OPTIMA HEALTH PLAN

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 1-844-668-1550**. 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) **(J1747) (Medical)**

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

Member Name: _____

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

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

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

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

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

Diagnosis: _____ **ICD Code:** _____

Weight: _____ **Date:** _____

❑ 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.**

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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.

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 at least 18 years of age
- ❑ Medication is prescribed by or in consultation with a dermatologist
- ❑ Member is experiencing an acute, moderate-to-severe intensity disease flare as defined by **ALL** the following **(verified by chart notes)**:
  - ❑ GPP-PGA total score of at least 3 (moderate) or greater
  - ❑ Presence of fresh pustules (new appearance or worsening of pustules)
  - ❑ GPP-PGA pustulation sub score of at least 2 (mild)
  - ❑ At least 5% of body surface area (BSA) covered with erythema and the presence of pustules
- ❑ If applicable: Member has previously received Spevigo treatment for a prior GPP flare, member achieved clinical response, as defined as achieving a GPPGA score of 0 or 1, to previous treatment but is now experiencing a new flare **AND** at least 12 weeks have elapsed since the last dose of Spevigo was administered **(verified by chart notes)**
- ❑ 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
- ❑ Member will **NOT** receive live vaccines during therapy
- ❑ Member is **NOT** on concurrent treatment with a TNF-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast, tofacitinib, baricitinib, upadacitinib)
- ❑ Member will **NOT** use concomitantly with systemic immunosuppressants (e.g., retinoids, cyclosporine, methotrexate) or other topical agents (e.g., corticosteroids, calcipotriene, tacrolimus)

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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

Medication being provided by a Specialty Pharmacy - PropriumRx

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

OR

- ❑ **Specialty Pharmacy - PropriumRx**

For urgent reviews: Practitioner should call Optima Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Optima'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.****