



5.01.046

Section:	Prescription Drugs	Effective Date:	October 1, 2024
Subsection:	Anti-Infective Agents	Original Policy Date:	August 10, 2018
Subject:	Xepi	Page:	1 of 4

Last Review Date: September 6, 2024

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).

Related policies

Policy

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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** if the conditions indicated below are met.

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

Prior-Approval Requirements

Age 2 months of age and older

Diagnosis

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

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*

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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

1. Xepi [package insert]. Woburn, MA: Biofrontera Inc.; January 2020.

Policy History

Date	Action
September 2018	Addition to PA
November 2018	Annual review
December 2019	Annual review and reference update

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December 2020	Annual review and reference update
December 2021	Annual review
December 2022	Annual review. Changed policy number to 5.01.046
September 2023	Annual review
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.