PRIOR AUTHORIZATION POLICY

POLICY: Inflammatory Conditions – Spevigo Intravenous Prior Authorization 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 of age and ≥ 40 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]

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 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 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 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; AND

ii. Patient is currently receiving Spevigo subcutaneous 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.

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.

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.