Oscar Clinical Guideline: Spevigo (spesolimab-sbzo) (CG071, Ver. 5)

Spevigo (spesolimab-sbzo)

- Spesolimab Subcutaneous 150mg/1mL Solution for injection
- Spesolimab Intravenous 450mg/7.5mL Solution for injection

Summary

Generalized pustular psoriasis (GPP) is a rare, severe form of psoriasis characterized by sudden, widespread eruptions of painful, sterile pustules accompanied by fever, malaise, and other systemic symptoms. Acute GPP can be life-threatening due to complications such as sepsis, acute respiratory distress syndrome, and multi-organ failure. Treatment options have been limited, often relying on off-label use of systemic therapies like interleukin (IL)-17 inhibitors (e.g., secukinumab, ixekizumab, brodalumab), IL-23 inhibitors (e.g., guselkumab, risankizumab, ustekinumab), cyclosporine, Infliximab, retinoids (e.g., acitretin, isotretinoin),, and methotrexate, which may have significant side effects and variable efficacy.

Spevigo (spesolimab-sbzo) is a targeted biologic therapy approved for the treatment of GPP flares in adults and adolescents. It is a monoclonal antibody that blocks the interleukin-36 receptor, a key driver of inflammation in GPP. Spevigo (spesolimab-sbzo) is administered intravenously for acute flares and subcutaneously for maintenance therapy to prevent flares. It is supplied in two formulations:

1. For intravenous use in acute flares:

a. Single-dose vials containing 450 mg/7.5 mL (60 mg/mL) of spesolimab-sbzo
b. Each carton contains two vials.
c. Initial dose: 900 mg intravenous infusion administered over 90 minutes
d. If flare symptoms persist, another intravenous dose of 900 mg one week after the initial dose.

2. For subcutaneous use in maintenance therapy:
    a. Single-dose prefilled syringes containing 150 mg/mL of spesolimab-sbzo
    b. Each carton contains two syringes.
    c. Initial (loading) dose: 600 mg administered subcutaneous dose
    d. Maintenance: 300 mg administered subcutaneously every 4 weeks.

Definitions

"Flare" refers to an acute episode of disease exacerbation in GPP, marked by the sudden appearance or worsening of pustules and associated symptoms.

"Generalized pustular psoriasis (GPP)" is a rare, severe, and potentially life-threatening form of psoriasis characterized by sudden, widespread eruptions of sterile pustules, often accompanied by systemic symptoms such as fever, malaise, and laboratory abnormalities.

"Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA)" is a validated assessment tool that evaluates the severity of an acute GPP event. The score ranges from 0 (clear) to 4 (severe).

"Interleukin-36 receptor (IL-36R)" is a key component of the immune system that, when activated, drives inflammation associated with GPP.

"Psoriasis" is a chronic inflammatory skin condition characterized by red, scaly patches (plaques) that can appear anywhere on the body, caused by rapid skin cell turnover.

Medical Necessity Criteria for General Clinical Review

The Plan considers Spevigo (spesolimab-sbzo) medically necessary when ALL of the following criteria are met:

1. The medication is prescribed by or in consultation with a dermatologist; *AND*
2. The member is 12 years of age or older and weighs at least 40 kg; *AND*
3. The member has a diagnosis of generalized pustular psoriasis (GPP); *AND*
4. The member meets the medical necessity criteria for the applicable indication listed below:

Treatment of acute GPP flares

5. The member has a flare of GPP of moderate-to-severe intensity, as defined by:

a. A Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of at least 3 (moderate)*; and*
b. The presence of fresh pustules (new appearance or worsening of pustules)*; and*
c. GPPPGA pustulation sub-score of at least 2 (mild)*; and*
d. At least 5% of body surface area covered with erythema and the presence of pustules*; and*

6. The member has primary, sterile, macroscopically visible pustules on non-acral skin (excluding cases where pustulation is restricted to psoriatic plaques)*; and*
7. The dosing regimen does NOT exceed a maximum of 1800 mg (two 900 mg doses):
    a. Initial dose: 900 mg administered intravenously*; and*
    b. If flare symptoms persist, a second 900 mg intravenous dose may be administered one (1) week after the initial dose.

Prevention of GPP flares (Maintenance Therapy)

5. The member has a history of at least two moderate-to-severe GPP flares in the past*; and*
6. The member has ONE (1) of the following:
    a. The member has previously responded to treatment with Spevigo (spesolimab-sbzo)*; or*
    b. The member has had an inadequate response, intolerance, or contraindication to at least one systemic therapy for GPP (e.g., acitretin, cyclosporine, methotrexate)*; and*
7. The member is not currently experiencing an acute GPP flare*; and*
8. The dosing regimen does NOT exceed a maximum of 600 mg (four 150 mg injections) for the initial (loading) dose, then 300 mg (two 150 mg injections) every 4 weeks:
    a. Initial (loading) dose: 600 mg administered subcutaneously*; and*
    b. Maintenance: 300 mg administered subcutaneously every 4 weeks.

If the above prior authorization criteria are met, the requested product will be authorized as follows:

- Treatment of Acute GPP Flares: A one-time treatment course of up to two doses (900 mg each) within a 2-week period.
- Prevention of GPP Flares (Maintenance Therapy): Initial authorization for up to 6 months

  NOTE: Members transitioning from acute flare treatment to maintenance therapy should initiate subcutaneous dosing 4 weeks after the last intravenous dose, starting with the 300 mg maintenance dose. A subcutaneous loading dose is not required when transitioning from IV to SC maintenance dosing.

Medical Necessity Criteria for Reauthorization

Prevention of GPP flares (Maintenance Therapy)

Reauthorization for up to 12-months will be granted if the member has recent (within the last 3 months) clinical chart documentation demonstrating ALL of the following criteria:

1. The member continues to meet applicable Initial Authorization criteria; *AND*
2. The member has demonstrated a positive clinical response to Spevigo (spesolimab-sbzo) therapy as evidenced by at least ONE (1) of the following:
    a. Reduction in frequency of GPP flares*; and/or*
    b. Reduction in severity of GPP flares*; and/or*
    c. Decreased duration of GPP flares*; and/or*
    d. Improvement in quality of life scores.

Experimental or Investigational / Not Medically Necessary

Spevigo (spesolimab-sbzo) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Treatment of hidradenitis suppurativa (HS). Only one published proof-of-concept study (n=52) and a case report support the use of Spevigo (spesolimab-sbzo) for HS. Two additional studies are lacking published results (NCT05819398, NCT06241573). More data is needed to support the safety and efficacy of Spevigo (spesolimab-sbzo) for the management of HS.
- Treatment of other pustular skin conditions such as palmoplantar pustulosis. There have been no positive findings from published studies supporting the use of Spevigo (spesolimab-sbzo) for the management of palmoplantar pustulosis.
- Treatment of plaque psoriasis without GPP. There is not enough high-quality evidence to support the safety and efficacy of Spevigo (spesolimab-sbzo) for the management of plaque psoriasis.
- Treatment of other autoimmune or inflammatory conditions not specified in the FDA-approved labeling. There is not enough high-quality evidence to support the safety and efficacy of Spevigo (spesolimab-sbzo) for the management of other autoimmune or inflammatory conditions.

Applicable Billing Codes (HCPCS/CPT Codes)

Service(s) name	
CPT/HCPCS Codes considered medically necessary if criteria are met:	
Code	*Description*
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)

96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
J1747	Injection, spesolimab-sbzo, 1 mg
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
L40.1	Generalized pustular psoriasis

References

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