment with 2 or more infusions of the requested agent for the current flare; **AND**
4. If the request is for subcutaneous administration, ALL of the following:
    a. The patient is NOT experiencing a moderate to severe flare of GPP; **AND**
    b. ONE of the following:
        i. The patient has a physical or cognitive limitation that makes the utilization of a self-administered formulation unsafe or otherwise not feasible, as demonstrated by BOTH of the following **[medical record documentation required]**:
            1. Inability to self-administer the medication; **AND**
            2. Lack of caregiver or support system for assistance with administration of self-administered products; **OR**
        ii. The request is for the 150 mg/mL prefilled syringe AND the requested agent will be administered as a 600 mg subcutaneous loading dose; **AND**
5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis; **AND**
6. The patient does NOT have any FDA labeled contraindications to the requested agent; **AND**
7. The patient has been tested for latent tuberculosis (TB) when required by the prescribing information for the requested agent AND if positive the patient has begun therapy for latent TB; **AND**
8. The requested quantity (dose) is within FDA labeled dosing for the requested indication; **AND**
9. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below); **AND**

10. For requests for injection or infusion administration of the requested medication in an **inpatient or outpatient hospital setting,** Site of Care Criteria applies (outlined below)*

Duration of Approval:
IV: 30 days (1 month)
SC: 365 days (1 year)

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
spesolimab-sbzo (Spevigo®) intravenous (IV) infusion, subcutaneous (SC) injection	Generalized pustular psoriasis in patients ≥ 12 years old weighing at least 40 kg	SC for treatment of GPP when not experiencing a flare: Loading dose (LD) of 600 mg SC followed by 300 mg SC 4 weeks later and every 4 weeks thereafter • Initiating or reinitiating SC after IV treatment of a GPP flare: 4 weeks after IV treatment of a flare, initiate or reinitiate SC GPP treatment at a dose of 300 mg SC every 4 weeks (SC LD not required following IV treatment of a flare) • If a GPP flare occurs while receiving SC GPP treatment, IV treatment may be administered for the flare IV for treatment of GPP flare: Administer IV as a single 900 mg dose. If flare symptoms persist, may administer an additional 900 mg dose IV one week after initial dose.	J1747	IV:1,800 SC: 4,200

***Maximum units allowed for duration of approval**

***Site of Care Medical Necessity Criteria**

1. For requests for injection or infusion administration in an **inpatient setting**, the injection or infusion may be given if the above medical necessity criteria are met AND the inpatient admission is NOT for the sole purpose of administering the injection or infusion; **OR**

2. For requests for injection or infusion administration in an **outpatient hospital setting**, the injection or infusion may be given if the above medical necessity criteria are met AND ONE of the following must be met:
    a. History of a severe adverse event following the injection or infusion of the requested medication (i.e., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure); **OR**
    b. Conditions that cause an increased risk for severe adverse event (i.e., unstable renal function, cardiopulmonary conditions, unstable vascular access); **OR**
    c. History of mild adverse events that have not been successfully managed through mild pre-medication (e.g., diphenhydramine, acetaminophen, steroids, fluids, etc.); **OR**
    b. Inability to physically and cognitively adhere to the treatment schedule and regimen complexity; **OR**
    c. New to therapy, defined as initial injection or infusion OR less than 3 months since initial injection or infusion; **OR**
    d. Re-initiation of therapy, defined as ONE of the following:
        i. First injection or infusion after 6 months of no injections or infusions for drugs with an approved dosing interval less than 6 months duration; **OR**
        ii. First injection or infusion after at least a 1-month gap in therapy outside of the approved dosing interval for drugs requiring every 6 months dosing duration; **OR**
    e. Requirement of a change in the requested restricted product formulation; **AND**
3. If the Site of Care Medical Necessity Criteria in #1 or #2 above are not met, the injection or infusion will be administered in a **home-based infusion** or physician office setting with or without supervision by a certified healthcare professional.

References: all information referenced is from FDA package insert unless otherwise noted below.

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q1 annually.

November 2025: Criteria change: Added requirement for self-administration unless certain criteria are met, or the request is for the 150 mg/mL prefilled syringe to be used as a 600 mg SC loading dose. Added Site of Care medical necessity criteria. Minor adjustments made throughout policy and to formatting for clarity according to FDA label. **Policy notification given 9/1/2025 for effective date 11/1/2025**.
May 2024: Criteria change: Added newly approved subcutaneous formulation and expanded indication to treatment of GPP in patients 12 years of age and older and weighing at least 40 kg, according to updated FDA labeling; added associated dosing and maximum units to FDA label reference table.
April 2023: Coding update: Added HCPCS code J1747 to dosing reference table effective 4/1/2023; deleted C9399, J3490, and J3590 termed 3/31/2023.
April 2023: Original medical policy criteria issued. **Policy notification given 12/30/2022 for effective date 4/1/2023**.