Reference number(s)
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Initial Prior Authorization with Quantity Limit
Xepi

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Xepi	ozenoxacin

Indications

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

Impetigo

Authorization may be granted when the requested drug is being prescribed for the topical treatment of impetigo due to Staphylococcus aureus or Streptococcus pyogenes when ALL of the following criteria are met:

- The patient is 2 months of age or older.
- The requested drug is NOT being used in a footbath.

- The patient meets ONE of the following:
  - The patient has experienced an inadequate treatment response to a trial of topical mupirocin.
  - The patient has experienced an intolerance to topical mupirocin.
  - The patient has a contraindication that would prohibit a trial of topical mupirocin.

Quantity Limits Apply

30 grams per 25 days.

This drug is for short-term acute use; therefore, the intent is for prescriptions of the requested drug to be filled one month at a time; 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.
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3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 09/11/2024).
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.
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. June 7, 2024. Available at: https://chemm.hhs.gov/burns.htm. Accessed September 11, 2024.

Reference number(s)
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Document History

Written by: UM Development (DRS)

Date Written: 07/2022

Revised: (MRS) 09/2022 (no clinical changes); (DRS) 09/2023 (no clinical changes); (KEJ) 09/2024 (no clinical changes)

Reviewed: Medical Affairs (CHART) 07/21/2022, 09/22/2022, 09/28/2023, 09/26/2024

External Review: 08/2022, 12/2022, 12/2023, 12/2024

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for the topical treatment of impetigo due to Staphylococcus aureus or Streptococcus pyogenes? [If Yes, then go to 2. If No, then no further questions.]	Yes	No
2	Is the patient 2 months of age or older? [If Yes, then go to 3. If No, then no further questions.]	Yes	No
3	Has the patient experienced an inadequate treatment response to a trial of topical mupirocin? [If Yes, then go to 6. If No, then go to 4.]	Yes	No
4	Has the patient experienced an intolerance to topical mupirocin? [If Yes, then go to 6. If No, then go to 5.]	Yes	No
5	Does the patient have a contraindication that would prohibit a trial of topical mupirocin? [If Yes, then go to 6. If No, then no further questions.]	Yes	No
6	Is the requested drug being used in a footbath? [If Yes, then no further questions. If No, then go to 7.]	Yes	No
7	Does the patient require MORE than the plan allowance of 30 grams per month? [No further questions]	Yes	No

RPH Note: If yes, then deny and enter a partial approval for 30 grams / 25 days.

Mapping Instructions

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	Yes	No	DENIAL REASONS
1.	Go to 2	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use is for impetigo due to certain bacteria. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]
2.	Go to 3	Deny	Your plan only covers this drug if you are 2 months old or older. We reviewed the information we had. Your request has been denied. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Age]
3.	Go to 6	Go to 4	
4.	Go to 6	Go to 5	
5.	Go to 6	Deny	Your plan only covers this drug if you have tried topical mupirocin and it did not work well for you. We have denied your request because: A) You have not tried it, and B) You do not have a medical reason not to take it. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Step therapy]
6.	Deny	Go to 7	We have denied your request because your plan does not cover this drug if it is being used in a footbath. Your request has been

			denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Footbath Use]
7.	Deny	[PA Approved for 1 month. Approve 30 grams/25 days. No 3 month supplies]. Approve, 1 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (30 grams per month). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial]