Drug Coverage Policy

Effective Date.....11/01/2024
Coverage Policy Number.....IP0649
Policy Title.....Spevigo Subcutaneous Prior Authorization Policy

Inflammatory Conditions – Spevigo Subcutaneous Prior Authorization Policy

- Spevigo® (spesolimab-sbzo subcutaneous injection - Boehringer Ingelheim)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

OVERVIEW

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

Spevigo subcutaneous is used for treatment of generalized pustular psoriasis when patient is not experiencing a flare. The recommended dosage of Spevigo subcutaneous for treatment of

generalized pustular psoriasis when not experiencing a flare in adults and pediatric patients ≥ 12 years of age and ≥ 40 kg is a loading dose of 600 mg (four 150 mg injections) followed by 300 mg (two 150 mg injections) administered subcutaneously 4 weeks later and every 4 weeks thereafter.

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.

Medical Necessity Criteria

POLICY STATEMENT
Prior Authorization is required for 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).

Spevigo subcutaneous is considered medically necessary when the following are met:

FDA-Approved Indication

1. **Generalized Pustular Psoriasis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, v, and vi):
     - **i.** Patient is ≥ 12 years of age; AND
     - **ii.** Patient weighs ≥ 40 kilograms (kg); AND
     - **iii.** Patient has history of at least two generalized pustular psoriasis flares of moderate-to-severe intensity in the past; AND
     - **iv.** Patient has a Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of 0 or 1; AND
     - **v.** Patient meets ONE of the following (a or b):
       - **a)** Patient meets BOTH of the following ([1] and [2]):
         - **(1)** Patient has had a 4-month trial of least one treatment for generalized pustular psoriasis; AND
           Note: Examples of treatment include methotrexate, acitretin, cyclosporine, or biologics.
         - **(2)** Patient has had a history of flaring while on treatment or with dose reduction or discontinuation of treatment; OR
       - **b)** Patient has tried at least one treatment for generalized pustular psoriasis but was unable to tolerate a 4-month trial; AND
     - **vi.** The medication is prescribed by or in consultation with a dermatologist.
   - **B)** Patient is Currently Receiving Spevigo Subcutaneous. Approve for 1 year if the patient meets BOTH of the following (i and ii):
     - **i.** Patient has been established on therapy for at least 6 months; AND

Note: A patient who has received < 6 months of therapy or who is restarting therapy should be considered under criterion A (Initial Therapy).

ii. Patient has experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating the requested drug) in at least one of the following: reduction of generalized pustular psoriasis flares or an improvement in Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) score.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Concomitant use with Another Biologic or Disease-Modifying Antirheumatic Drugs (DMARD) 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.

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.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	9/15/2024
Selected Revision	**Updated** policy title from "Inflammatory Conditions – Spevigo Subcutaneous" to "Inflammatory Conditions – Spevigo Subcutaneous Prior Authorization Policy"	11/01/2024

The policy effective date is in force until updated or retired.

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.