PREMERA HMO

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PHARMACY / MEDICAL POLICY – 5.01.652

Miscellaneous Pharmacologic Treatments of Psoriasis

Effective Date:	**Oct. 3, 2025**	RELATED MEDICAL POLICIES:
Last Revised:	Jun. 10, 2025	5.01.629 Pharmacologic Treatment of Psoriasis
Replaces:	N/A	5.01.647 Medical Necessity Criteria for Custom Open and Preferred Formularies

The Site of Service Medical Necessity criteria within this policy DOES NOT apply to Alaska fully-insured members; refer to the infusion and injection drug Medical Necessity criteria only.

Site of Service *and* the infusion and injection drug Medical Necessity criteria apply to all other plan members.

Please contact Customer Service for more information.

Select a hyperlink below to be directed to that section.

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Psoriasis is a skin condition caused by inflammation. It causes a red, scaly rash that can occur anywhere on the body. The treatment of psoriasis often starts with medications that are applied to the skin. If these don't help clear the skin, or if psoriasis affects a large part of the body, light therapy and drugs that are taken by mouth may be used. This policy discusses when each type of therapy may be considered medically necessary for psoriasis.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Site of Service (SOS) Medical Necessity criteria applies ONLY to medical benefit reviews. SOS Medical Necessity criteria does NOT apply to Alaska fully-insured members; refer to the infusion and injection drug Medical Necessity criteria only. Please contact Customer Service for more information.

We will review specific intravenous (IV) and injectable drugs for medical necessity for all ages.

For those age 13 and older, we also will review the site of service for medical necessity. Site of service is defined as the location where the drug is administered, such as a hospital-based outpatient setting, an infusion center, a physician's office, or at home. Click **here** to be directed to the site of service review criteria.

Drugs subject to site of service review addressed in this policy are:

- Spevigo (spesolimab-sbzo)

Site of Service Administration	Medical Necessity
Medically necessary sites of service • **Physician's office** • **Infusion center** • **Home infusion**	**IV infusion and injection therapy of various medical or biologic agents will be covered in the most appropriate, safe and cost-effective site:** • These are the preferred **medically necessary** sites of service for specified drugs.
Hospital-based outpatient setting • **Outpatient hospital IV infusion department** • **Hospital-based outpatient clinical level of care**	**IV infusion and injection therapy of various medical or biologic agents will be covered in the most appropriate, safe and cost-effective site.** **This site is considered medically necessary for the first 90 days for the following:** • The initial course of infusion or injection of a pharmacologic or biologic agent **OR**

Site of Service Administration	Medical Necessity

	• Re-initiation of an agent after 6 months or longer following discontinuation of therapy*
	
	***Note:** This does not include when standard dosing between infusions or injections is 6 months or longer
	
	This site is considered medically necessary when there is no outpatient infusion center within 50 miles of the individual's home and there is no contracted home infusion agency that will travel to their home, or a hospital is the only place that offers infusions or injections of this drug.
	
	This site is considered medically necessary only when the individual has a clinical condition which puts him or her at increased risk of complications for infusions or injections, including any 1 of the following:
	• Known cardiac condition (e.g., symptomatic cardiac arrhythmia) or pulmonary condition (e.g., significant respiratory disease, serious obstructive airway disease, %FVC less than or equal to 40%) that may increase the risk of an adverse reaction
	• Unstable renal function which decreases the ability to respond to fluids
	• Difficult or unstable vascular access
	• Acute mental status changes or cognitive conditions that impact the safety of infusion or injection therapy
	• A known history of severe adverse drug reactions and/or anaphylaxis to prior treatment with a related or similar drug
	
	This site is considered medically necessary when the individual has cytokine release syndrome (CRS) and all the following are met:
	• CRS is grade 3 or 4 as evidenced by ALL the following:
	  ○ Temperature at least 38 °C
	  ○ Hypotension that requires 1 or more vasopressors

