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5.90.008

Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Topical Products	**Original Policy Date:**	December 4, 2015
Subject:	Zyclara	**Page:**	1 of 4

Last Review Date: September 6, 2024

Zyclara

Description

Zyclara (imiquimod)

Background
Zyclara (imiquimod) cream is used topically 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
FDA-approved indications: 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 acuminate (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, Klisyri, 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** if the conditions indicated below are met.

Zyclara 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. **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. Generic imiquimod
      iii. Cryotherapy

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

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 months

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 months (One renewal only)

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Rationale

Summary

Zyclara (imiquimod) cream is a prescription medicine used topically 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

1. Zyclara [package Insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC.; February 2018.

Policy History

Date	Action
December 2015	Addition to PA
March 2016	Annual review Policy number changed from 5.14.08 to 5.90.08
December 2016	Annual editorial review Addition of not immunocompromised in AK and dosing limits (3.75% only) for EGW
September 2017	Annual editorial review and reference update
September 2018	Annual review and reference update
September 2019	Annual review and reference update
September 2020	Annual review
March 2021	Annual editorial review
December 2022	Annual review. Changed policy number to 5.90.008
September 2023	Annual review
June 2024	Annual review. Per SME, changed step requirement for trichloroacetic acid to cryotherapy and fluorouracil to generic imiquimod
September 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.