Zyclara

Description

Zyclara (imiquimod)

Background
Zyclara cream is used on the skin for actinic keratosis and external genital and perianal warts. 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. 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
Zyclara cream, 2.5% and 3.75% are indicated for the topical treatment of clinically typical, visible or palpable actinic keratosis (AK) of the full face or balding scalp in immunocompetent adults. Zyclara cream, 3.75% is also indicated for the topical treatment of external genital and perianal warts/condyloma acuminata (EGW) in patients 12 years and older (1).

Limitations of Use:
Efficacy of imiquimod cream was not demonstrated for molluscum contagiosum in children 2 to 12 years of age (1).

Related policies
Aldara, Solaraze
Policy

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

Zyclara may be considered medically necessary in patients 18 years of age or older with actinic keratosis and if the conditions below are met.

Zyclara is considered investigational in patients less than 12 years of age and with 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. NOT immunocompromised
   c. Inadequate treatment response, intolerance, or contraindication to TWO of the following:
      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:
      i. Podofilox
      ii. Fluorouracil
      iii. Trichloroacetic acid

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

   AND ALL of the following:
   Re-evaluation of lesion(s) / warts for improvement

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**Policy Guidelines**

**Pre - PA Allowance**

None

**Prior - Approval Limits**

**Quantity**

**Actinic keratosis (AK)**
- Zyclara 2.5% Pump 2 bottles OR
- Zyclara 3.75% Pump 2 bottles OR
- Zyclara 3.75% Packets 56 (2 boxes)

**External genital and perianal warts (EGW)**
- Zyclara 3.75% Pump 2 bottles OR
- Zyclara 3.75% Packets 56 (2 boxes)

**Duration**
3 month

**Prior – Approval Renewal Limits**

**Quantity**

**Actinic keratosis (AK)**
- Zyclara 2.5% Pump 2 bottles OR
- Zyclara 3.75% Pump 2 bottles OR
- Zyclara 3.75% Packets 56 (2 boxes)

**External genital and perianal warts (EGW)**
- Zyclara 3.75% Pump 2 bottles OR
- Zyclara 3.75% Packets 56 (2 boxes)

**Duration**
3 month (One renewal only)
Rationale

Summary
Zyclara is a prescription medicine used on the skin for actinic keratosis and external genital and perianal warts. Actinic keratosis (AK) is a chronic (long-term) condition of the skin and can be linked to the development of skin cancer. 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. Efficacy of imiquimod cream was not demonstrated for molluscum contagiosum in children 2 to 12 years of age (1).

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

References

Policy History

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<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>December 2015</td>
<td>Addition to PA</td>
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<tr>
<td>March 2016</td>
<td>Annual review</td>
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<td>Policy number changed from 5.14.08 to 5.90.08</td>
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<tr>
<td>December 2016</td>
<td>Annual editorial review</td>
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<td>Addition of not immunocompromised in AK and dosing limits (3.75% only) for EGW</td>
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<tr>
<td>September 2017</td>
<td>Annual editorial review and reference update</td>
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</tbody>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 15, 2017 and is effective on October 1, 2017.