Policy and Procedure	
PHARMACY STEP THERAPY POLICY AND CRITERIA ORPTCTOP003.0625	**TOPICAL PRODUCTS** **ELIDEL®** (pimecrolimus cream)
Effective Date: 8/1/2025	**Review/Revised Date**: 01/17, 03/17, 03/18, 01/19, 10/19, 10/20, 04/21, 04/22, 05/23, 05/24, 04/25 (KN)
Original Effective Date: 03/17	**P&T Committee Meeting Date**: 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 and Providence Health Assurance as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:
Commercial

POLICY CRITERIA:

COVERED USES:
All medically accepted indications not otherwise excluded from the benefit.

REQUIRED MEDICAL INFORMATION:
Documented trial or contraindication to tacrolimus 0.1% ointment or tacrolimus 0.03% ointment

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS: N/A

PRESCRIBER RESTRICTIONS: N/A

COVERAGE DURATION:
Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

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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.

PHARMACY STEP THERAPY POLICY AND CRITERIA ORPTCTOP003.0624	TOPICAL PRODUCTS ELIDEL® (pimecrolimus cream)

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:

Elidel® (pimecrolimus cream) is a macrolactam (ascomycin derivative) and possesses immunosuppressive properties. Systematic reviews of the randomized trials comparing topical calcineurin inhibitors and low potency topical corticosteroids demonstrate that topical calcineurin inhibitors have similar effectiveness when used to treat severe atopic dermatitis (AD). Either Elidel® (pimecrolimus cream) or Protopic® (tacrolimus ointment) is recommended for use in patients at risk of atrophy from topical steroids.

FDA APPROVED INDICATIONS:

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 non-immunocompromised 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.

POSITION STATEMENT:

Topical calcineurin inhibitors are recommended for the treatment of atopic dermatitis (AD) in patients 3 months or older who have uncontrolled AD despite the use of moisturizers.

A meta-analysis comparing tacrolimus and pimecrolimus found that tacrolimus may be more effective after six weeks. While tacrolimus may have more adverse effects in adults patients, more patients withdrew from pimecrolimus treatment due to adverse effects, indicating tacrolimus may be more tolerable.[11]

The American Academy of Dermatology recommends that tacrolimus and pimecrolimus may be considered for facial and intertriginous psoriasis.

The American Academy of Dermatology has not issued a consensus statement on the treatment of seborrheic dermatitis. An evidence review published in New England Journal of Medicine (NEJM) in 2009 summarizes first line treatment options as topical antifungal agents or topical corticosteroids.

Studies evaluating the use of tacrolimus and pimecrolimus for treating oral lichen planus demonstrated short term effectiveness however there is a need for large, placebo controlled, randomized studies with standardized outcome measures.

REFERENCE/RESOURCES:

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2. Protopic® [Package Insert]; Deerfield, IL. Astellas Pharma; updated June 2022.
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11. Yin Z, Xu J, Luo D. Efficacy and tolerance of tacrolimus and pimecrolimus for atopic dermatitis: a meta-analysis. *J Biomed Res*. 2011;25(6):385-391. doi:10.1016/S1674-8301(11)60051-1