MEDICAL MUTUAL®

# Drug Policy

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| **Policy:**<br><br>**Impacted Drugs:** | **Actinic Keratosis**<br>**Preferred Step Therapy**<br><br>• Aldara 5% cream<br>• Efudex 5% cream<br>• Klisyri 1% ointment | **Annual Review Date:**<br>**02/20/2025**<br><br>**Last Revised Date:**<br>**02/20/2025** |

## OVERVIEW

Actinic keratosis (AK) is a common dermatologic skin condition and affects an estimated 58 million people in the US. AKs (also known as solar keratoses) are discrete, premalignant, intraepidermal lesions that appear on chronically sun-exposed areas (face, scalp, lips, forearms, and hands) of fair-skinned, middle-aged, and older individuals. Cumulative exposure to ultraviolet (UV) radiation from sunlight is considered the leading cause of AK. Topical products listed below are used to treat this condition.

## POLICY STATEMENT

A preferred step therapy program has been developed to encourage the use of a Step 1 product prior to the use of a Step 2 product. If the preferred step therapy rule is not met for a Step 2 agent at the point of service, coverage will be determined by the preferred step therapy criteria below.

**Automation:** A patient with a history of one Step 1 drug within the 365-day look-back period is excluded from Step Therapy.

**Preferred Medications:**

- fluorouracil 2% solution
- fluorouracil 5% solution
- fluorouracil 5% cream
- imiquimod 5% cream

**Non-preferred Medications:**

- Aldara 5% cream
- Efudex 5% cream
- Klisyri 1% ointment

## CRITERIA

**1.** If the patient has tried one preferred product, then authorization for a non-preferred product may be given.

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**Initial Approval/ Extended Approval.**
**A)** *Initial Approval:* 365 days (1 year)
**B)** *Extended Approval:* 365 days (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*; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent*; **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 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.

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