Site of Service Administration	Medical Necessity
	○ Hypoxia that requires oxygen through a high-flow nasal cannula, face mask, non-rebreather mask, or Venturi mask OR positive pressure (continuous positive airway pressure [CPAP], bilevel positive airway pressure [BiPAP], intubation, or mechanical ventilation) **AND** • The individual will be admitted into an inpatient setting as soon as possible
Hospital-based outpatient setting • **Outpatient hospital IV infusion department** • **Hospital-based outpatient clinical level of care**	**These sites are considered not medically necessary for infusion and injectable therapy services of various medical and biologic agents when the site-of-service criteria in this policy are not met.**

Plaque Psoriasis Topical Treatments – Second Line			
Aryl Hydrocarbon Receptor Agonist	**PDE-4 Inhibitor**	**Steroid Combinations**	**Vitamin D Analogs**
• Vtama (topical cream)	• Zoryve (topical cream)	• Duobrii (topical lotion)	• Brand calcipotriene (topical foam)
		• Enstilar (topical foam)	• Dovonex (topical cream)
		• Taclonex (topical ointment, suspension)	• Sorilux (topical foam)
		• Wynzora (topical cream)	• Vectical (topical ointment)

Drug	Medical Necessity
Plaque Psoriasis Topical Treatments – Second Line	
Aryl Hydrocarbon Receptor Agonist (Topical)	
Vtama (tapinarof) cream	**Vtama (tapinarof) may be considered medically necessary for the treatment of plaque psoriasis when:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 3% of his or her body surface area (BSA)

Drug	Medical Necessity
Plaque Psoriasis Topical Treatments – Second Line	
	AND • Has a history of an adequate trial and treatment failure with at least 1 topical corticosteroid (e.g., betamethasone, clobetasol, mometasone) unless contraindicated or not tolerated **AND** • Has a history of an adequate trial and treatment failure with at least 1 vitamin D analogue (e.g., calcipotriene or calcitriol) unless contraindicated or not tolerated **AND** • Medication is being prescribed by or in consultation with a dermatologist
PDE-4 Inhibitor (Topical)	
Zoryve (roflumilast) 0.3% cream	**Zoryve (roflumilast) 0.3% cream may be considered medically necessary for the treatment of plaque psoriasis when:** • The individual is aged 6 years or older **AND** • Has a diagnosis of chronic plaque psoriasis involving at least 2% of his or her body surface area (BSA) **AND** • Has a history of an adequate trial and treatment failure with at least 1 topical corticosteroid (e.g., betamethasone, clobetasol, mometasone) unless contraindicated or not tolerated **AND** • Has a history of an adequate trial and treatment failure with at least 1 vitamin D analogue (e.g., calcipotriene or calcitriol) unless contraindicated or not tolerated **AND** • Medication is being prescribed by or in consultation with a dermatologist
Steroid Combinations (Topical)	
Duobrii (halobetasol and tazarotene) lotion	**Duobrii (halobetasol and tazarotene) may be considered medically necessary for the treatment of plaque psoriasis when the following criteria are met:**

Drug	Medical Necessity
Plaque Psoriasis Topical Treatments – Second Line	
	• The individual has tried and had an inadequate response or intolerance to using concurrent generic topical halobetasol and generic topical tazarotene
• **Enstilar (betamethasone and calcipotriene) foam** • **Taclonex (betamethasone and calcipotriene) ointment, suspension** • **Wynzora (betamethasone and calcipotriene) cream**	**Enstilar (betamethasone and calcipotriene), Taclonex (betamethasone and calcipotriene), and Wynzora (betamethasone and calcipotriene) may be considered medically necessary for the treatment of plaque psoriasis when the following criteria are met:** • The individual has tried and had an inadequate response or intolerance to using concurrent generic topical betamethasone and generic topical calcipotriene
Vitamin D Analogs (Topical)	
• **Brand calcipotriene foam** • **Dovonex (calcipotriene) cream** • **Sorilux (calcipotriene) foam**	**Brand calcipotriene foam, Dovonex (calcipotriene), and Sorilux (calcipotriene) may be considered medically necessary for the treatment of plaque psoriasis when:** • The individual has tried and had an inadequate response or intolerance to generic topical calcipotriene
Vectical (calcitriol) ointment	**Vectical (calcitriol) may be considered medically necessary for the treatment of plaque psoriasis when:** • The individual has tried and had an inadequate response or intolerance to generic topical calcitriol

