

Clinical Policy: Ozenoxacin (Xepi)

Reference Number: PA.CP.PMN.119

Effective Date: 01.30.18

Last Review Date: 04.17.19

[Revision Log](#)

Description

Ozenoxacin (Xepi™) is a quinolone antimicrobial.

FDA Approved Indication(s)

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.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness® that Xepi is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Impetigo (must meet all):

1. Diagnosis of impetigo;
2. Age \geq 2 months;
3. Failure of a trial of mupirocin 2% ointment or cream at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed BID topical application for five days.

Approval duration: 1 month (1 tube)

B. Other diagnoses/indications

1. Refer to the off-label use policy PA.CP.PMN.53.

II. Continued Therapy

A. Impetigo (must meet all):

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed BID topical application for five days.

Approval duration: 1 month (1 tube)

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via PA Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
mupirocin (Bactroban [®]) 2% cream, ointment	Apply a small amount to affected area (up to 10 cm in length or 100 cm ² in area) TID x 10 days	TID application as outlined x 10 days

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): none reported

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Impetigo	BID topical application (thin layer) for five days (for up to 100 cm ² in patients ≥ 12 years or 2% of the total body surface area and not exceeding 100 cm ² if age < 12 years.	BID application as outlined x 5 days

V. Product Availability

Cream (1%): 30 g

VI. References

1. Xepi Prescribing Information. Fairfield, NJ: Medimetrick's Pharmaceuticals, Inc.; January 2019. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=3361dd6c-4b03-4c42-9b95-4ecd43c34294>. Accessed February 24, 2019.
2. Bactroban Cream Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; March 2017. Available at <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&applno=050746>. Accessed February 24, 2019.
3. Bactroban Ointment Prescribing Information. Research Triangle Park, NC: GalxoSmithKline; December 2015. Available at: https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Bactroban_Ointment/pdf/BACTROBAN-OINTMENT-PI-PIL.PDF. Accessed February 24, 2019.

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. *Clinical Infectious Diseases* 2014;59(2):e10–52
5. Koning S, van der Sande R, Verhagen AP, et al. Interventions for impetigo (review). *Cochrane Database of Systematic Reviews*. 2012, Issue 1. Art. No.: CD003261.
6. Hartman-Adams H, Banvard C, Juckett G. Impetigo: diagnosis and treatment. *Am Fam Physician*. 2014;90(4):229-235.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	01.30.18	04.18.18
2Q 2019 annual review: product availability updated; references reviewed and updated.	04.17.19	