Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCTOP048.1225	**TOPICAL PRODUCTS** **TOPICAL AGENTS FOR SKIN CONDITIONS** See Table 1 for Applicable Medications
Effective Date: 2/1/2026	**Review/Revised Date**: 10/24,04/25, 05/25, 10/25, 10/25 (snm/kn)
Original Effective Date: 08/24	**P&T Committee Meeting Date**: 06/24, 10/24, 04/25, 06/25, 10/25, 12/25
Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:
Providence Health Plan and Providence Health Assurance as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:
Medicaid

POLICY CRITERIA:

COVERED USES:
All Food and Drug Administration (FDA)-Approved Indications

Coverage for Medicaid is limited to a condition that has been designated a covered line-item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services when all applicable indication-specific criteria below are met. The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit provides comprehensive and preventive health care services for children and adolescents up to their 21st birthday who are enrolled in Medicaid. Management of unfunded conditions falls under this benefit when it impacts the ability to grow, develop or participate in school and the applicable indication-specific criteria below are met.

Treatments for adults greater than or equal to 21 years of age are only funded if the condition is considered severe, as defined below. Seborrheic dermatitis, mild to moderate atopic dermatitis, and mild to moderate plaque psoriasis are considered unfunded conditions and will not be covered in patients greater than or equal to 21 years of age.

REQUIRED MEDICAL INFORMATION:
For patients less than 21 years of age:
1. Documentation of covered disease severity as defined by one of the following:
    a. Documentation of severe disease as defined by both of the following:
        i. Documentation that patient is having functional impairment as indicated by one of the following:

1) Dermatology Life Quality Index (DLQI) of at least 11
2) Children's Dermatology Life Quality Index (CDLQI) of at least 13
3) Severe score on other validated tool

ii. Documentation of one of the following:
1) At least 10% of body surface area involved
2) Hand, foot, face, or mucous membrane involvement

b. Documentation that the condition is of sufficient severity that it impacts the patient's health (such as quality of life, function, growth, development, ability to participate in school, or perform activities of daily living)

2. Documentation that they meet the following indication-specific criteria:
   a. For **Mild to moderate Plaque Psoriasis (PP):** Enstilar, Wynzora, Vtama cream, or Zoryve foam or 0.3% cream may be covered if there is documentation of contraindication, intolerance, or failed trial of two of the following:
      i. Moderate to high-potency topical corticosteroid for at least four weeks
      ii. Topical vitamin D analogues (calcitriol, calcipotriene) for at least four weeks
      iii. Tazarotene for at least eight weeks
      iv. Calcineurin inhibitor (tacrolimus, pimecrolimus) for at least eight weeks
   b. For **Severe Plaque Psoriasis (PP):** Enstilar, Wynzora, Vtama cream, or Zoryve foam or 0.3% cream may be covered if there is documentation of contraindication, intolerance, or failed four-week trial of at least two different high to super-high potency topical corticosteroids
   c. For **Atopic Dermatitis (AD):** Eucrisa, Opzelura, Vtama or Zoryve 0.15% or 0.05% cream may be covered if there is documentation of contraindication, intolerance, or failed two-week trials of at least two different topical agents from one or both of the following categories
      i. Topical corticosteroids (e.g., mometasone, betamethasone, clobetasol)
      ii. Topical calcineurin inhibitors (e.g., tacrolimus)
   d. For **Nonsegmental Vitiligo (NSV):** Opzelura may be covered if there is an inadequate response, contraindication, or intolerance to at least two agents from the following categories:
      i. Topical calcineurin inhibitors (such as tacrolimus) for at least three months
      ii. Moderate- to high-potency topical corticosteroids (such as clobetasol 0.05%) for at least two months
   e. For **Seborrheic Dermatitis (SD):** Documentation of confirmed diagnosis

For adult patients greater than or equal to 21 years of age:

1. Documentation of severe disease as defined by both of the following:
    a. Documentation that patient is having functional impairment as indicated by one of the following:
        i. Dermatology Life Quality Index (DLQI) of at least 11
        ii. Children's Dermatology Life Quality Index (CDLQI) of at least 13
        iii. Severe score on other validated tool
    b. Documentation of one of the following:
        i. At least 10% of body surface area involved
        ii. Hand, foot, face, or mucous membrane involvement
2. Documentation that they meet the following indication-specific criteria:
    a. For **Severe Atopic Dermatitis (AD):** Vtama may be covered if there is documentation of contraindication, intolerance, or failed two-week trials of at least two different topical agents from one or both of the following categories
        i. High to super-high potency topical corticosteroids (e.g., mometasone, betamethasone, clobetasol)
        ii. Topical calcineurin inhibitors (e.g., tacrolimus)
    b. For **Severe Plaque Psoriasis (PP):** Enstilar, Wynzora, Vtama cream, or Zoryve foam or 0.3% cream may be covered if there is documentation of contraindication, intolerance, or failed four-week trial of at least two different high to super-high potency topical corticosteroids
    c. For **Severe Nonsegmental Vitiligo (NSV)**: Opzelura may be covered if there is an inadequate response, contraindication, or intolerance to at least two agents from the following categories:
        i. Topical calcineurin inhibitors (such as tacrolimus) for at least three months
        ii. Moderate- to high-potency topical corticosteroids (such as clobetasol 0.05%) for at least two months

For reauthorization:
Must have documentation of response to therapy indicating improvement or stabilization of condition (e.g., reduced symptoms and/or affected BSA)

EXCLUSION CRITERIA:
For Opzelura: Concurrent use with biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication

PRESCRIBER RESTRICTIONS: N/A

COVERAGE DURATION:
Initial authorization will be approved for six months. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

QUANTITY LIMIT:
One tube (60 grams) per 30 days

Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:
Janus kinase (JAK) inhibitors mediate the signaling of cytokines and growth factors involved in hematopoiesis and immune function. Ruxolitinib has black box warnings for increased risk of serious infections, mortality (based on a study comparing an oral JAK inhibitor to a tumor necrosis factor blocker), malignancies, major adverse cardiovascular events, and thrombosis. It is the first FDA approved drug for a form of vitiligo.

Phosphodiesterase-4 (PDE-4) inhibitors cause an increase in intracellular cyclic adenosine monophosphate (cAMP) levels.

It is currently unclear the mechanism by which JAK and PDE-4 inhibitors exert their effects on AD and vitiligo.

Tapinarof (Vtama)1% cream and roflumilast (Zoryve) 0.3% cream are once-daily topical non-corticosteroid creams for the treatment of plaque psoriasis with novel mechanism of actions. Tapinarof is also for treatment of atopic dermatitis. Tapinarof is an aryl hydrocarbon receptor (AhR) agonist and roflumilast is a PDE4 inhibitor.

Other topical therapies for the treatment of plaque psoriasis include topical corticosteroids and vitamin D analogs (such as calcipotriene).

FDA APPROVED INDICATIONS:

Table 1. Topical Agents for skin conditions and their respective FDA-approved ages and indications

Drug	MOA	AD	NSV	PP	SD
Enstilar foam (calcipotriene/ betamethasone)	VDA			X (age 12+)	
Eucrisa ointment (crisaborole)	PDE-4 inhibitor	X Mild-Moderate (age 3 months+)			
Opzelura cream (ruxolitinib)	JAK inhibitor	X Mild-Moderate (age 2+)	X (age 12+)		
Vtama cream (tapinarof)	AHR agonist	X (age 2+)		X (age 18+)	
Wynzora cream (calcipotriene/ betamethasone)	VDA			X (age 18+)	
Zoryve 0.3% cream (roflumilast)	PDE-4 inhibitor			X (age 6+)	
Zoryve 0.15% cream (roflumilast)	PDE-4 inhibitor	X Mild-Moderate (age 6+)			
Zoryve 0.05% cream (roflumilast)	PDE-4 inhibitor	X Mild-Moderate (age 2-5)			
Zoryve 0.3% foam (roflumilast)	PDE-4 inhibitor			X (age 12+)	X (age 9+)

Abbreviations: AD = Atopic Dermatitis; AHR = Aryl Hydrocarbon Receptor, JAK = Janus kinase; MOA = Mechanism of Action; NSV = Nonsegmental Vitiligo; PDE = Phosphodiesterase; PP = Plaque Psoriasis, SD = Seborrheic Dermatitis, VDA = Vitamin D Analogue

POSITION STATEMENT:

Atopic Dermatitis:

The 2014 American Academy of Dermatology (AAD) guidelines for the management of atopic dermatitis (AD) recommend topical therapies as first-line treatment options due to their efficacy and safety profiles, starting with moisturizers. For patients with uncontrolled AD despite the use of moisturizers, topical corticosteroids (TCSs) and topical calcineurin inhibitors (TCIs) are recommended for both adults and children. In 2023, the AAD released an update to this guideline for adults which included recommendations for two newer classes of topical therapies, phosphodiesterase-4 (PDE-4) inhibitors (crisaborole) and Janus kinase (JAK) inhibitors (ruxolitinib). Moisturizers remained first line followed by TCSs and TCIs however the work group also strongly recommended both crisaborole (high certainty of evidence) and ruxolitinib (moderate certainty of evidence).

While the AAD has not yet provided updated guidance for children with AAD, the American Academy of Allergy, Asthma, and Immunology and the American College of Allergy, Asthma, and Immunology formed a Joint Task Force and published new guidelines for adults and children in 2023 (replacing their 2012 guidelines) which provided similar recommendations with the TCS and TCI agents receiving strong recommendations based on high certainty evidence however they were less supportive of the newer agents. Crisaborole received a conditional recommendation with high certainty evidence, stating that patients may prefer the greater efficacy and tolerability of the TCS and TCI agents over the PDE-4 agent. The Task Force conditionally recommended against the use of ruxolitinib based on low-certainty evidence due to the “uncertain small increase in serious harms.” Use of ruxolitinib should be limited to an area of less than 20% BSA to decrease the potential from harm through systemic absorption and should not be utilized on a continuous basis.

Both the AAD and AAAAI/ACAAI Task Force consider high to very high potency TCSs to have the most efficacy followed by the medium potency TCS agents and tacrolimus. Pimecrolimus efficacy was considered to be between that of medium-low and low to lowest potency TCS agents. High potency TCSs are very effective for flares, however their use should not exceed 4 weeks and use should be limited in sensitive areas such as the face, intertriginous folds, and groin. Low potency TCSs utilized in sensitive areas for an extended period may also cause adverse side effects.

Nonsegmental Vitiligo:

Vitiligo is a frequent cause of skin depigmentation with unknown etiology. It is suspected to have genetic and autoimmune components. Notably, vitiligo has been associated with other genetic syndromes and autoimmune diseases. Depigmentation from vitiligo directly affects the patient by increasing photosensitivity and being drier than other parts of the skin. Vitiligo is also associated with psychological (such as depression, low self-esteem) and social problems.

Nonsegmental vitiligo is the most common form of vitiligo and is symmetrical. Though it may initially have acrofacial distribution (limited to face, head, hands, and feet), it may continually spread to other body sites. This is contrasted to segmental vitiligo, which usually affects the body unilaterally and is characterized by rapid stabilization (new lesions stop appearing and the affected BSA does not grow).

According to the 2021 guidelines by the British Association of Dermatologists (BAD), vitiligo may be treated with initial three to six month trials of topicals such as TCIs and Phototherapy is a first line treatment for those with vitiligo who have an inadequate response to topical therapy and/or who have extensive or progressive disease. Options include narrowband ultraviolet B phototherapy (NBUVB) for full body therapy and excimer laser or light therapy for localized treatment. Repigmentation may begin as early as after three months of therapy. However, NBUVB may require six months to achieve a mild response and one year of treatment for optimal stabilization and repigmentation. Psoralen plus ultraviolet A (PUVA) photochemotherapy is a second-line phototherapy option associated with more adverse effects than first-line options. The international Vitiligo Task Force released worldwide expert recommendations in 2023 which are aligned with these guidelines.