Retinoids - Psoriasis – Systemic Treatment – Second Line
• Soriatane (oral)

Drug	Medical Necessity
Retinoids - Psoriasis – Systemic Treatment – Second Line	
Soriatane (acitretin) oral	**Soriatane (acitretin) may be considered medically necessary for the treatment of psoriasis when:** • The individual has had a trial and had an inadequate response or intolerance to generic oral acitretin

IL-36 Receptor Antagonist – First Line

- Spevigo (SC/IV)

Drug	Medical Necessity
IL-36 Receptor Antagonist – First Line	
Spevigo (spesolimab-sbzo) SC/IV	**Spevigo (spesolimab-sbzo) IV is subject to review for site of service administration.** **Spevigo (spesolimab-sbzo) may be considered medically necessary for the treatment of generalized pustular psoriasis (GPP) when:** • The individual is aged 12 years or older **AND** • Is experiencing a GPP flare **AND** • Has documentation of a Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of at least 3 (moderate) [the total GPPPGA score ranges from 0 (clear) to 4 (severe)] **AND** • The dose prescribed is 900 mg given as an IV infusion (an additional 900 mg dose may be administered one week after the initial dose) OR 600 mg given as a SC loading dose followed by 300 mg every 4 weeks **AND** • Medication is being prescribed by or in consultation with a dermatologist

Drug	Not Medically Necessary
As listed	**All other uses of the drugs for approved conditions listed in this policy are considered not medically necessary.**

Drug	Investigational
As listed	**The medications listed in this policy are subject to the product's US Food and Drug Administration (FDA) dosage and administration prescribing information.**

Drug	Investigational
	All other uses of the above-named agents when used in combination with each other or for conditions not outlined in this policy are considered investigational.

Length of Approval	
Approval	**Criteria**
Initial authorization	**Non-formulary exception reviews for all drugs listed in the policy may be approved up to 12 months.** **All other reviews for all drugs listed in the policy EXCEPT Spevigo (spesolimab-sbzo) may be approved up to 12 months.** **All other reviews for Spevigo (spesolimab-sbzo) may be approved for one month.**
Re-authorization criteria	**Non-formulary exception reviews and all other reviews for all drugs listed in the policy may be approved up to 12 months as long as the drug-specific coverage criteria are met and chart notes demonstrate that the individual continues to show a positive clinical response to therapy.**

Documentation Requirements
The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following: • Office visit notes that contain the diagnosis, relevant history, physical evaluation, and medication history

Coding

HCPCS	
J1747	Injection, spesolimab-sbzo (Spevigo), 1 mg

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Consideration of Age

Age limits specified in this policy are determined according to FDA-approved indications, where applicable.

For site of service for medical necessity the age described in this policy is 13 years of age or older. Site of service is defined as the location where the drug is administered, such as a hospital-based outpatient setting, an infusion center, a physician's office, or at home. The age criterion for site of service for medical necessity is based on the following: Pediatric individuals are not small adults. Pediatric individuals differ physiologically, developmentally, cognitively, and emotionally from adult individuals, and vary by age groups from infancy to teen. Children often require smaller doses than adults, lower infusion rates, appropriately sized equipment, the right venipuncture site determined by therapy and age, and behavioral management during administration of care. Specialty infusion training is therefore necessary for pediatric IV insertions and therapy. Due to pediatrics unique physiology and psychology, site of service review is limited to individuals above the age of 13.

Benefit Application

Pharmacy Benefit

Brand calcipotriene foam, Dovonex (calcipotriene), Duobrii (halobetasol and tazarotene) Enstilar (betamethasone and calcipotriene), Soriatane (acitretin), Sorilux (calcipotriene), Taclonex (betamethasone and calcipotriene), Vectical (calcitriol), Vtama (tapinarof), Wynzora (betamethasone and calcipotriene), and Zoryve (roflumilast) cream are managed through the pharmacy benefit.

