

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

XEPI
(ozenoxacin)

Status: CVS Caremark® Criteria

Type: Initial Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS

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.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for the topical treatment of impetigo due to *Staphylococcus aureus* or *Streptococcus pyogenes*

AND

- The patient is 2 months of age or older

AND

- The patient has experienced an inadequate treatment response to a trial of topical mupirocin

OR

- The patient has experienced an intolerance to topical mupirocin

OR

- The patient has a contraindication that would prohibit a trial of topical mupirocin

AND

- The requested drug is not being used in a footbath

Quantity Limits apply.

30 grams per 25 days*

**This drug is for short-term acute use; therefore, the mail limit will be the same as retail limit. The intent is for prescriptions of the requested drug to be filled one month at a time, even if filled at mail order; there should be no 3-month supplies filled.*

Duration of Approval (DOA):

- 5466-C: DOA: 1 month

REFERENCES

1. Xepi [package insert]. Woburn, MA: Biofrontera Inc.; January 2020.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. <https://online.lexi.com>. Accessed August 7, 2023.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 08/07/2023).
4. Stevens DL, Bisno AL, Chambers HF, et al: Practice guidelines for the diagnosis and management of skin and soft tissue infections: 2014 Update by the Infectious Diseases Society of America. *Clin Infect Dis* 2014;59(2):e10-e52.
5. Hartman-Adams H, Banvard C, Juckett G. Impetigo: Diagnosis and Treatment. *Am Fam Physician*. 2014;90(4):229-235.

Xepi PA with Limit Policy 5466-C UDR 10-2023

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

6. Eichenfield L, Tom W, Berger T, et al. Guidelines of Care for the Management of Atopic Dermatitis Section 2. Management and Treatment of Atopic Dermatitis with Topical Therapies. *J Am Acad Dermatol*. 2014;71:116-32.
7. U.S. Department of Health & Human Services. Burn Triage and Treatment – Thermal Injuries. Chemical Hazards Emergency Medical Management. November 16, 2022. Available at: <https://chemm.hhs.gov/burns.htm>. Accessed August 21, 2023.

Xepi PA with Limit Policy 5466-C UDR 10-2023

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

©2023 CVS Health and/or its affiliates. All rights reserved. 106-58428B 021423