VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Inflammatory Conditions – Spevigo Intravenous Utilization Management Medical Policy
- Spevigo® (spesolimab-sbzo intravenous infusion – Boehringer Ingelheim)

REVIEW DATE: 04/10/2024

OVERVIEW

Spevigo, an interleukin-36 receptor antagonist, is indicated for the treatment of generalized pustular psoriasis in adults and pediatric patients ≥ 12 years old and ≥ 40 kilogram (kg).[1]

Spevigo intravenous (IV) use is only for the treatment of generalized pustular psoriasis flares. IV infusion of Spevigo is only to be administered by a healthcare professional in a healthcare setting.[1]

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.[1]

Guidelines

Spevigo is not listed in guidelines for generalized pustular psoriasis. Treatment guidelines from the Medical Board of the National Psoriasis Foundation (2012) address the management of generalized pustular psoriasis in different clinical scenarios.[2] Recommended therapies include acitretin, cyclosporine, methotrexate, and infliximab for adults with generalized pustular psoriasis as first-line therapy. Second-line therapy includes Humira, Enbrel, topical therapy (e.g. corticosteroids, calcipotriene, and tacrolimus), and PUVA (psoralen and ultraviolet A). There are also separate recommendations for pediatric and pregnant patients.

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

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1. **Generalized Pustular Psoriasis Flare.** Approve for up to two doses if the patient meets ALL of the following (A, B, C, D, E and F:
   - **A)** Patient is ≥ 12 years of age; AND
   - **B)** Patient weighs ≥ 40 kilograms (kg); AND
   - **C)** Patient is experiencing a flare of a moderate-to-severe intensity; AND
   - **D)** Patient meets ONE of the following (i or ii):
     - **i.** Patient is not currently receiving Spevigo subcutaneous injection and meets ALL of the following (a, b, c, and d):
       - **a)** 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).
       - **b)** Patient has a Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) pustulation subscore of ≥ 2 points; AND
       - **c)** Patient has new or worsening pustules; AND
       - **d)** Patient has erythema and pustules which affects ≥ 5% of body surface area; OR
     - **ii**. Patient is currently receiving Spevigo subcutaneous injection and meets BOTH of the following (a and b):
       - **a)** Patient has had an increase in Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of ≥ 2 points; AND
       - **b)** Patient has Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) pustulation subscore of ≥ 2 points; AND
   - **E)** If patient has already received Spevigo intravenous, patient meets BOTH of the following (i and ii):
     - **i.** Patient has not already received two doses of Spevigo intravenous for treatment of the current flare; AND
     - **ii.** If patient has previously received two doses of Spevigo intravenous, at least 12 weeks have elapsed since the last dose of Spevigo; AND
   - **F)** 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 and subcutaneous injection [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; March 2024.
2. Robinson A, Van Voorhees AS, Hsu S, et al. Treatment of pustular psoriasis: from the medical board of the National Psoriasis Foundation. *J Am Acad Dermatol.* 2012;67(2):279-288.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	10/04/2023
Early Annual Revision	The name of the policy was changed to Inflammatory Conditions – Spevigo Intravenous UM Medical Policy. Previously it was Inflammatory Conditions – Spevigo UM Medical Policy. **Generalized Pustular Psoriasis Flare**: The word "flare" was added the condition of approval. The age requirement was changed from ≥ 18 years of age to ≥ 12 years of age. The weight requirement of ≥ 40 kilogram (kg) was added. Clarification was added that the following criteria apply to a patient who is not currently taking Spevigo subcutaneous: patient has Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of ≥ 3 points; and patient has a GPPGA pustulation subscore of ≥ 2 points; and patient has new or worsening pustules; and patient has erythema and pustules which affects ≥ 5% of body surface area. Criteria was added for patient currently taking Spevigo subcutaneous which are: patient has had an increase in GPPGA total score of ≥ 2 points and patient has GPPGA pustulation subscore of ≥ 2 points. Reference to Spevigo was reworded to Spevigo intravenous in the following criterion "if patient has already received Spevigo intravenous (IV), patient has not already received two doses of Spevigo IV for treatment of the current flare". The following criterion was reworded from "if this is a new flare" to state "if patient has previously received two doses of Spevigo IV" at least 12 weeks have elapsed since the last dose of Spevigo.	04/10/2024

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.