**Effective Date** ..... **2/15/2024**
**Next Review Date**… ..... **2/15/2025**
**Coverage Policy Number** ..... **IP0501**

# Spesolimab

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## Related Coverage Resources

***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. 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.*

## Overview

This policy supports medical necessity review for spesolimab-sbzo intravenous infusion (**Spevigo**®).

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

## Medical Necessity Criteria

**Spesolimab-sbzo (Spevigo) is considered medically necessary when the following are met:**

**Generalized Pustular Psoriasis, Moderate-to-Severe Flare.** Individual meets **ALL** of the following criteria:
A. 18 years of age or older
B. New or worsening pustules
C. Erythema and pustules affecting at least 5% of body surface area
D. The medication is prescribed by, or in consultation with, a dermatologist.

**Dosing for Generalized Pustular Psoriasis, Moderate-to-Severe Flare. BOTH** of following are met:
A. Up to two 900 mg doses, 7 days apart
B. If this a new flare, at least 12 weeks have elapsed since the last treatment course of Spevigo

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.

## Authorization Duration

Approval duration: 3 months

## Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

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.

2. **Plaque Psoriasis.** Spevigo has not been studied in individuals with plaque psoriasis without generalized pustular psoriasis.

## Coding

1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

| HCPCS Codes | Description |
|---|---|
| J1747 | Injection, spesolimab-sbzo, 1 mg (Code effective 04/01/2023) |

## Background

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

## References

1. Spevigo® intravenous infusion [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; September 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 |
| **Oral Therapies/Targeted Synthetic DMARDs** | | |
| **Otezla®** (apremilast tablets) | Inhibition of PDE4 | PsO, PsA |
| **Cibinqo™** (abrocitinib tablets) | Inhibition of JAK pathways | AD |
| **Olumiant®** (baricitinib tablets) | Inhibition of JAK pathways | RA |
| **Rinvoq®** (upadacitinib extended-release tablets) | Inhibition of JAK pathways | AD, AS, RA, PsA, UC |
| **Xeljanz®** (tofacitinib tablets) | Inhibition of JAK pathways | RA, PJIA, PsA, UC |
| **Xeljanz® XR** (tofacitinib extended-release tablets) | Inhibition of JAK pathways | RA, PsA, 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.*