Medical Benefit

Spevigo (spesolimab-sbzo) is managed through the medical benefit.

Psoriasis

Psoriasis is a chronic, multifactorial, noncontagious skin disorder that affects about 2.1% of the US population and 1-3% of persons worldwide. About 4.5 million, or 1 in 65, Americans have psoriasis. Onset is typically between the ages of 15 and 35 and prevalence is slightly greater in women. It is also more common in some ethnic groups (Caucasians) than others (African American or Asians). A genetic component has also been identified. There are several forms of psoriasis, but plaque psoriasis (or psoriasis vulgaris) is the most common form of the disease, affecting about 80% of psoriatic individuals.

About 20-30% of people with psoriasis have cases that are considered moderate to severe (covering more than 3% of their body). Although not typically life-threatening, psoriasis can have a large impact on quality of life. Seventy-five percent of people with moderate to severe psoriasis report their disease has a moderate to large impact on their everyday lives. Individuals with palmar-plantar disease may have less than 3% involvement, but often have debilitating and recalcitrant disease. Further, approximately 7% of psoriatic individuals have concurrent arthritis (which may be particularly relevant to one's choice of therapy).

Psoriasis is a chronic immune-mediated inflammatory disease characterized by T-cell activation and accumulation in the epidermis and dermis, leading to abnormal differentiation and hyperproliferation of keratinocytes. Recent advances in the understanding of the cellular mechanisms underlying psoriasis have given rise to a generation of highly targeted biotechnologies for this indication.

As the severity of psoriasis ranges from mild to severe, with or without concurrent arthritis, available treatments lie along a spectrum from minimally invasive with a low risk of systemic side effects, to systemic therapy with a risk of potentially severe side effects. Non-invasive, topical treatments may also have significant side effects; for example, topical corticosteroids applied to large areas of skin may result in significant levels of systemic absorption. Many treatments have a cumulative toxicity potential, but the benefit of prolonged remissions makes the use of the more potent treatments relatively attractive.

Topical therapy, usually corticosteroids, is recommended as first-line treatment in psoriasis because these products are easy to administer, inexpensive, and safe. However, application to large areas of involvement can be time-consuming, expensive, and messy. Most individuals with moderate to severe disease will not achieve clearance or long-term remission. Tachyphylaxis

may also develop with long-term use of topical corticosteroids. In individuals whose moderate to severe psoriasis fails topical therapy, the therapeutic options that remain are systemic agents, phototherapy and biologics.

Approved systemic agents (methotrexate, cyclosporine, and acitretin) are highly effective in the treatment of psoriasis; however, these therapies have limitations due to serious toxicities that require monitoring. Methotrexate can cause hepatotoxicity. Methotrexate is also associated with bone marrow toxicity, severe pulmonary toxicity, and serious drug-drug interactions (e.g., trimethoprim-sulfamethoxazole). Cyclosporine is nephrotoxic and can cause interstitial fibrosis and renal tubular atrophy in individuals treated for more than two years. Hypertension, laboratory abnormalities (electrolytes, liver function tests, lipids), and numerous drug-drug interactions are also among the problems associated with cyclosporine. Because methotrexate and cyclosporine are potent immunosuppressive drugs, individuals are at increased risk of infections and malignancies, including skin cancers and lymphoproliferative disorders. Like all retinoids, acitretin is highly teratogenic, posing a long-lasting risk (up to three years) in women of childbearing potential. Elevation in liver function tests, hyperlipidemia, and mucocutaneous reactions are additional adverse events associated with acitretin. Systemic corticosteroids are generally avoided as they may be associated with severe exacerbations, both during and after treatment.

