Washington State Health Care Authority

Cytokine and CAM Antagonists: IL-36 Inhibitors

Medical policy no. 66.27.00.AL-1 Effective Date: Month, 1, Year

Related medical policies:

Policy Number	Policy Name
66.27.00.AA	Cytokine and CAM Antagonists: Tumor Necrosis Factors
66.27.00.AB	Cytokine and CAM Antagonists: IL-4/IL-13 Inhibitors
66.27.00.AC	Cytokine and CAM Antagonists: IL-6 Inhibitors
66.27.00.AD	Cytokine and CAM Antagonists: IL-12/IL-23 Inhibitors
66.27.00.AE	Cytokine and CAM Antagonists: IL-17 Inhibitors
66.27.00.AF	Cytokine and CAM Antagonists: Oral PDE-4 Inhibitors
66.27.00.AG	Cytokine and CAM Antagonists: T-Lymphocyte Inhibitors
66.27.00.AH	Cytokine and CAM Antagonists: Janus Associated Kinase (JAK) Inhibitors
66.27.00.AI	Cytokine and CAM Antagonists: IL-1 Inhibitors
66.27.00.AJ	Cytokine and CAM Antagonists: Integrin Receptor Antagonists
66.27.00.AK	Cytokine and CAM Antagonists: S1-P Receptor Modulator

Note: *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit: https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx

Medical necessity

Drug	Medical Necessity
spesolimab-sbzo (Spevigo)	**IL-36 Inhibitors- spesolimab-sbzo** may be considered medically necessary in patients who meet the criteria described in the clinical policy below. If all criteria are not met, the clinical reviewer may determine there is a medically necessary need and approve on a case-by-case basis. The clinical reviewer may choose to use the reauthorization criteria when a patient has been previously established on therapy and is new to Apple Health.

Clinical policy:

Clinical Criteria	
Generalized Pustular Psoriasis (GPP) spesolimab-sbzo (Spevigo)	Spesolimab-sbzo (Spevigo) may be approved when all the following documented criteria are met: 1. Patient is 12 years of age or older, **AND** 2. Patient's weight is ≥ 40 kg; **AND** 3. Prescribed by, or in consultation with a dermatologist; **AND** 4. Not used in combination with another Cytokine and CAM medication; **AND** 5. Diagnosis of generalized pustular psoriasis (GPP); **AND** 6. Patient meets one of the following: a. Patient is experiencing an acute, moderate-to-severe intensity disease flare confirmed by all the following: i. Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of at least 3; **AND** ii. At least 5% body surface area (BSA) covered with erythema and presence of pustules; **AND** iii. Presence of fresh pustules; **AND** iv. The request is for the intravenous formulation; **OR** b. Patient is not currently experiencing a disease flare and documentation is submitted showing all the following: i. GPPGA total score of 0 or 1; **AND** ii. History of 2 GPP flares of moderate-to-severe intensity with fresh pustulation within the past year; **AND** iii. The request is for the subcutaneous formulation; **AND** 7. If patient has previously received spesolimab-sbzo IV infusion for a GPP flare, the subcutaneous formulation will be initiated no earlier than four weeks after the most recent infusion. If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) Spesolimab-sbzo (Spevigo) may be approved when all the following documented criteria are met: 1. Not used in combination with another Cytokine and CAM medication; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., improvement in BSA, GPPGA score). If ALL criteria are met, the request will be authorized for **12 months.**

Dosage and quantity limits

Drug	Indication	Approved Dose	Dosage Form and Quantity Limit
Spevigo	**Generalized Pustular Psoriasis (GPP)**	IV dosage for treatment of GPP Flare: 900 mg infusion over 90 minutes. If flare symptoms persist, may administer an additional 900 mg dose IV one week after the initial dose SubQ dosage for treatment of GPP when not experiencing a flare: Four weeks after IV Spevigo administration—300 mg every 4 weeks Loading dose, 600 mg subQ , followed by 300 mg subQ 4 weeks later and every 4 weeks thereafter	• 450 mg/7.5 mL vial • 150 mg/mL prefilled syringe Loading dose: 4 mL for one dose Maintenance: 2 mL/28 days

Coding:

HCPCS Code	Description
<HCPCS Code>	Formulation, generic name, max fill

Background:

Generalized pustual psoriasis (GPP) is a rare inflammatory skin condition that is characterized by recurrent pustules that vary in severity and size. Patients experience recurrent sudden onset flare ups with widespread pustules and often systemic inflammation. GPP flares can occur multiple times per year or may not occur for years at a time. Flares are often caused by the withdrawal of systemic corticosteroids being the most common reason. GPP has two major clinical presentations, acute GPP and generalized annular pustular psoriasis. A phase 2, multicenter, randomized, double-blind, placebo-controlled trial (Study Effisayil-1) evaluated the safety and efficacy of spesolimab-sbzo in patients 18-75 years old who had GPP and had a GPP flare of moderate-to-severe intensity. GPP glare of moderate-to-severe intensity was defined as a GPPGA total score of ≥ 3, new or worsening pustules, a GPPGA pustulation sub score of ≥ 2 and ≥ 5% of BSA with erythema and the presence of pustules. Patients were randomly assigned in a 2:1 ratio to receive a single IV dose of 900 mg or placebo. The primary endpoint was a GPPGA pustulation subscore of 0 (no visible pustules) at the end of week 1. At the end of week 1, 19/35 patients who were assigned to the spesolimab-sbzo group and 1/18 patients assigned to placebo had a GPPGA pustulation subscore of 0. A totally of 15 patients who were assigned to the spesolimab-sbzo group and two patients assigned to placebo had a GPPGA total score of 0 or 1. Subjects in either treatment group who continued to experience flare symptoms at Week 1 were eligible to receive a single open-label IV dose of 900 mg of spesolimab-sbzo.

A randomized, double-blind, placebo-controlled study (Study Effisayil-2) evaluated the efficacy and safety of spesolimab-sbzo for subQ administration in adults and pediatric patients (12 years or older and weighing at least 40 kg) with a history of at least two GPP flares of moderate-to-severe intensity in the past. Patients were randomized to one of four treatments arms, including three different regimens for spesolimab-sbzo and one placebo arm. The primary endpoint was the time to the first GPP flare up to week 48.

The National Psoriasis Foundation has a written consensus statement for GPP (2024). The statement strongly advocates for timely access to FDA approved therapy for GPP because delays can increase the risk of mortality in patients.

References

1. Armstrong AW, Elston CA, Elewski BE. Generalized pustular psoriasis: A consensus statement from the National Psoriasis Foundation. J Am Acad Dermatol. 2024; 90(4):727-730.
2. Bachelez H, Choon SE, Marrakchi S, et al. Trial of Spesolimab for Generalized Pustular Psoriasis. *New England Journal of Medicine*. 2021;385(26):2431-2440. doi:https://doi.org/10.1056/nejmoa2111563
3. Morita A, Choon SE, Bachelez H, et al. Design of Effisayil™ 2: A Randomized, Double-Blind, Placebo-Controlled Study of Spesolimab in Preventing Flares in Patients with Generalized Pustular Psoriasis. *Dermatology and Therapy*. 2023;13(1):347-359. doi:https://doi.org/10.1007/s13555-022-00835-6
4. Spevigo. Package Insert. Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT; 2024.

History

Approved Date	Effective Date	Version	Action and Summary of Changes
MM/DD/YYY	MM/DD/YYYY	66.27.00.AL-1	Pending Approval (draft version) -New draft created

Washington State Health Care Authority

Cytokine and CAM Antagonists: IL-36 Inhibitors

Please provide the information below, please print your answer, attach supporting documentation, sign, date, and return to our office as soon as possible to expedite this request. **Without this information, we may deny the request in seven (7) working days.**

Date of request:	Reference #:	MAS:	
Patient	Date of birth	ProviderOne ID	
Pharmacy name	Pharmacy NPI	Telephone number	Fax number
Prescriber	Prescriber NPI	Telephone number	Fax number
Medication and strength	Directions for use	Qty/Days supply	

1. Is this request for a continuation of existing therapy? ☐ Yes ☐ No
   If yes, is there documentation of a positive clinical response? ☐ Yes ☐ No

2. What is the patient's diagnosis?
   ☐ Generalized Pustular Psoriasis (GPP)
   ☐ Other Specify: _____

3. Provide the following for the patient:
   Indicate disease stage:
   Indicate disease type (i.e. New onset, refractory, etc.):

4. Indicate if prescribed by or in consultation with:
   ☐ Dermatologist ☐ Other Specify: _____

5. Will the requested medication be used in combination with another Cytokine and CAM medication?
   ☐ Yes ☐ No

6. Is the patient currently experiencing an acute, moderate-to-severe intensity disease flare? ☐ Yes ☐ No

   If yes, please check all that apply:
   - ☐ Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of at least 3
   - ☐ At least 5% body surface area (BSA) covered with erythema and presence of pustules
   - ☐ Presence of fresh pustules
   - ☐ The request is for the intravenous formulation
   - ☐ Other Specify: _____

   If no, please check all that apply:
   - ☐ GPPGA total score of 0 or 1
   - ☐ History of 2 GPP flares of moderate-to-severe intensity with fresh pustulation in the past
   - ☐ The request is for the subcutaneous formulation
   - ☐ Other Specify: _____

7. Indicate for patient: Height (cm): **Date taken:** Weight (kg): **Date taken:** Body surface area (m^2): **Date taken:**		
CHART NOTES ARE REQUIRED WITH THIS REQUEST		
Prescriber signature	Prescriber specialty	Date