Clinical Policy: Ozenoxacin (Xepi)

Reference Number: ERX.NPA.69
Effective Date: 06.01.18
Last Review Date: 05.20
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 ≥ 2 months;
3. Failure 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 five days.

Approval duration: 1 month (1 tube)

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Impetigo (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
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 five days.

Approval duration: 1 month (1 tube)

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 1 month (1 tube) (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. 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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
mupirocin (Bactroban®) 2% cream, ointment	Apply 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
None reported

V. 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

VI. Product Availability

Tube containing 1% cream: 30 g

VII. References

1. Xepi Prescribing Information. Fairfield, NJ: Medimetricks Pharmaceuticals, Inc.; January 2019. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=3361dd6c-4b03-4c42-9b95-4ecd43c34294. Accessed February 6, 2020.
2. Bactroban Cream Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; March 2017. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/050746s021lbl.pdf. Accessed February 6, 2020.
3. Bactroban Ointment Prescribing Information. Research Triangle Park, NC: GalxoSmithKline; December 2015. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/050703s017lbl.pdf. Accessed February 6, 2020.
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	05.18
2Q 2019 annual review: no significant changes; references reviewed and updated.	02.24.19	05.19
2Q 2020 annual review: no significant changes; references reviewed and updated.	02.06.20	05.20

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.