Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCTOP003O.0625	**TOPICAL PRODUCTS** **ELIDEL®** (pimecrolimus cream) **PROTOPIC®** (tacrolimus ointment)
Effective Date: 8/1/2025	**Review/Revised Date**: 05/01, 05/02, 05/03, 06/04, 06/05, 04/06, 04/07, 04/08, 04/09, 04/10, 12/10, 04/11, 08/11, 12/11, 02/12 , 04/12, 04/13, 06/13, 04/14, 04/15, 08/15, 03/16, 01/17, 03/17, 03/18, 01/19, 10/19, 10/20, 05/21, 04/22, 05/23, 05/24, 05/25 (KN)
Original Effective Date: 05/01	**P&T Committee Meeting Date**: 04/02, 06/04, 06/05, 04/06, 04/07, 04/08, 04/09, 04/10, 12/10, 04/11, 08/11, 12/11, 02/12, 04/12, 04/13, 06/13, 04/14, 10/14, 04/15, 08/15, 04/16, 02/17, 04/17, 04/18, 04/19, 12/19, 12/20, 06/21, 06/22, 06/23, 06/24, 06/25
Approved by: Oregon Region Pharmacy and Therapeutics Committee	

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

APPLIES TO:
Medicaid

POLICY CRITERIA:

COVERED USES:
Psoriasis, oral lichen planus, vitiligo, and all Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

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 or if the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit applies.

REQUIRED MEDICAL INFORMATION:
For atopic dermatitis, psoriasis, oral lichen planus, and vitiligo: one of the following:
1. Diagnosis of severe disease as defined by all 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. One of the following:
        i. At least 10% of body surface area involved
        ii. Hand, foot, face, or mucous membrane involvement
2. Patient qualifies for EPSDT review

Reauthorization requires documentation of reduction or stabilization from baseline of flares, pruritis, erythema, edema, xerosis, erosions/excoriation, oozing/crusting, lichenification or affected BSA

EXCLUSION CRITERIA:
Requests for coverage for **rosacea** will not be approved due to the lack of evidence supporting their effectiveness and safety in these conditions.

AGE RESTRICTIONS: N/A

PRESCRIBER RESTRICTIONS: N/A

COVERAGE DURATION:
Initial authorization for six months. Reauthorization for 12 months.

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:[1,2]
Elidel® (pimecrolimus cream) is a macrolactam (ascomycin derivative) and Protopic® (tacrolimus ointment) is a macrolide antibiotic produced by *Streptomyces tsukubaensis.* Both possess immunosuppressive properties.

FDA APPROVED INDICATIONS:[1,2]
ELIDEL® (pimecrolimus) Cream 1%: is indicated as second-line therapy for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in nonimmunocompromised adults and children two years of age and older, who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable.

PROTOPIC® Ointment, both 0.03% and 0.1% for adults, and only 0.03% for children aged two to fifteen years, is indicated as second-line therapy for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis in non immunocompromised adults and children who have failed to respond adequately to other topical prescription treatments for atopic dermatitis, or when those treatments are not advisable.

POSITION STATEMENT:

Atopic Dermatitis (AD)

Atopic dermatitis (also known as eczema) is a chronic, and relapsing inflammatory skin condition that typically causes red, swollen, itchy, and dry skin (erythema, edema, pruritis, and xerosis). This can lead to breakdown of the skin barrier and skin thickening from scratching (erosions/excoriations, oozing/crusting, and lichenification). This condition occurs most frequently in young children and many young patients will have resolution of symptoms by adulthood. However, some will continue to have symptoms into adulthood and some cases start in adulthood.[3]

The American Academy of Dermatology (AAD) guidelines for the management of AD recommend topical therapies as first-line treatment options due to their efficacy and safety profiles. Topical therapies that should be tried include skin hydration with moisturizers, wet-wrap therapy techniques for flares, and eliminating/avoiding triggers. Topical corticosteroids and topical calcineurin inhibitors are recommended for both adults and children. They can be used for acute treatment (typically twice daily) and for maintenance (1-2 times per week).[3.4] For adults, topical Janus kinase (JAK) inhibitors and topical phosphodiesterase-4 (PDE-4) inhibitors are also considered strong recommendations for use in mild to moderate atopic dermatitis.[4,5]

Off label prescribing of Elidel® and Protopic®:

Psoriasis: There is moderate evidence to support the effectiveness of calcineurin inhibitors in the treatment of facial or intertriginous psoriasis for short periods of time (the longest studies were eight weeks). No long-term studies are available to assess the safety and efficacy of these agents beyond eight weeks.[6-8,]

The joint American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) guidelines make recommendations for use of topical therapies. Topical corticosteroids are the mainstay of treatment of plaque psoriasis due to their excellent efficacy. Moderate to ultra-high potency steroids should be considered for the treatment of psoriasis not involving intertriginous areas. Tacrolimus 0.1% ointment is recommended to use off-label for psoriasis involving the face as well as inverse psoriasis (for up to eight weeks); pimecrolimus is also recommended for inverse psoriasis for 4-8 weeks. Tazarotene or Vitamin D analogues can be used for the treatment of mild to moderate psoriasis (including those included as a combination with corticosteroids).[9]

The joint AAD/NPF guidelines for pediatric patients recommend the treatment of psoriasis in children with the following topical therapies (Strength of recommendation A and B included):

- Corticosteroids
- Calcipotriene/calcipotriol (not recommended to be applied to large body surface area)
- Combination of calcipotriol/betamethasone dipropionate ointment/suspension for children ages 12 years and older with mild to moderate plaque psoriasis
- Long-term use (12 weeks or longer) of topical anthralin is recommended for the treatment of mild to moderate psoriasis. Short-contact anthralin protocols are recommended to limit adverse effects.
- NB-UVB for moderate to severe pediatric plaque and guttate psoriasis.[10]

Seborrheic dermatitis: There is limited evidence demonstrating the safety and efficacy of calcineurin inhibitors in the treatment of SD. The evidence that is available for review is not compelling due to small study populations leading to limited statistical power. The American Academy of Dermatology has not issued a consensus statement on the treatment of seborrheic dermatitis. An evidence review published in NEJM in 2009 summarizes first line treatment options as topical antifungal agents or topical corticosteroids.[13-15]

Oral lichen planus (OLP)
The evidence for treating OLP is focused on finding a treatment that can control the symptoms of OLP with minimal side-effects. The studies evaluating tacrolimus and pimecrolimus demonstrated their short-term effectiveness for treatment of OLP. There is a need for large, placebo controlled, randomized studies with standardized outcome measures.[16-17]

Vitiligo and additional skin conditions
Protopic® and Elidel® have evidence for use in a variety of skin conditions outside of atopic dermatitis. Coverage of these products for adults with Medicaid is limited to conditions that have been designated as covered line-item numbers by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services. Some conditions of the skin, such as seborrheic dermatitis are considered below the line or "unfunded" conditions. Other conditions such as atopic dermatitis, psoriasis and oral lichen planus are only covered for severe cases in adults. Per guideline note 21, severe inflammatory skin disease is defined as having functional impairment as indicated by a Dermatology Life Quality Index (DLQI) ≥ 11 or Children's Dermatology Life Quality Index (CDLQI) ≥ 13 (or severe score on other validated tool) and one or more of the following: at least 10% of body surface area involved; and/or hand, foot or mucous membrane involvement. The DLQI is a

validated measure developed to provide a standard and easy process for determining the impact of skin disease on a patient's quality of life (See a sample of DLQI). The CDLQI is a questionnaire that is geared towards children and has the rate symptoms of the condition using pictorial representations (See a version of the CDLQI).[18,19]

Fingertip units with relation to body surface area

Area to be treated	No. of fingertip units	Approximate Body surface area (%)
Scalp	3	6
Face and Neck	2.5	5
One hand (front and back) including fingers	1	2
One entire arm including entire hand	4	8
Elbows (large plaque)	1	2
Both soles	1.5	3
One foot (dorsum and sole), including toes	1.5	3
One entire leg including entire foot	8	16
Buttocks	4	8
Knees (large plaque)	1	2
Trunk (anterior)	8	16
Trunk (posterior)	8	16
Genitalia	0.5	1

Early and Periodic Screening Diagnostic and Treatment (EPSDT) Review

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit includes comprehensive preventative health care services for Medicaid members until they turn age 21 and for members with qualifying special health care needs (Youth with Special Healthcare Needs (YSHCN)) as they turn 21. This benefit applies when a condition is determined to impact the ability to grow, develop or participate in school and the applicable criteria above are met.

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