RX.PA.112.MPC Spevigo® (spesolimab-sbzo)

The purpose of this policy is to define the prior authorization process for Spevigo® (spesolimab-sbzo**).** Spevigo® (spesolimab-sbzo) is an interleukin-36 receptor antagonist indicated for the treatment of generalized pustular psoriasis (GPP) in adults and pediatric patients 12 years of age and older and weighing at least 40kg.

PROCEDURE

A. Initial Authorization Criteria

1. Generalized Pustular Psoriasis (GPP) Active Flare

- Member is ≥ 12 years of age
- Member weighs ≥ 40kg
- Must have a documented generalized active pustular psoriasis flare with a known and documented history of GPP with previous evidence of at least one of the following:
  - Fever, and/or
  - Asthenia, and/or
  - Myalgia, and/or
  - Elevated C-reactive protein, and/or
  - Leucocytosis with peripheral blood neutrophilia (per ERASPEN criteria) regardless of IL-36RN gene mutation status.
- Must have a documented Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of at least 2 or more
- Must have documentation of at last 5% of the body surface area coverage with erythema and the presence of pustules
- Must not have any of the following:
  - SAPHO (Synovitis-acne-pustulosis-hyperostosis-osteitis) 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
  - Immediate life-threatening flare of GPP or requiring intensive care treatment, according to the investigator's judgement. Life-threatening complications mainly include, but are not limited to, cardiovascular/cytokine driven shock, pulmonary distress syndrome, or renal failure.
  - Severe, progressive, or uncontrolled hepatic disease, defined as >3- fold

    Upper Limit of Normal (ULN) elevation in AST or ALT or alkaline phosphatase, or >2-fold ULN elevation in total bilirubin

- Documented failed treatment to at least two systemic therapies or contraindication/intolerance to all listed below:
  - cyclosporine
  - mycophenolate mofetil
  - methotrexate
  - systemic retinoids
  - infliximab

- Must be prescribed by or in consultation with a dermatologist
- Must not be used concurrently with other biologics for treatment of Generalized Pustular Psoriasis

2. **Generalized Pustular Psoriasis, Not experiencing a flare**
   - Member is ≥ 12 years of age
   - Member weighs ≥ 40kg
   - Must have a documented diagnosis and a history of at least two moderate to severe Generalized Pustular Psoriasis flares with fresh pustulation with previous evidence of at least 1 of the following:
     - Fever, and/or
     - Asthenia, and/or
     - Myalgia, and/or
     - Elevated C-reactive protein, and/or
     - Leucocytosis with peripheral blood neutrophilia regardless of Interleukin 36 Receptor Antagonist (IL-36RN) gene mutation status.
   - Must have a current Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) pustulation sub-score of 0 or 1 Must not have any of the following:
     - SAPHO (Synovitis-acne-pustulosis-hyperostosis-osteitis) 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
     - Immediate life-threatening flare of GPP or requiring intensive care treatment, according to the investigator's judgement. Life-threatening complications mainly include, but are not limited to, cardiovascular/cytokine driven shock, pulmonary distress syndrome, or renal failure.
     - Severe, progressive, or uncontrolled hepatic disease, defined as >3- fold Upper Limit of Normal (ULN) elevation in AST or ALT or alkaline phosphatase, or >2-fold ULN elevation in total bilirubin

- Must have a documented history of frequent GPP flares in the past
- Documented failed treatment to at least two immunosuppressive therapies or contraindication/intolerance to all listed below:
    - cyclosporine
    - mycophenolate mofetil
    - methotrexate
    - systemic retinoids
    - infliximab
- Must be prescribed by or in consultation with a dermatologist
- Must not be used concurrently with other biologics for treatment of Generalized Pustular Psoriasis

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. <u>Reauthorization Criteria:</u>

<u>MPC Renewal:</u>

- Chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy
    - Documentation confirming that the member has had a significant response to therapy, as assessed by an improvement in the Pustular Psoriasis Physician Global Assessment (GPPGA) Pustulation Subscore, and improvement in the Psoriasis Area and Severity Index for Generalized Pustular Psoriasis (GPPASI)
- Must be prescribed by or in consultation with a dermatologist

<u>Renewal from Previous Insurer:</u>

- Members who have received prior approval (from insurer other than MPC), or have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria)
- Provider has documented clinical response of the member's condition which has stabilized or improved based upon the prescriber's assessment

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 3 months
Reauthorization	Up to 1 year

APPLICABLE CODES:	
CODE	**DESCRIPTION**
J1747	Injection, spesolimab-sbzo, 1 mg

REFERENCES

1. Spevigo [package insert]. Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT 06877 USA.
2. Spevigo clinical trial NCT06013969

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/2026*
New Policy	*09/2025*