Xepi

Description

Xepi (ozenoxacin)

Background

Xepi (ozenoxacin) cream is a quinolone antimicrobial for the topical treatment of impetigo due to *Staphylococcus aureus* or *Streptococcus pyogenes* in adult and pediatric patients 2 months of age and older. Xepi is a quinolone antimicrobial drug whose mechanism of action involves the inhibition of bacterial DNA replication enzymes, DNA gyrase A and topoisomerase IV. Xepi has been shown to be bactericidal against *S. aureus* and *S. pyogenes* organisms (1).

Regulatory Status

FDA-approved indication: Xepi is indicated for the topical treatment of impetigo due to *Staphylococcus aureus* or *Streptococcus pyogenes* in adult and pediatric patients 2 months of age and older (1).

Prolonged use of Xepi may result in overgrowth of non-susceptible bacteria and fungi. If such infections occur, discontinue use and institute alternative therapy (1).

The safety and effectiveness of Xepi in pediatric patients younger than 2 months of age have not been established (1).
Section: Prescription Drugs  Effective Date: January 1, 2020
Subsection: Anti-Infective Agents  Original Policy Date: August 10, 2018
Subject: Xepi  Page: 2 of 4

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

Xepi may be considered medically necessary in patients age 2 months of age or older for the treatment of impetigo and if the conditions indicated below are met.

Xepi is considered investigational in patients less than 2 months of age and for all other indications.

Prior-Approval Requirements

Age 2 months of age and older

Diagnosis

The patient must have the following:

Impetigo

AND ALL of the following:
1. Laboratory and clinical documentation of ONE of the infections:
   a. *Staphylococcus aureus*
   b. *Streptococcus pyogenes*
2. Inadequate response, intolerance, or contraindication to mupirocin

Prior – Approval Renewal Requirements

Age 2 months of age and older

Diagnosis

The patient must have the following:

Impetigo

AND ALL of the following:
1. Laboratory and clinical documentation of ONE of the infections:
   a. *Staphylococcus aureus*
   b. *Streptococcus pyogenes*
Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Quantity 1 tube
Duration 1 month

Prior – Approval Renewal Limits

Quantity 1 tube
Duration 1 month (1 renewal per 365 days)

Rationale

Summary
Xepi (ozenoxacin) cream is a quinolone antimicrobial for the topical treatment of impetigo due to *Staphylococcus aureus* or *Streptococcus pyogenes* in adult and pediatric patients 2 months of age and older. The safety and effectiveness of Xepi in pediatric patients younger than 2 months of age have not been established (1).

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

References

Policy History

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**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.