Oscar Clinical Guideline: Spevigo (spesolimab-sbzo) (CG071, Ver. 3)

Spevigo (spesolimab-sbzo)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Spevigo is a monoclonal antibody used to treat flares by a rare type of psoriasis known as generalized pustular psoriasis (GPP). GPP has varying levels of severity, however if left unmanaged, may cause severe systemic disease with fever, dehydration, and can be life threatening. Current treatment options for acute and maintenance of GPP flares are limited, by off-label use of medications such as retinoids (e.g., acitretin), systemic immunosuppressants (e.g., oral steroids, cyclosporine, methotrexate), and immunomodulators (e.g., infliximab).

Definitions

"**Generalized Pustular Psoriasis**" is a rare form of psoriasis. It is a serious and sometimes fatal multisystem disorder.

"**Psoriasis**" is a long-term (chronic) skin condition that makes parts or all of the body's skin red, thick and flaky. Red patches (plaques) that often look silvery can show up anywhere on the body and vary in size, shape, and severity (mild to very severe).

Medical Necessity Criteria for Authorization

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 18 years of age or older; ***AND***
3. The member has a diagnosis of generalized pustular psoriasis (GPP) **AND ALL** of the following:
    a. The requested medication is being used for the treatment and **NOT** for the prevention of GPP flares; ***and***
    b. The member has a flare of GPP of moderate-to-severe intensity, as defined by:
        i. A Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of at least 3 (moderate); ***and***
        ii. Presence of fresh pustules (new appearance or worsening of pustules); ***and***
        iii. GPPPGA pustulation sub-score of at least 2 (mild); ***and***
        iv. At least 5% of body surface area covered with erythema and the presence of pustules; ***and***
    c. The member has primary, sterile, macroscopically visible pustules on non-acral skin (excluding cases where pustulation is restricted to psoriatic plaques); ***AND***
4. The member does **NOT** have **ANY** of the following:
    a. SAPHO (Synovitis-acne-pustulosis-hyperostosis-osteitis) syndrome; ***or***
    b. primary erythrodermic psoriasis vulgaris; ***or***
    c. primary plaque psoriasis vulgaris without presence of pustules or with pustules that are restricted to psoriatic plaques; ***or***
    d. Drug-triggered Acute Generalized Exanthematous Pustulosis (AGEP); ***or***
    e. Immediate life-threatening flare of GPP or requiring intensive care treatment. Life-threatening complications mainly include, but are not limited to, cardiovascular/cytokine driven shock, pulmonary distress syndrome, or renal failure; ***or***
    f. Severe, progressive, or uncontrolled hepatic disease, defined as:
        i. >3- fold Upper Limit of Normal (ULN) elevation in AST or ALT or alkaline phosphatase; ***or***
        ii. >2-fold ULN elevation in total bilirubin; ***AND***
5. The requested medication is being used within the Plan's Quantity Limit of:
    a. Maximum of 15 mL (900 mg) per dose; ***and***
    b. Maximum of 45 mL (2,700 mg) within a 12-week period.

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:

- maintenance treatment for the prevention of GPP flares.
- hidradenitis suppurativa
- palmoplantar pustulosis.

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)
J1747	Injection, spesolimab-sbzo, 1 mg
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
L40.1	Generalized pustular psoriasis

References

1. Bachelez H, Choon SE, Marrakchi S, et al. Trial of spesolimab for generalized pustular psoriasis. N Engl J Med. 2021;385(26):2431-2440. doi:10.1056/NEJMoa2111563
2. Krueger, J., Puig, L., & Thaçi, D. (2022). Treatment options and goals for patients with generalized pustular psoriasis. American Journal of Clinical Dermatology, 1-14.
3. Marrakchi, S., & Puig, L. (2022). Pathophysiology of generalized pustular psoriasis. American Journal of Clinical Dermatology, 1-7.
4. Menter, A., Van Voorhees, A. S., & Hsu, S. (2021). Pustular psoriasis: a narrative review of recent developments in pathophysiology and therapeutic options. Dermatology and Therapy, 11(6), 1917-1929.

5. Mrowietz, U., Burden, A. D., Pinter, A., Reich, K., Schäkel, K., Baum, P., ... & Bissonnette, R. (2021). Spesolimab, an anti-interleukin-36 receptor antibody, in patients with palmoplantar pustulosis: results of a phase IIa, multicenter, double-blind, randomized, placebo-controlled pilot study. Dermatology and therapy, 11(2), 571-585.
6. Spevigo (spesolimab) [prescribing information]. Ridgefield, Connecticut: Boehringer Ingelheim Pharmaceuticals Inc; September 2022.

Clinical Guideline Revision / History Information

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