Phototherapy (e.g., UVB, narrowband UVB, PUVA) is used for individuals who fail topicals or those with disease too extensive for topical therapy. Phototherapy can be effective for many individuals, but may be inconvenient and time-consuming, if frequent office or clinic visits are required and the availability of specialized phototherapy clinics may be limited. Individuals with a durable medical equipment (DME) benefit may purchase a home unit for easier access. Cumulative exposure to PUVA is associated with an increased risk of squamous cell carcinoma and malignant melanoma.

Various other strategies using traditional therapies have also been used to maintain remission and decrease the risk of cumulative end-organ toxicities. Rotational therapy involves the use of a therapy for some time and then switching to another form of therapy. Combination therapy uses low-dosages of different treatments concurrently to minimize toxicity and enhance efficacy. Traditionally, these strategies usually involve topicals, phototherapy, and systemics in various combinations.

Pustular psoriasis

Pustular psoriasis is characterized by neutrophil-filled pustules and is distinct from plaque psoriasis, though the two may occur concurrently. The ERASPEN defines three subtypes of pustular psoriasis.

1. Generalized pustular psoriasis: sterile, visible pustules on non-acral skin which may occur with or without systemic inflammation or psoriasis vulgaris.[8] Generalized pustular psoriasis is a rare, multisystem disease which can cause life-threatening systemic disease as well as chronic skin disease and symptoms.

2. Palmoplantar pustulosis: persistent disease (greater than 3 months) with sterile, visible pustules on the palms and soles.[8] There is some disagreement if PPP is a subtype of pustular psoriasis, closely related to GPP, or a distinct entity.

3. Acrodermatitis continua of Hallopeau: persistent symptoms (greater than 3 months) with sterile, visible pustules impacting the nails.

Pustular psoriasis makes up 1% of all psoriasis. The global prevalence of GPP is 1.76/million; the US prevalence is estimated at less than 1/10,000.7 Overall, GPP is more common in Asian populations than Caucasian.[10] While GPP can occur at any age, it is less common among children.

Generalized pustular psoriasis is characterized by disease flares which can be triggered by a variety of factors including withdrawal of systemic steroids, certain medications such as lithium, infections especially streptococcal, stress, hypocalcemia associated with hypoparathyroidism, and pregnancy. Gene mutations also play a role in pustular psoriasis, particularly GPP. Overall, GPP has a relapsing/remitting course which can include relapsing disease with recurrent flares, or persistent symptoms with intermittent flares. Symptoms of GPP include sudden appearance of extensive superficial pustules on the trunk and limbs, erythema, inflammation, and systemic symptoms.[10] Pustules seen with GPP often coalesce. Typically, individuals report less than or equal to 1 flare per year; however, almost one-third report two to three flares annually. Length of flares ranges from 2 weeks to 3 months.[7] During a flare, the skin loses its protective barrier functions and risk of bacterial infection is high. Time to resolution is 2-4 weeks for pustules and 1-3 months for erythema and scaling. Symptoms seen with persistent disease may include erythematous plaques and pustules. Systemic symptoms may include fever, chills, malaise, nausea, and pain. Extracutaneous symptoms such as sublingual pustules, fissured tongue, arthritis, uveitis, acute respiratory distress syndrome, cardiovascular shock, and neutrophilic cholangitis can also occur. Laboratory changes include elevated C-reactive protein, leukocytosis,

neutrophilia, and abnormal liver function tests. Mortality rates due to flares range from 3%-25% of individuals, most commonly due to bacterial infection and/or cardiorespiratory failure.

Palmoplantar pustulosis differs from GPP in several ways. Palmoplantar pustulosis is characterized by pustules on the palms and soles, pain, and pruritus. Risk factors for PPP include tobacco smoke and oral infections. The clinical course is chronic and relapsing, often impacting QoL. Depression is common. The prevalence of PPP ranges from 0.01% to 0.05%, but has been reported to occur in 0.12% of the population in Japan. Mutations involving the IL-36 receptor are less common in individuals with PPP than GPP.