Plaque Psoriasis:

Plaque psoriasis is a chronic inflammatory skin disease which impacts over 3% of the population and is characterized by well-demarcated erythematous plaques with silver scales. The American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) published joint guidelines for the use of topical therapies in psoriasis in 2021. Topical corticosteroids play a key role in the treatment of plaque psoriasis however agents such as vitamin D analogues, calcineurin inhibitors, and retinoids also play a role as steroid-sparing therapies. Tapinarof and roflumilast cream were not mentioned in these guidelines as they were not yet available.[6]

The efficacy and safety of tapinarof cream was established in two phase 3, multicenter, randomized, double-blind, vehicle-controlled trials, PSOARING 1 and PSOARING 2. Study participants must have met the following criteria:

1. Age 18-75
2. Diagnosis of chronic plaque psoriasis considered stable for at least six months
3. Body Surface Area (BSA) of 3-20% (excluding scalp, hand, and feet)
4. Physician's Global Assessment (PGA) score of 2, 3, or 4

Patients enrolled in the study were randomized to receive either tapinarof 1% cream or vehicle control cream for 12 weeks. The primary efficacy end point was reduction of PGA score by at least two from baseline at week 12. Secondary end points

included reduction in the Psoriasis Area and Severity Index (PASI) score by at least 75%, reduction in the PASI score by at least 90%, percentage of patients achieving a PGA score of 1 or less, and mean change in total BSA. The primary end point was achieved in 35.4% of patients in the tapinarof treatment group versus 6.0% in the vehicle control group (95% Confidence Interval [CI], 2.9 to 11.6; p<0.001) in PSOARING 1. The primary end point was achieved in 40.2% in the tapinarof treatment group versus 6.3% in the vehicle control group (95% CI, 3.3 to 11.4; p<0.001) in PSOARING 2. Secondary end points also achieved statistical significance. Adverse events occurring more frequently with tapinarof cream vs vehicle cream included folliculitis (23.5% vs 1.2% in PSOARING 1 and 17.8% vs 0.6% in PSOARING 2), contact dermatitis (5.0% vs 0.6% in PSOARING 1 and 5.8% vs 0% in PSOARING 2), and headache (3.8% vs 2.4% in PSOARING 1 and 3.8% vs 0.6% in PSOARING 2). There were no statistically significant differences in application site reactions, vital signs, laboratory values, or other medical examinations between the treatment and control groups in either study.

The safety and efficacy of roflumilast were evaluated in two Phase 3, multicenter, randomized, double-blind, vehicle-controlled trials, DERMIS-1 and DERMIS-2, which enrolled a total of 881 patients, two years and older, with mild to severe plaque psoriasis and BSA of 2%–20%. Patients were randomized to receive roflumilast or vehicle applied once daily for eight weeks. Roflumilast met its primary endpoint in both trials, which was the proportion of subjects who achieved IGA success at week eight. Success was defined as a score of “Clear” (0) or “Almost Clear” (1), plus a 2-grade improvement from baseline. The roflumilast group had an IGA success rate of 41.5% in DERMIS-1 and 36.7% in DERMIS-2 vs. placebo (5.8% vs. 7.1%, respectively).

Seborrheic Dermatitis:

SD is a chronic inflammatory skin condition characterized by white-yellowish erythematous, scaly plaques. The mechanism by which SD occurs is not fully understood however is multifactorial, involving environmental triggers as well as factors such as colonization by Malassezia spp., sebaceous gland activity, and immunosuppression. Endocrine and neurogenic factors have also been proposed. Topical antifungal agents (e.g., ketoconazole) are considered first-line therapy followed by TCSs (e.g., betamethasone) and TCIs (e.g., tacrolimus). Roflumilast foam has also been recognized as well-tolerated and effective topical therapy for SD.

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11. Jackson JM, Alexis A, Zirwas M, et al. Unmet needs to patients with seborrheic dermatitis. *J Am Acad Dermatol* 2024;90(3):597-604.