PHARMACY POLICY STATEMENT
Michigan Medicaid

DRUG NAME	Spevigo (spesolimab-sbzo)
BENEFIT TYPE	Medical or pharmacy
STATUS	Prior Authorization Required

Spevigo, approved by the FDA in 2022, is an interleukin-36 receptor antagonist indicated for the treatment of generalized pustular psoriasis (GPP) in adults and pediatric patients 12 years of age and older and weighing at least 40 kg. It was the first treatment specifically approved for GPP 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 (spesolimab-sbzo) will be considered for coverage when the following criteria are met:

Generalized Pustular Psoriasis (GPP)

For **initial** authorization:
1. Member is at least 12 years of age and weighs at least 40 kg; AND
2. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has a diagnosis of GPP; AND
4. Member is *not* experiencing a flare and has **ALL** the following:
    a. History of at least **TWO** GPP flares of moderate-to-severe intensity;
    b. Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of 0 or 1;
    c. Member has a history of flaring while on concomitant treatment for GPP or a history of flaring upon dose reduction or discontinuation of these concomitant medications (such as retinoids, cyclosporine, methotrexate, etc.); OR
5. Member has an acute flare of GPP of moderate to severe intensity, defined by **ALL** the following:
    a. GPPPGA total score of at least 3;
    b. GPPPGA pustulation sub score of at least 2;
    c. Presence of fresh pustules (new appearance or worsening of pustules);
    d. At least 5% of body surface area covered with erythema and the presence of pustules; AND
6. Member has had a negative tuberculosis test within the past 12 months.
7. **Dosage allowed/Quantity limit**:
    a. If member is experiencing a flare: 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 21 days.
    b. If member is *not* experiencing a flare: Administer a subcutaneous loading dose of 600 mg (four 150 mg injections), followed by 300 mg (two 150 mg injections) subcutaneously 4 weeks later

and every 4 weeks thereafter. Quantity Limit: 6 syringes per 30 days for loading dose and 2 syringes per 30 days for maintenance dosing.

If all the above requirements are met the medication will be approved for 3 weeks for members with flares and 12 weeks for members who are not experiencing a flare.

For **reauthorization**:

1. If the request is for members experiencing a flare, the medication will not be approved for continuous use.
2. If the request is for members *not* experiencing a flare, chart notes have been provided showing an improvement in signs and symptoms of disease (such as decrease in number of flares etc.)

HAP 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.
05/13/2024	Lowered age limit from 18 to 12 and added that member must be at least 40 kg; removed exclusion that member cannot have pustulation restricted to psoriatic plaques; changed quantity limit for flares from per 365 days to per 21 days; added pharmacy benefit option for syringe; added criteria for if member is not experiencing a flare; added subcutaneous dosing information; added references

References:

1. Spevigo [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; 2024.
2. 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
3. Navarini AA, Burden AD, Capon F, et al. European consensus statement on phenotypes of pustular psoriasis. *J Eur Acad Dermatol Venereol*. 2017;31(11):1792-1799. doi:10.1111/jdv.14386
   Hoegler KM, John AM, Handler MZ, Schwartz RA. Generalized pustular psoriasis: a review and update on treatment. *J Eur Acad Dermatol Venereol*. 2018;32(10):1645-1651. doi:10.1111/jdv.14949
4. Morita A, Strober B, Burden AD, et al. Efficacy and safety of subcutaneous spesolimab for the prevention of generalised pustular psoriasis flares (Effisayil 2): an international, multicentre, randomised, placebo-controlled trial. *Lancet.* 2023;402(10412):1541-1551. doi:10.1016/S0140-6736(23)01378-8
5. Kodali N, Blanchard I, Kunamneni S, Lebwohl MG. Current management of generalized pustular psoriasis. *Exp Dermatol.* 2023;32(8):1204-1218. doi:10.1111/exd.14765

Effective date: 10/01/2024
Revised date: 05/13/2024