MEDICAL MUTUAL®

Drug Policy

Policy:	**Atopic Dermatitis Preferred Step Therapy**	**Annual Review Date:** **10/19/2023**
Impacted Drugs:	**Elidel (pimecrolimus cream)** **Eucrisa (crisaborole ointment)** **Pimecrolimus cream** **Protopic (tacrolimus ointment)** **Tacrolimus ointment**	**Last Revised Date:** **10/19/2023**

OVERVIEW

Tacrolimus ointment and pimecrolimus cream are topical calcineurin inhibitors (immunomodulators) indicated as *second-line therapy* for the short-term and non-continuous chronic treatment of AD in non-immunocompromised patients who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable. Tacrolimus ointment is indicated for moderate to severe AD while pimecrolimus cream is indicated for mild to moderate AD. Tacrolimus 0.03% ointment and pimecolimus 1% cream are indicated in adults and children aged ≥ 2 years. Although there are data documenting the tacrolimus 0.1% strength's safety and efficacy in children, this product is not approved for use in pediatric patients. Neither tacrolimus ointment nor pimecrolimus cream are indicated for use in children < 2 years of age; however, both agents have been studied in this patient population. Eucrisa, a phosphodiesterase 4 inhibitor, is indicated for the topical treatment of mild to moderate AD in patients ≥ 3 months of age.

Based on concerns of the potential carcinogenicity (skin cancer and lymphomas) that may be associated with using a topical immunomodulator continuously over a prolonged period, a Black Box Warning was added to pimecrolimus cream and tacrolimus ointment product labeling However, there have been no empirical data to date definitively linking the topical immunomodulators to an increased cancer risk in humans and a causal relationship has not been established.

POLICY STATEMENT

A preferred step therapy program has been developed to encourage the use of a preferred product prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a non-preferred agent at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 1 year in duration.

Preferred Medications

- Prescription topical corticosteroids (brand or generic)

Non-Preferred Medications (step 2)

- Pimecrolimus 1% cream (generic)
- Tacrolimus 0.03% and 0.1% ointment (generic)

Non-Preferred Medication (step 3)

- Protopic 0.03% and 0.1% (tacrolimus ointment)
- Elidel 1% (pimecrolimus cream)
- Eucrisa 2% (crisaborole ointment)

Automation: This program uses one topical steroid (brand or generic) in the previous 130 days as a surrogate marker for recommended use of tacrolimus ointment or pimecrolimus (generic). This program also uses one topical steroid (brand or generic) AND generic (tacrolimus ointment OR pimecrolimus cream) in the previous 130 days as a surrogate marker for recommended use of brand Eucrisa, Protopic or Elidel. If criteria for use of one prescription topical steroid (AND generic tacrolimus ointment OR pimecrolimus cream, if use of Protopic brand, Eucrisa OR Elidel brand, respectively) within the last 130 days (automated) are not met at the point of service, coverage will be determined by the step therapy criteria below.

PREFERRED STEP THERAPY CRITERIA

1. If the patient has tried a preferred medication, then authorization for a non-preferred (step 2) medication may be given

2. If the patient has tried a preferred medication AND generic tacrolimus ointment, then authorization may be given for brand Protopic ointment

3. If the patient has tried a preferred medication AND generic pimecrolimus cream, then authorization may be given for brand Elidel cream

4. If the patient has tried a preferred medication AND a non-preferred (step 2) medication, then authorization may be given for Eucrisa ointment

5. Authorization may be given for a generic, non-preferred medication if the patient has a dermatologic condition affecting the face, eyes/eyelids, axilla, genitalia, and/or other skin folds

6. Authorization may be given for Eucrisa if the patient is between the age of 3 months and 1 year old OR if the patient is between the ages of 1 and 2 years old and has tried a preferred product.

Initial Approval/ Extended Approval.

A) *Initial Approval:* 1 year

B) *Extended Approval:* 1 year

Step Therapy Exception Criteria

In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a

pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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4. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. *J Am Acad Dermatol*. 2009;60:643-659.
5. Eucrisa™ ointment [prescribing information]. Palo Alto, CA and New York, NY: Anacor Pharmaceuticals and Pfizer; March 2020.
6. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis. Section 2: management and treatment of atopic dermatitis with topical therapies. *J Am Acad Dermatol*. 2014;71(1):116-132.
7. Pimecrolimus. In: DRUGDEX [online database]. Truven Health Analytics. Greenwood Village, CO. Last updated 27 December 2018. Accessed on 17 January 2019,