

Clinical Policy Title:	ozenoxacin
Policy Number:	RxA.321
Drug(s) Applied:	Xepi®
Original Policy Date:	02/07/2020
Last Review Date:	06/10/2021
Line of Business Policy Applies to:	All lines of business

Background

Xepi® is a quinolone antimicrobial 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
ozenoxacin (Xepi®)	Impetigo	Topical application (thin layer) twice daily for 5 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	Twice daily application as outlined x 5 days

Dosage Forms

- Cream: Each gram contains 10 mg of ozenoxacin (1%)

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the provisions of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Impetigo (must meet all):

1. Diagnosis of impetigo;
2. Age ≥ 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 twice daily topical application for 5 days.

Approval duration

Commercial: 1 month (1 tube)

Medicaid: 1 month (1 tube)

II. Continued Therapy Approval

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

A. Impetigo (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed twice daily topical application for 5 days.

Approval duration

Commercial: 1 month (1 tube)

Medicaid: 1 month (1 tube)

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
mupirocin 2% cream, ointment	Apply small amount to affected area (up to 10 cm in length or 100 cm ² in area) three times daily x 10 days	Three times daily 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

APPENDIX D: General Information

Prolonged use of Xepi® may result in overgrowth of nonsusceptible bacteria and fungi. If such infections occur, discontinue use and institute alternative therapy.

References

1. Xepi® Prescribing Information. Fairfield, NJ: Medimetrix Pharmaceuticals, Inc.; January 2020. Available at: <https://www.xepicream.com/>. Accessed February 26, 2021.
2. mupirocin Ointment Prescribing Information. Daily Med; October 2015. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=3c4accb1-749d-4b89-bec5-5b9b7ea9dd23&type=display>. Accessed February 26, 2021.
3. 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.
4. 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.
5. Hartman-Adams H, Banvard C, Juckett G. Impetigo: diagnosis and treatment. *Am Fam Physician*. 2014;90(4):229-235.

Review/Revision History	Review/Revised Date	P&T Approval Date
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Policy established.	01/2020	02/07/2020
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Policy title table was updated. 2. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance...”. 3. Approval duration was updated to include commercial and Medicaid plan in initial approval as well as in clinical therapy criteria. 4. Bactroban is removed from therapeutic alternatives as it is off market now. 5. References were updated. 	07/10/2020	09/14/2020
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Last review date was updated. 2. Clinical policy verbiage added “The provision of provider samples does not guarantee...”. 3. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance...”. 4. Appendix B: "Therapeutic alternatives verbiage was updated to below are suggested therapeutic alternatives based on clinical guidance...." 5. Appendix D: updated to “Prolonged use of Xepi® may result in overgrowth of nonsusceptible bacteria and fungi. If such infections occur, discontinue use and institute alternative therapy.” 6. References were reviewed and updated. 7. Dosage form updated to 	02/26/2021	06/10/2021

<p>Cream: Each gram contains 10 mg of ozenoxacin (1%)</p> <p>8. Dosage Regimen reworded to: Topical application (thin layer) twice daily for 5 days (for up to 100 cm² in patients ≥ 12 years or 2% of the total body surface area and not exceeding 100 cm² if age < 12 years</p>		
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