Spevigo (spesolimab-sbzo) Prior Authorization with Quantity Limit Program Summary

This program applies to Medicaid.

POLICY REVIEW CYCLE

Effective Date	Date of Origin
10-01-2024	10-01-2024

FDA LABELED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Spevigo® (spesolimab-sbzo) Prefilled syringe for subcutaneous injection	Treatment of generalized pustular psoriasis (GPP) in adults and pediatric patients 12 years of age and older and weighing at least 40 kg		1

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Generalized Pustular Psoriasis	Generalized pustular psoriasis (GPP) is a rare inflammatory skin condition characterized by recurrent pustules that vary in size and severity. GPP is a distinctly different disease from plaque psoriasis, but often occurs in patients that have a diagnosis of psoriasis. Both adults and children are affected by GPP with severity ranging from mild to severe with each flare. Affected patients experience recurrent sudden onset flare ups with widespread pustules and often times systemic inflammation. Patients may also experience fevers, leukocytosis, malaise, and at times extracutaneous organ involvement, such as sepsis and/or renal, hepatic, respiratory, and heart failure, which can be life threatening. Due to the rarity of the disease, there is very little consensus on the definition and different phenotypes.(2) GPP flares can occur multiple times per year or may not occur for years at a time. Flares are often provoked, with withdrawal of systemic corticosteroids being the most common precipitating factor. Other precipitating factors include infections, sunlight, pregnancy, menstruation, and numerous systemic medications. Other medications known to precipitate flares include lithium, progesterone, infliximab, adalimumab, and apremilast. Flares typically last between 2 to 5 weeks but some flares may last for up to 3 months. Patients do not always achieve completely clear skin between flares of GPP. Roughly 30% of patients may have persistent pustular lesions.(2,3) GPP has two major clinical presentations, acute GPP (aka generalized pustular psoriasis of von Zumbusch) and generalized annular pustular psoriasis. Acute GPP is characterized by the abrupt development of widespread, painful erythematous patches or thin plaques that rapidly become studded with numerous pinhead-sized sterile pustules. Some pustules will then coalesce resulting in larger collections referred to as "lakes of pus." Generalized annual pustular psoriasis presents as a recurring, subacute eruption characterized by the development of annular or figurate erythematous plaques with peripheral pustules and scale. Pustules expand out over hours to days. Acute GPP and generalized annular pustular psoriasis pustules typically resolve within a few days, leaving erythema and extensive scaling.(3)

	There are no consensus criteria for the diagnosis of GPP. The diagnosis is suspected in patients that present with widespread pustules arising on erythematous skin. GPP is diagnosed using a combination of patient history of symptoms, physical examination, skin biopsy, and labs.(4,5) Treatment consists of a combination of systemic, topical, and phototherapy, and can be broken down into supportive care and long-term management. Initial management usually consists of systemic therapy to rapidly stabilize acute flares. Cyclosporine, infliximab, IL-17 or IL-23 agents are fast acting agents that may be used first line to obtain stability in severe acute flares. Patients that have tolerable, nondisabling disease are often treated with oral retinoids or methotrexate. Topical agents are generally used as adjunct to soothe the skin. Patients that do not respond to first line therapies move to phototherapy, an alternative biologic therapy, or combination therapy with two or more different classes.(6)
Efficacy	A randomized, double-blind, placebo-controlled study (Study Effisayil-2) [NCT04399837] evaluated the efficacy and safety of Spevigo for subcutaneous administration in adults and pediatric subjects (12 years of age and older and weighing at least 40 kg) with a history of at least two GPP flares of moderate-to-severe intensity in the past. Subjects were randomized if they had a Generalized Pustular Psoriasis Physician Global Assessment GPPPGA total score of 0 or 1 at screening and randomization. Subjects were required to discontinue systemic and topical therapy for GPP prior to or at randomization. These subjects must have had a history of flaing while on concomitant treatment for GPP or a history of flaring upon dose reduction or discontinuation of these concomitant medications. A total of 123 subjects were randomized (1:1:1:1) to one of four treatment arms:(1) • SPEVIGO: 600 mg subcutaneous loading dose (LD) followed by 300 mg subcutaneously every 4 weeks • SPEVIGO: 600 mg subcutaneous LD followed by 300 mg subcutaneously every 12 weeks • SPEVIGO: 300 mg subcutaneous LD followed by 150 mg subcutaneously every 12 weeks • Placebo: subcutaneous LD followed by subcutaneous treatment every 4 weeks Despite alternative dosing being used in this trial, (600 mg LD dose followed by 300 mg every 12 weeks dosage and a 300 mg LD followed by 150 mg every 12 weeks), these dosages are not approved. The recommended dosage of Spevigo for treatment of GPP when not experiencing a flare is a subcutaneous LD of 600 mg followed by 300 mg subcutaneously, administered every 4 weeks. The study population was 38% male and 62% female. The mean age was 40 years old (range: 14 to 75 years) with 8 (7%) pediatric subjects (2 per treatment arm); 64% of subjects were Asian and 36% were White. For ethnicity, 6% of subjects identified as Hispanic or Latino. Subjects included in the study had a GPPPGA pustulation sub score of 1 (28%) or 0 (72%), and subjects had a GPPPGA total score of 1 (86%) or 0 (14%). At the time of randomization, 75% of subjects were treated with systemic therapy for GPP, which was discontinued at the start of the randomized study treatment. Subjects who experienced a GPP flare were eligible to receive up to two open-label intravenous doses of 900 mg Spevigo. Two subjects in the subcutaneous Spevigo 600 mg LD/300 mg every 4 weeks arm and 15 subjects in the placebo arm received intravenous Spevigo for treatment of GPP flare. The primary endpoint of the study was the time to the first GPP flare up to Week 48 (defined by a GPPPGA pustulation sub score of greater than or equal to 2 and an increase in GPPPGA total score by greater than or equal to 2 from baseline). The key secondary endpoint was the occurrence of at least one GPP flare up to Week 48.(1) Spevigo significantly reduced the risk of GPP flares by 84% over 48 weeks compared to placebo. In the trial with 123 patients, no flares were observed after Week 4 of treatment in the high dose group.(1)
Safety	Spevigo is contraindicated in patients with severe or life-threatening hypersensitivity to spesolimab-sbzo or to any of the excipients in Spevigo.(1)

