PRIOR AUTHORIZATION POLICY

POLICY: Inflammatory Conditions – Spevigo Subcutaneous Prior Authorization Policy
- Spevigo® (spesolimab-sbzo subcutaneous injection – Boehringer Ingelheim)

REVIEW DATE: 04/10/2024

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.

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 subcutaneous is recommended in those who meet the following criteria:

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 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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Spevigo is not recommended in the following situations:

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.

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.