Aldara

Description

Aldara (imiquimod)

Background
Aldara cream is used for the treatment of actinic keratosis, external genital and perianal warts, and primary superficial basal cell carcinoma. 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 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 indication: 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**
Solaraze, Zyclara

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**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** in patients 18 years of age or older with actinic keratoses and if the conditions indicated below are met.

Aldara may be considered **medically necessary** in patients 12 years of age or older with external genital and perianal warts and if the conditions indicated below are met.

Aldara may be considered **medically necessary** in patients 18 years of age or older with superficial basal cell carcinoma (sBCC) and if the conditions indicated below are met.

Aldara is considered **investigational** in patients with all other indications.

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**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 ALL of the following:
   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 is a prescription medicine used on the skin for actinic keratosis, external genital and perianal warts, and superficial basal cell carcinoma. 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 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

Policy History

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<tbody>
<tr>
<td>April 2016</td>
<td>Addition to PA</td>
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<tr>
<td>June 2016</td>
<td>Annual review</td>
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<td>December 2016</td>
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<td>March 2017</td>
<td>Addition age requirements to renewal criteria</td>
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<td>September 2018</td>
<td>Annual review and reference update</td>
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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective on October 1, 2019.