REFERENCES

Number	Reference
1	Spevigo prescribing information. Boehringer Ingelheim Pharmaceuticals, Inc. March 2024.
2	Choon, S.E., Navarini, A.A. & Pinter, A. Clinical Course and Characteristics of Generalized Pustular Psoriasis. Am J Clin Dermatol 23 (Suppl 1), 21–29 (2022). https://doi.org/10.1007/s40257-021-00654-z.
3	Choon SE, Lai NM, Mohammad NA, et al. Clinical profile, morbidity, and outcome of adult-onset generalized pustular psoriasis: analysis of 102 cases seen in a tertiary hospital in Johor, Malaysia. Int J Dermatol 2014; 53:676.
4	Ly K, Beck KM, Smith MP, Thibodeaux Q, Bhutani T. Diagnosis and screening of patients with generalized pustular psoriasis. Psoriasis (Auckl). 2019 Jun 20;9:37-42. doi: 10.2147/PTT.S181808.
5	Fujita, H., Gooderham, M. & Romiti, R. Diagnosis of Generalized Pustular Psoriasis. Am J Clin Dermatol 23 (Suppl 1), 31–38 (2022). https://doi.org/10.1007/s40257-021-00652-1.
6	Falto-Aizpurua LA, Martin-Garcia RF, Carrasquillo OY, et al. Biological therapy for pustular psoriasis: a systematic review. Int J Dermatol 2020; 59:284.

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Spevigo	spesolimab-sbzo subcutaneous soln pref syr	150 MG/ML	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Spevigo	spesolimab-sbzo subcutaneous soln pref syr	150 MG/ML	2	Syringes	28	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Spevigo	spesolimab-sbzo subcutaneous soln pref syr	150 MG/ML	Medicaid

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Spevigo	spesolimab-sbzo subcutaneous soln pref syr	150 MG/ML	Medicaid

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of generalized pustular psoriasis (GPP) AND ALL of the following: 1. The patient has moderate to severe GPP **AND** 2. The patient has a history of 2 or more flares **AND** 3. The patient is NOT currently experiencing an acute flare **OR** B. The patient has another FDA labeled indication for the requested agent **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following: A. The patient does NOT have active or latent tuberculosis (TB) **OR** B. The patient has latent tuberculosis (TB) and the patient has begun or completed therapy for latent TB prior to initiating with the requested agent **AND** 5. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (copy of support required, i.e., clinical trials, phase III studies, guidelines) **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months **<u>Note</u>: If patient is NOT transitioning from IV to SC maintenance:** Approve Spevigo loading dose for 1 month, then maintenance dose can be approved for the remainder of 12 months. **Patient IS transitioning from IV to SC maintenance dosing due to a recent flare:** Approve 12 months for maintenance therapy. NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**

Module	Clinical Criteria for Approval
	2. There is support for the use of combination therapy (copy of support required, i.e., clinical trials, phase III studies, guidelines) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly Abrilada (adalimumab-afzb) Actemra (tocilizumab) Adalimumab Adbry (tralokinumab-ldrm) Amjevita (adalimumab-atto) Arcalyst (rilonacept) Avsola (infliximab-axxq)

Contraindicated as Concomitant Therapy
Benlysta (belimumab)
Bimzelx (bimekizumab-bkzx)
Cibinqo (abrocitinib)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Litfulo (ritlecitinib)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)

Contraindicated as Concomitant Therapy
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simlandi (adalimumab-ryvk)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Spevigo (spesolimab-sbzo)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tofidence (tocilizumab-bavi)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tyenne (tocilizumab-aazg)
Tysabri (natalizumab)
Velsipity (etrasimod)

Contraindicated as Concomitant Therapy
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zeposia (ozanimod)
Zymfentra (infliximab-dyyb)