BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
750 9th St NW
Washington, D.C. 20001
202.942.1000
Fax 202.942.1125

5.90.019

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Topical Products	**Original Policy Date:**	April 29, 2016
Subject:	Aldara	**Page:**	1 of 5

Last Review Date: March 8, 2024

Aldara

Description

Aldara (imiquimod)

Background
Aldara (imiquimod) cream is used for the treatment of actinic keratosis (AK), external genital and perianal warts, and primary superficial basal cell carcinoma (sBCC). Actinic keratosis (AK), also called solar keratosis, which is a chronic (long-term) condition of the skin caused by a chemical reaction to ultraviolet (UV) rays. Actinic keratosis (AK) can be linked to the development of skin cancer. Superficial basal cell carcinoma (sBCC) is the most common form of skin cancer. It usually develops on skin that gets the most sun exposure such as on the backs of hands, on the head, and neck. External genital and perianal warts, also called condyloma acuminata (EGW), are caused by a virus known as human papillomavirus (HPV), and spread through sexual contact. Genital warts rarely cause health problems, but local symptoms of pain and itching may occur (1).

Regulatory Status
FDA-approved indications: Aldara cream is indicated for the topical treatment of: (1)

1. Clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratoses (AK) on the face or scalp in immunocompetent adults.
2. Biopsy-confirmed, primary superficial basal cell carcinoma (sBCC) in immunocompetent adults; maximum tumor diameter of 2.0 cm on trunk, neck, or extremities (excluding hands and feet), only when surgical methods are medically less appropriate and patient follow-up can be reasonably assured.
3. External genital and perianal warts/condyloma acuminata in patients 12 years old or older

Warning and precautions that should be discussed with the patient on Aldara therapy include intense local inflammatory reactions at application site which can lead to severe vulvar swelling. Severe vulvar swelling can lead to urinary retention (1).

Related policies
Klisyri, Solaraze, Zyclara

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Aldara may be considered **medically necessary** if the conditions indicated below are met.

Aldara may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** the following:

1. Actinic keratosis (AK)
   a. 18 years of age or older
   b. Inadequate treatment response, intolerance, or contraindication to **TWO** of the following topical formulations:
      i. Generic imiquimod
      ii. Fluorouracil
      iii. Diclofenac

2. External genital and perianal warts (EGW)
   a. 12 years of age or older
   b. Inadequate treatment response, intolerance, or contraindication to **TWO** of the following topical formulations:
      i. Generic imiquimod
      ii. Podofilox
      iii. Fluorouracil
      iv. Trichloroacetic acid

3. Superficial basal cell carcinoma (sBCC)
    a. 18 years of age or older
    b. Biopsy-confirmed with a maximum tumor diameter of 2.0 cm.
    c. **NOT** for treatment on head, hands, feet, and anogenital skin
    d. Inadequate treatment response, intolerance, or contraindication to **TWO** of the following:
        i. Generic imiquimod
        ii. Mohs surgery
        iii. Surgical excision
        iv. Radiation

Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** the following:

1. Actinic keratosis (AK)
    a. 18 years of age or older
2. External genital and perianal warts (EGW)
    a. 12 years of age or older
3. Superficial basal cell carcinoma (sBCC)
    a. 18 years of age or older

AND the following:

1. Re-evaluation of lesion(s) / warts for improvement

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity	5% Packets	48 (2 boxes)
Duration	3 month	

Prior – Approval *Renewal* Limits

Quantity	5% Packets	48 (2 boxes)

Duration 3 month (One renewal only)

Rationale

Summary

Aldara (imiquimod) cream is a prescription medicine used on the skin for actinic keratosis (AK), external genital and perianal warts, and superficial basal cell carcinoma (sBCC). Actinic keratosis (AK) is a chronic (long-term) condition of the skin and can be linked to the development of skin cancer. Superficial basal cell carcinoma (sBCC) is cancer of the skin caused by excessive sun exposure. External genital and perianal warts, also called condyloma acuminata (EGW), are caused by a virus known as human papillomavirus (HPV) and spread through sexual contact. Genital warts rarely cause health problems, but local symptoms of pain and itching may occur (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Aldara while maintaining optimal therapeutic outcomes.

References

1. Aldara [package Insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC.; June 2022.

Policy History

Date	Action
April 2016	Addition to PA
June 2016	Annual review
December 2016	Annual editorial review Addition age requirements to renewal criteria
March 2017	Annual review
September 2018	Annual review and reference update
September 2019	Annual review and reference update
September 2020	Annual review
March 2021	Annual editorial review
March 2022	Annual review
March 2023	Annual review and reference update. Changed policy number to 5.90.019
September 2023	Annual review
March 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.