CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Arkansas PASSE

DRUG NAME	Spevigo (spesolimab-sbzo)
BILLING CODE	J3590
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Spevigo is an interleukin-36 receptor antagonist initially approved by the FDA in 2022. It is the first treatment specifically approved for Generalized Pustular Psoriasis flares and the first IL-36 receptor antagonist to be approved. GPP is a rare, potentially life-threatening neutrophilic skin condition, and individuals with GPP typically experience episodes of widespread eruptions of painful, sterile pustules. While the severity of GPP flares can vary, if left untreated they can be life-threatening due to complications such as sepsis and multisystem organ failure. A preceding history of plaque psoriasis may or may not be present in individuals presenting with GPP. Spevigo was studied in the Effisayil-1 trial, a randomized, double-blind, placebo-controlled trial comparing a single intravenous 900 mg dose of Spevigo with placebo in subjects with generalized pustular psoriasis flare. In the trial, which lasted for 12 weeks, 53 patients experiencing a GPP flare were randomized to receive either Spevigo or placebo. At the beginning of the trial, most patients had a high or very high density of pustules and impaired quality of life. After 1 week, 54% of patients treated with Spevigo showed no visible pustules, compared with 6% of patients receiving placebo.

Spevigo (spesolimab-sbzo) will be considered for coverage when the following criteria are met:

Generalized Pustular Psoriasis

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has a diagnosis of Generalized Pustular Psoriasis (GPP);
4. Member has an acute flare of GPP of moderate to severe intensity, defined by ALL of the following:
   a. Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of at least 3;
   b. Presence of fresh pustules (new appearance or worsening of pustules);
   c. GPPPGA pustulation sub score of at least 2; AND
   d. At least 5% of body surface area covered with erythema and the presence of pustules; AND
5. Member does NOT have any of the following:
   a. Pustulation restricted to psoriatic plaques;
   b. Active tuberculosis infection.
6. **Dosage allowed/Quantity limit**: Administer a single 900 mg (2 vials) dose by intravenous infusion over 90 minutes. If flare symptoms persist, administer an additional intravenous 900 mg dose one week after the initial dose. Quantity Limit: 4 vials per 365 days.

If all the above requirements are met the medication will be approved for 3 weeks.

For **reauthorization**:
Medication will not be authorized for continuous use.

CareSource considers Spevigo (spesolimab-sbzo) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
09/21/2022	New policy for Spevigo created.

References:

1. Spevigo [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; September 2022.
2. Bachelez H, Choon SE, Marrakchi S, et al; for the Effisayil 1 Trial Investigators. Trial of spesolimab for generalized pustular psoriasis. *N Engl J Med.* 2021;385(26):2431-2440.
3. Navarini AA, Burden AD, Capon F, et al. European consensus statement on phenotypes of pustular psoriasis. J Eur Acad Dermatol Venereol 2017;31:1792-9.
4. Hoegler KM, John AM, Handler MZ, Schwartz RA. Generalized pustular psoriasis: a review and update on treatment. J Eur Acad Dermatol Venereol. 2018 Oct;32(10):1645-1651.

Effective date: 03/01/2024
Revised date: 09/21/2022