UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Inflammatory Conditions – Spevigo Utilization Management Medical 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.

Dosing Information
Spevigo is given as a single 900 mg dose by intravenous (IV) infusion over 90 minutes. If the generalized pustular psoriasis flare symptoms persist, an additional 900 mg dose given IV (over 90 minutes) may be administered one week after the initial dose.

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

POLICY STATEMENT
Prior Authorization is recommended for medical benefit coverage of Spevigo. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for 1 month (30 days). Because of the specialized skills required for evaluation and diagnosis of patients treated with Spevigo approval requires Spevigo to be prescribed by or in consultation with a physician who specializes in the condition being treated.

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.

Dosing. Approve the following dosing regimens (A, B, and C):

A) Approve 900 mg per dose administered by intravenous (IV) infusion; AND

B) If a second dose is administered, 7 days elapse between the doses; AND

C) If this a new flare, at least 12 weeks have elapsed since the last dose of Spevigo.

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.

HISTORY

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

	Mechanism of Action	Examples of Inflammatory Indications*
Biologics		
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
Cimzia® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
Simponi®, Simponi® Aria™ (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA
Actemra® (tocilizumab IV infusion, tocilizumab SC injection)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	RA
Orencia® (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PsA, RA
		IV formulation: JIA, PsA, RA
Rituximab IV Products (Rituxan®, biosimilars)	CD20-directed cytolytic antibody	RA
Kineret® (anakinra SC injection)	Inhibition of IL-1	JIA^, RA
Stelara® (ustekinumab SC injection, ustekinumab IV infusion)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Siliq™ (brodalumab SC injection)	Inhibition of IL-17	PsO
Cosentyx® (secukinumab SC injection)	Inhibition of IL-17A	AS, ERA, nr-axSpA, PsO, PsA
Taltz® (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Ilumya™ (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Skyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PsA, PsO
		IV formulation: CD
Tremfya™ (guselkumab SC injection)	Inhibition of IL-23	PsO
Entyvio™ (vedolizumab IV infusion)	Integrin receptor antagonist	CD, UC

* 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.