In individuals with GPP, excess inflammatory signaling recruits immune cells, leading to symptoms of GPP. Overexpression of IL-36 and loss-of-function mutations in IL-36 receptor antagonists have been reported in individuals with GPP. Interleukin-36 receptors are expressed in keratinocytes, fibroblasts, macrophages, dendritic cells, and certain T cell subsets. Activation of IL-36 leads to neutrophil chemotaxis and neutrophil inflammatory response. When cytokines bind to the IL-36 receptor, pro-inflammatory responses occur such as activation of transcription factors, secretion of IL-8 (a chemokine), and increased proinflammatory cytokines such as tumor necrosis factor-α (TNF-α), IL-1, IL-23, and T helper-17 (Th17). This increases inflammation and recruitment of neutrophils and macrophages, resulting in the symptoms of GPP.

Spesolimab has been studied in a Phase 2 trial in individuals with a current GPP flare and a Phase 2 trial in individuals with PPP.[1,2] Another Phase 2 trial is under way in individuals with a history of GPP without a current flare. To date, the manufacturer is seeking a GPP flare indication only.

The EFFISAYIL 1 trial is a 12-week, multicenter, double-blind, placebo-controlled, Phase 2 trial in which 53 individuals with a current GPP flare were randomized to spesolimab 900 mg IV or placebo. Inclusion criteria were age 18-75 years, history of GPP according to European Rare and Severe Psoriasis Expert Net-work (ERASPEN) criteria, and a current moderate-to-severe flare defined as a GPPGA pustulation sub-score greater than or equal to 2 and greater than or equal to 5% body surface area (BSA) involvement. Individuals received study drug on Day 1. All individuals with persistent symptoms at the end of Week 1, defined as GPPGA total score greater than or equal to 2 and GPPGA pustulation subscore greater than or equal to 2, were eligible to receive an open-label dose of spesolimab 900 mg IV on Day 8. After this point, those with a reoccurrence of flare could receive a rescue dose of spesolimab. Flare recurrence was defined as GPPGA total score increase of greater than or equal to 2 points after a score of 0/1 had been achieved. Individuals could also receive escape treatment (physician's choice standard of care therapy) if immediate treatment was required during Week 1, or if the individual was not eligible for a rescue dose of spesolimab. Individuals receiving escape treatment were considered nonresponders. Baseline characteristics included median age 43 years, 60%-83% female, 46%-

72% Asian, and generalized pustular psoriasis area and severity index (GPPASI) total score 29.0-27.4. Of note, baseline characteristics differed be-tween groups for the proportion of female and Asian individuals as well as GPPASI total score. Significantly more individuals on spesolimab than placebo were able to achieve the primary endpoint of GPPGA pustulation subscore 0 at the end of Week 1 (54% vs 6%, pless than 0.001). Additionally, the key secondary endpoint of the proportion of individuals with GPPGA total score 0/1 at the end of Week 1 also was significantly in-creased with spesolimab compared to placebo (43% vs 11%, p=0.002). However, 15 of 18 individuals randomized to placebo received an open-label dose of spesolimab on Day 8. Because of this, the planned hierarchical testing of secondary outcomes with endpoints occurring after Day 8 was not possible. Instead, these outcomes were reported descriptively. In individuals who received greater than or equal to 1 dose of spesolimab (n=50), GPPASI-75 occurred in 11.4% of individuals at Week 1 and 51.4% at Week 8. Pain visual analogue scores (VAS) decreased 21.3 and 53.4 points on a 100 point scale at Weeks 1 and 8. The change from baseline (BL) in psoriasis symptom scale (PSS), a 17 point scale, was -4.0 at Week 1 and -7.0 at Week 8. The change from BL in Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) increased by 7.0 at Week 1 and 22.0 at Week 8, indicating an improvement in quality of life (QoL). Lastly, the GPPGA pustulation subscore 0 outcome was assessed at Week 8 for each subgroup of individuals who received spesolimab. The proportion of individuals achieving a score of 0 at Week 8 was 71%, 78%, 58%, and 60% for those randomized to spesolimab (n=35), randomized to spesolimab who received a single dose (n=23), randomized to spesolimab who received greater than 1 dose (n=12), and those randomized to placebo who received open-label spesolimab (n=15).

