PRIOR AUTHORIZATION POLICY

POLICY: Inflammatory Conditions – Spevigo Prior Authorization Policy
- Spevigo® (spesolimab-sbzo intravenous infusion – Boehringer Ingelheim)

REVIEW DATE: 09/07/2022; selected revision 09/28/2022

OVERVIEW
Spevigo, an interleukin-36 receptor antagonist is indicated for the treatment of generalized pustular psoriasis flares in adults.

Guidelines
Spevigo is not listed in guidelines for generalized pustular psoriasis.

POLICY STATEMENT
Prior Authorization is recommended for prescription benefit coverage of Spevigo. Because of the specialized skills required for evaluation and diagnosis of patients treated with Spevigo, initial approval requires Spevigo to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for 1 month (30 days).

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Spevigo is recommended in those who meet the following criteria:

FDA-Approved Indication

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 ≥ 18 years of age; AND
   - **B)** Patient is experiencing a flare of a moderate-to-severe intensity and meets all of the following criteria (i, ii, iii, and iv)
     - **i.** 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].
     - **ii.** Patient has a GPPGA pustulation subscore of ≥ 2 points; AND
     - **iii.** Patient has new or worsening pustules; AND
     - **iv.** Patient has erythema and pustules which affects ≥ 5% of body surface area; AND
   - **C)** 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; AND
   - **D)** The medication is prescribed by or in consultation with a dermatologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Spevigo is not recommended in the following situations:

1. **Concomitant use with Another Biologic Prescribed for Treatment of Generalized Pustular Psoriasis.** Although not approved, there are case reports documenting use of some biologics approved for plaque psoriasis (see Appendix for examples) for treatment of generalized pustular psoriasis. In the pivotal study, patients were required to discontinue therapy for generalized pustular psoriasis prior to receiving Spevigo.
   Note: Patients with concomitant plaque psoriasis and generalized pustular psoriasis may be receiving a biologic for treatment of plaque psoriasis.

2. **Plaque Psoriasis.** Spevigo has not been studied in patients with plaque psoriasis without generalized pustular psoriasis.
   Note: Patients with concomitant plaque psoriasis and generalized pustular psoriasis may be reviewed under the generalized pustular psoriasis criteria above.

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Spevigo® intravenous infusion [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; September 2022.

Type of Revision	Summary of Changes	Review Date
New Policy	--	09/07/2022
Selected Revision	**Conditions Not Recommended for Approval:** Concurrent Use with a Disease-modifying Antirheumatic Drug or Retinoid was removed. Concurrent Use with a Biologic was reworded to say "Concomitant Use with Another Biologic Prescribed for Treatment of Generalized Pustular Psoriasis." A note was added to clarify that a patient with concomitant plaque psoriasis and generalized pustular psoriasis may be receiving a biologic for treatment of plaque psoriasis.	09/28/2022

APPENDIX

* Not an all-inclusive list of indications (e.g., oncology indications and rare inflammatory conditions are not listed). Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn's disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis.