spesolimab SC (Spevigo®)

EOCCO POLICY

Policy Type:PA/SP Pharmacy Coverage Policy: EOCCO311

Description

Spesolimab SC (Spevigo) is an IL-36 receptor antagonist that is administered subcutaneously.

Length of Authorization

- Initial: Six months
- Renewal: 12 months

Quantity Limits

Product Name	Indication	Dosage Form	Quantity Limit
spesolimab SC (Spevigo)	Generalized pustular psoriasis (GPP), when not experiencing a flare	150 mg/mL pre-filled syringe	2 mL/28 days

Initial Evaluation

I. **Spesolimab SC (Spevigo)** may be considered medically necessary when the following criteria are met:
   A. Member is 12 years of age or older; **AND**
   B. Medication is prescribed by, or in consultation with, a dermatologist; **AND**
   C. Medication will not be used in combination with any of the following:
      1. Systemic immunomodulators (e.g., retinoids); **AND**
      2. Systemic immunosuppressants (e.g., cyclosporine, methotrexate, etc.); **AND**
      3. Biologic agents [e.g., Taltz (ixekizumab), Siliq (brodalumab), Stelara (ustekinumab), Skyrizi (risankizumab), Cimzia (certolizumab), Simponi (golimumab), etc.]; **AND**
      4. Other non-biologic specialty agents [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), etc.]; **AND**
   D. Documentation member weighs at least 40 kg; **AND**
   E. Documentation member has a diagnosis of **generalized pustular psoriasis (GPP)**; **AND**
   F. Provider attestation medication is intended for use of generalized pustular psoriasis (GPP) flare prevention; **AND**
   G. Provider attestation member has experienced at least one generalized pustular psoriasis (GPP) flare

II. Spesolimab SC (Spevigo) is considered investigational when used for all other conditions, including but not limited to:
   A. Pyoderma gangrenosum
   B. Palmoplantar pustulosis

C. Crohn's disease
D. Hidradenitis suppurativa
E. Ulcerative colitis
F. Atopic eczema
G. Netherton syndrome
H. Plaque psoriasis

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan or has been established on therapy from a previous health plan; **AND**
II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise. If they have, initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
III. Documentation that member has exhibited improvement or stability of disease symptoms [e.g., reduction in flares, improved quality of life] **AND**
IV. Medication will not be used in combination with any of the following:
    A. Systemic immunomodulators (e.g., retinoids); **AND**
    B. Systemic immunosuppressants (e.g., cyclosporine, methotrexate, etc.); **AND**
    C. Biologic agents [e.g., Taltz (ixekizumab), Siliq (brodalumab), Stelara (ustekinumab), Skyrizi (risankizumab), Cimzia (certolizumab), Simponi (golimumab), etc.]; **AND**
    D. Other non-biologic specialty agents [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), etc.]

Supporting Evidence

I. Generalized pustular psoriasis (GPP) is a rare subtype of psoriasis that can develop independently or in association with pre-existing psoriasis. Generalized pustular psoriasis (GPP) differs from other forms of psoriasis because it presents as widespread skin plaques with pustules surrounded by erythematous skin with intense itching and/or pain throughout the body. Generalized pustular psoriasis (GPP) flares are often accompanied by systemic symptoms (e.g., high fever, chills, rapid pulse, fatigue, nausea, etc.) and may lead to hospitalizations. The duration of these flares varies, lasting for a few weeks to a few months before spontaneously clearing and remaining latent until re-exposure to a precipitating factor or for unknown reasons. Currently, GPP is diagnosed by provider assessments since there is no scoring tool or rubric that is used clinically. Historically, GPP is treated with off-label systemic immunomodulators, systemic immunosuppressants, biologics, and other non-biologic specialty agents. However, off-label treatments are supported by low-quality evidence (e.g., case reports, single arm open-label trials). Spesolimab SC (Spevigo) is the first medication to receive a specific indication for

the treatment of GPP when not experiencing a flare (i.e., for flare prevention). The goal of treatment is to improve quality of life by minimizing the recurrence of flares to reduce complications, hospitalizations, morbidity, and mortality associated with GPP.

II. Treatment with spesolimab (Spevigo) is considered medically necessary in those 12 years of age and older. This requirement is supported by Effisayil 2, the pivotal clinical trial that evaluated the safety and efficacy of spesolimab SC (Spevigo). This trial enrolled patients 12 years of age and older weighing at least 40 kg. In addition, the FDA-approved label requirement is also in those 12 years of age and older when used in treatment of GPP when not experiencing a flare. Per the package insert, pharmacokinetic analyses show similar drug exposure levels in adults and pediatric patients 12 years of age and older and weighing 40 kg or more. Due to uncertainties regarding adolescent organ development and ability to clear or metabolize spesolimab SC (Spevigo), current data does not support use of this product in members younger than 12 years of age.

III. Given the rarity and complexity of GPP, diagnosis and therapy choices should be directed by a specialist such as a dermatologist.

IV. Spesolimab SC (Spevigo) has not been adequately studied in combination with other off-label therapies used for the treatment of GPP. Participants in the Effisayil 2 trial were required to discontinue systemic and topical GPP therapy prior to or at randomization. However, the guidelines do support topical medications as adjunctive treatment options. Even though the use of spesolimab SC (Spevigo) in combination with topical medications hasn't been studied, there is less concern with them being used together due to lower systemic absorption with topical drugs and guideline support as adjunctive treatments. On the other hand, systemic immunomodulators, systemic immunosuppressants, biologics, and other non-biologic specialty agents pose a concern regarding safety due to additive systemic effects and drug-drug interactions. Thus, their use in combination with spesolimab SC (Spevigo) is considered experimental and investigational at this time.

V. A consensus statement from the National Psoriasis Foundation (NPF) states the diagnosis of GPP is made based on the assessment of clinical features such as recurrent episodes of disseminated, sterile, monomorphic pustules on a background of widespread erythema. The NPF states skin biopsy is not required for the diagnosis of GPP because histologic features may be nonspecific, and it may delay treatment. The NPF further states GPP phenotype classification criteria are informative for clinical trials, but it should not be used to deny or delay treatment in clinical practice.

VI. Spesolimab (Spevigo) has different routes of administration. It is available as a subcutaneous (SC) and an intravenous (IV) formulation. The FDA-approved indication and dosing is different for each dosage form. Spesolimab SC (Spevigo) is FDA-approved for the prevention of GPP flares; while, spesolimab IV (Spevigo) is FDA-approved for the treatment of GPP flares.

VII. The study population in the Effisayil 2 trial included patients that had at least two past GPP flares. Generalized pustular psoriasis (GPP) flares are difficult to diagnose; thus, having two

previous GPP flares helped identify true flare episodes in the pivotal trial. There is uncertainty in the benefit provided by spesolimab SC (Spevigo) for those with a history of one previous flare as this patient population has not been adequately studied and may not be representative of a patient population in need of preventative treatment. However, given the potential severe complications associated with each GPP flare (e.g., renal, hepatic, respiratory, or heart failures, etc.), history of one past GPP flare may be adequate to support medical necessity for preventative use. While there is a lack of literature regarding the incidence and timing of GPP flare recurrence, the information that is available suggests patients with GPP experience one flare every couple of years. There are multiple retrospective studies with follow-up data extending out as long as five years that suggest most patients experience at least one flare during that time frame.

VIII. The American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) guidelines for the management of psoriasis with biologics (2019) and systemic non-biologic therapies (2020) recommend cyclosporine, ixekizumab (Taltz), and brodalumab (Siliq) specifically for the treatment of generalized pustular psoriasis (strength of recommendation grade B with a level of evidence I-II, meaning the recommendation was based on good, inconsistent, or limited-quality patient-oriented evidence). The evidence supporting use of these therapies is of low-quality as the information and data come primarily from case reports and/or single arm, open-label trials.

Investigational or Not Medically Necessary Uses

I. Spesolimab SC (Spevigo) has not been FDA-approved, or sufficiently studied for safety and efficacy for the conditions or settings listed below:
   A. Pyoderma gangrenosum
      i. Spesolimab SC (Spevigo) is currently under investigation for the treatment of pyoderma gangrenosum in a Phase 2, open-label, single group assignment trial designed to evaluate change in global pyoderma gangrenosum (GPG) severity score in male or females subject $\geq$ 18 years of age with clinical diagnosed ulcerative pyoderma gangrenosum with PARACELSUS score $\geq$ 10. Primary completion is expected in September 2025. Requests for this indication are considered experimental and investigational at this time.
   B. Palmoplantar pustulosis
      i. There is currently no active trial evaluating the use of spesolimab SC (Spevigo) in patients with palmoplantar pustulosis. There is insufficient evidence to support the safety and efficacy of spesolimab SC (Spevigo) in this disease space. Requests for this indication are considered experimental and investigational at this time.
   C. Crohn's disease

i. There is currently no active trial evaluating the use of spesolimab SC (Spevigo) in patients with Crohn's disease. There is insufficient evidence to support the safety and efficacy of spesolimab SC (Spevigo) in this disease space. Requests for this indication are considered experimental and investigational at this time.

D. Hidradenitis suppurativa
   i. Spesolimab SC (Spevigo) is currently under investigation for the treatment of hidradenitis suppurativa. There are multiple trials currently recruiting (estimated primary completion 2024-2030) as well as several trials that have been completed with results yet to be posted. Requests for this indication are considered experimental and investigational at this time.

E. Ulcerative colitis, Atopic eczema
   i. There is currently no active trial evaluating the use of spesolimab SC (Spevigo) in patients with ulcerative colitis or atopic eczema. There is insufficient evidence to support the safety and efficacy of spesolimab SC (Spevigo) in this disease space. Requests for this indication are considered experimental and investigational at this time.

F. Netherton syndrome
   i. Spesolimab SC (Spevigo) is currently under investigation for the treatment of Netherton syndrome in a phase 2/3, randomized, parallel assignment, place-controlled, double-blinded trial designed to measure ichthyosis area severity index (IASI) response in male or female patients $\geq$ 12 years of age and $\geq$ 35 kg in weight with a diagnosis of Netherton syndrome. Primary completion is expected in December 2024. Requests for this indication are considered experimental and investigational at this time.

G. Plaque psoriasis
   i. There is currently no active trial evaluating the use of spesolimab SC (Spevigo) in patients with plaque psoriasis. There is insufficient evidence to support the safety and efficacy of spesolimab SC (Spevigo) in this disease state. Requests for this indication are considered experimental and investigational at this time.

Appendix

I. Dosing regimens of spesolimab SC (Spevigo) in members 12 years of age and older and weighing at least 40 kg:
   A. Initiating spesolimab SC (Spevigo) for the first time
      1. 600 mg SC (4 x 150 mg injections) loading dose followed by 300 mg SC (2 x 150 mg injections) 4 weeks later and every 4 weeks thereafter
   B. Initiating or reinitiating spesolimab SC (Spevigo) following treatment of a GPP flare with spesolimab IV (Spevigo)

1. 300 mg SC (2 x 150 mg injections) 4 weeks after treatment of the flare and every 4 weeks thereafter
2. A subcutaneous loading dose is not required following treatment of a GPP flare with spesolimab IV (Spevigo)

References

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Related Policies

Currently there are no related policies.

Policy Implementation/Update:

Action and Summary of Changes	Date
Policy created	11/2024