



5.01.046

Section:	Prescription Drugs	Effective Date:	October 1, 2023
Subsection:	Anti-Infective Agents	Original Policy Date:	August 10, 2018
Subject:	Xepi	Page:	1 of 4

Last Review Date: September 8, 2023

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
December 2020	Annual review and reference update

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December 2021	Annual review
December 2022	Annual review. Changed policy number to 5.01.046
September 2023	Annual review

[Keywords](#)

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 8, 2023 and is effective on October 1, 2023.