Individuals in the EFFISAYIL 1 trial were eligible for enrollment in a 5-year, open-label trial extension with spesolimab SC if the individual had a response to spesolimab and did not have an additional flare during the trial.1 No results are available to date.

The EFFISAYIL 2 trial is a 48-week, multicenter, randomized, double-blind, placebo-controlled Phase 2b trial in individuals 12-75 years of age with a history of GPP flares in the past who have clear/almost clear skin at the time of enrollment. Individuals are randomized to one of four arms including three spesolimab SC arms and placebo.[3] Study drug is administered once a month. The primary endpoint is time to first GPP flare. Study completion is expected in February 2023; no data is available to date.

Spesolimab has also been studied in individuals with PPP, a type of pustular psoriasis, in a 16-week, multi-center, double-blind, placebo-controlled, Phase 2a trial. The manufacturer is not currently seeking FDA approval for treatment of PPP. The trial included 59 individuals with PPP who were randomized to spesolimab 900 mg IV q4 weeks, spesolimab 300 mg IV q4 weeks, or placebo. Inclusion criteria were age 18-65 years, diagnosis of PPP with active pustules present,

PPPASI greater than or equal to 12, and palmoplantar pustulosis physician's global assessment (PPPGA) greater than or equal to 3. Of note, the trial was considered exploratory and formal statistical analysis was not done. Also, there were differences in baseline characteristics between groups for time since diagnosis (6.7 years placebo vs 10.4 years spesolimab). No difference was found between spesolimab and placebo in the primary outcome of PPPASI-50 at Week 16 (23.8% placebo, 31.6% spesolimab 300 mg, and 31.6% spesolimab 900 mg, risk difference vs placebo 0.078). The secondary end-point of PPPASI-75 was achieved in 9.5%, 0%, and 21%, respectively, while the mean change in PPPASI from BL was -40%, -32.7%, and -45.8%, respectively.

In the GPP trial, Grade 3/4 AEs occurred in less than 10% of individuals on spesolimab; no further information was provided. Serious AEs with spesolimab occurred in 6% of individuals in Week 1 and 12% in Week 12.1 At Week 12, the most common SAE was DRESS (n=2 [4%]); all remaining SAEs occurred in single individuals (UTI, drug-induced hepatic injury, arthritis, worsening plaque psoriasis, influenza, and squamous cell skin carcinoma). Of the two individuals listed as DRESS, one had a RegiSCAR score of 1 (no DRESS) and the other had a score of 3 (possible DRESS). Symptoms resolved without drug treatment in both cases. Both individuals developed ADAs. No deaths occurred in the trial.

In the PPP trial, Grade 3/4 AEs occurred in 10.5% of individuals on spesolimab 900 mg and 300 mg compared to 9.5% on placebo. Drug-related Grade 3/4 AEs included syncope in the spesolimab 900 mg group and worsening PPP in the placebo group. Serious AEs occurred in 4.8% of individuals on placebo, 5.3% on spesolimab 300 mg, and none on spesolimab 900 mg. Of these, one SAE was considered drug related (worsening PPP in the placebo group). No DRESS was reported. No deaths occurred.

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History

Date	Comments
07/01/25	New policy, approved June 10, 2025, effective for dates of service on or after October 3, 2025, following 90-day provider notification. Clarified that the Site of Service Medical Necessity criteria can apply to injection drugs. Moved the following drugs from policy 5.01.629 to policy 5.01.652: Vtama (tapinarof), Zoryve (roflumilast) cream, Duobrii (halobetasol and tazarotene), Enstilar (betamethasone and calcipotriene), Taclonex (betamethasone and calcipotriene), Wynzora (betamethasone and calcipotriene), brand calcipotriene foam, Dovonex (calcipotriene), Sorilux (calcipotriene), Vectical (calcitriol), Soriatane (acitretin), and Spevigo (spesolimab-sbzo). Added HCPCS code J1747 for Spevigo.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.