# AvMed

## MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

**Directions:** **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

**For Medicare Members:** Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

**Drug Requested: Spevigo®** (spesolimab-sbzo) **(J1747) (Medical)**

**MEMBER & PRESCRIBER INFORMATION:** Authorization may be delayed if incomplete.

**Member Name:** _____

**Member AvMed #:** _____ **Date of Birth:** _____

**Prescriber Name:** _____

**Prescriber Signature:** _____ **Date:** _____

**Office Contact Name:** _____

**Phone Number:** _____ **Fax Number:** _____

**NPI #:** _____

**DRUG INFORMATION:** Authorization may be delayed if incomplete.

**Drug Name/Form/Strength:** _____

**Dosing Schedule**: _____ **Length of Therapy**: _____

**Diagnosis:** _____ **ICD Code, if applicable:** _____

**Weight (if applicable):** _____ **Date weight obtained:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

## Dosing Limits

**A. Quantity Limit (max daily dose) [NDC Unit]:**

- **Spevigo 450 mg/7.5 mL (60 mg/mL) two-pack single-dose vial (SDV): 00597-0035-xx**
- **Spevigo 450 mg/7.5 mL solution in an SDV: 2 vials one time only**

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

- **900 mg (2 vials) on day 1**

***NOTE: Spevigo has NOT been studied in patients with plaque psoriasis without generalized pustular psoriasis and will NOT be permitted for treatment of this condition.**

**(Continued on next page)**

**The Health Plan considers the use of concomitant therapy with more than one biologic immunomodulator (e.g., Dupixent, Entyvio, Humira, Rinvoq, Stelara) prescribed for the same or different indications to be experimental and investigational. Safety and efficacy of these combinations has NOT been established and will NOT be permitted.**

**CLINICAL CRITERIA:** Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

## ❑ Diagnosis: Generalized Pustular Psoriasis (GPP) flare

**Initial Authorization: For one initial 900 mg dose [2 vials] of Spevigo® (spesolimab-sbzo) at the beginning of each Generalized Pustular Psoriasis (GPP) flare**

- ❑ Member is 12 years of age or older and weighs at least 40 kg
- ❑ Medication is prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist in the treatment of psoriasis
- ❑ Member has a known documented history of GPP (either relapsing [≥1 episode] or persistent [≥3 months] and is experiencing an acute, moderate-to-severe intensity disease flare
- ❑ Member is presenting with primary, sterile, macroscopically visible pustule on non-acral skin (excluding cases where pustulation is restricted to psoriatic plaques)
- ❑ Diagnosis of GPP flare has been confirmed by documentation of at least **ONE** of the following **(verified by chart notes)**:
  - ❑ IL36RN, CARD14, or AP1S3 gene mutation
  - ❑ Skin biopsy confirming presence of Kogoj's spongiform pustules
  - ❑ Systemic symptoms or laboratory abnormalities commonly associated with GPP flare (e.g., fever, asthenia, myalgia, elevated C-reactive protein [CRP], leukocytosis, neutrophilia [above ULN]
  - ❑ GPP flare of moderate-to-severe intensity (BSA ≥ 5% covered with erythema and the presence of fresh pustules, GPPPGA total score ≥ 3, GPPPGA pustulation sub score ≥ 2 (mild) )
- ❑ Member has received all age-appropriate vaccinations according to current immunization guidelines prior to initiating treatment
- ❑ Member does **NOT** have any of the following conditions
  - Synovitis-acne-pustulosis-hyperostosis-osteitis (SAPHO) syndrome
  - Primary erythrodermic psoriasis vulgaris
  - Primary plaque psoriasis vulgaris without presence of pustules or with pustules that are restricted to psoriatic plaques
  - Drug-triggered Acute Generalized Exanthematous Pustulosis (AGEP)
- ❑ Member has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment
- ❑ Member does **NOT** have an active infection, including clinically important localized infections

**(Continued on next page)**

- ❑ Member will **NOT** receive live vaccines during therapy
- ❑ Member is **NOT** on concurrent treatment with an IL-inhibitor, TNF-inhibitor, biologic response modifier or other non-biologic agent (e.g., apremilast, abrocitinib, tofacitinib, baricitinib, upadacitinib, deucravacitinib)
- ❑ Member will **NOT** use concomitantly with systemic immunosuppressants (e.g., retinoids, cyclosporine, methotrexate) or other topical agents (e.g., corticosteroids, calcipotriene, tacrolimus)

## ❑ Diagnosis: Generalized Pustular Psoriasis (GPP) flare

**Reauthorization: For 2 additional vials (1 additional carton) one week after the initial dose for treatment of the same GPP flare.** Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member is still experiencing persistent symptoms of an acute flare of GPP of moderate to severe intensity, as defined by **BOTH** of the following:
  - ❑ Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) score of at least 2
  - ❑ GPPGA pustulation sub score of at least 2 (i.e., moderate to very high-density pustules)
- ❑ Second infusion will take place no sooner than one week after the initial infusion

**NOTE**: For a new flare, refer to initial authorization criteria

## Medication being provided by (check applicable box below):

- ❑ **Location/site of drug administration:** _____
- ❑ **NPI or DEA # of administering location:** _____

**OR**

- ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****