



Original Effective Date: 11/01/2015
Current Effective Date: 05/31/2024
Last P&T Approval/Version: 04/24/2024
Next Review Due By: 04/2025
Policy Number: C8409-A

Topical Antibacterials

PRODUCTS AFFECTED

Altabax (retapamulin 1% ointment), Bactroban (mupirocin), Centany (mupirocin 2% ointment), mupirocin 2% cream, Xepi (ozenoxacin 1% cream)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:

Impetigo, Secondarily infected traumatic skin lesion and eradication of nasal colonization of MRSA

REQUIRED MEDICAL INFORMATION:

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. FOR ALL INDICATIONS:

1. Documentation member is being treated for impetigo or infection suspected to be *Staphylococcus aureus* or *Streptococcus pyogenes* susceptible to mupirocin for topical treatment
AND

Drug and Biologic Coverage Criteria

2. FOR ALTABAX, CENTANY, XEPI, AND MUPIROCIN CREAM REQUESTS ONLY: Documentation of a trial and failure or absolute FDA labeled contraindication to mupirocin ointment

CONTINUATION OF THERAPY:

NA

DURATION OF APPROVAL:

Initial authorization: 30 days, Continuation of therapy: NA

PRESCRIBER REQUIREMENTS:

No requirement

AGE RESTRICTIONS:

ALTABAX (retapamulin 1% ointment): 9 months of age and older

XEPI (ozenoxacin 1% cream): 2 months of age and older

MUPIROCIN: No restriction

QUANTITY:

Altabax (retapamulin) up to 30 grams/30 days

Xepi (ozenoxacin) up to 30 grams/30 days

Mupirocin: no quantity limit

PLACE OF ADMINISTRATION:

The recommendation is that topical medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Topical

DRUG CLASS:

Antibiotics - Topical

FDA-APPROVED USES:

Mupirocin 2% ointment is indicated for the topical treatment of impetigo due to susceptible isolates of *Staphylococcus aureus* and *Streptococcus pyogenes*.

Mupirocin 2% cream is indicated for the treatment of secondarily infected traumatic skin lesions (up to 10 cm in length or 100 cm² in area) due to susceptible isolates of *Staphylococcus aureus* and *Streptococcus pyogenes*.

Altabax (retapamulin 1% ointment) is indicated for use in adults and pediatric patients aged 9 months and older for the topical treatment of impetigo (up to 100 cm² in total area in adults or 2% total body surface area in pediatric patients aged 9 months or older) due to *Staphylococcus aureus* (methicillin-susceptible isolates only) or *Streptococcus pyogenes*. Safety in patients younger than 9 months has not been established. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Altabax and other antibacterial drugs, Altabax should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

Xepi (ozenoxacin 1% cream) 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.

COMPENDIAL APPROVED OFF-LABELED USES:

None

APPENDIX

APPENDIX:

None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Bactroban/Centany (mupirocin), Altabax (retapamulin), and Xepi (ozenoxacin) are considered experimental/investigational and therefore, will follow Molina’s Off-Label policy. Contraindications to mupirocin include: known hypersensitivity to mupirocin or any of the excipients of the formulation. Contraindications to Altabax (retapamulin) include: No labeled contraindications. Contraindications to Xepi (ozenoxacin) include: No labeled contraindications.

OTHER SPECIAL CONSIDERATIONS:

None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

- Altanax OINT 1%
- Centany AT KIT 2%
- Centany OINT 2%
- Mupirocin Calcium CREA 2%
- Xepi CREA 1%

REFERENCES

1. Altanax (retapamulin ointment) for topical use [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; June 2023.
2. Bactroban (mupirocin) ointment [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; March 2017.
3. Bactroban (mupirocin) cream [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; February 2020.
4. Centany (mupirocin) ointment [prescribing information]. Allegan, MI: Medimetriks Pharmaceuticals Inc; May 2017.
5. Mupirocin [prescribing information]. Mahwah, NJ: Glenmark Pharmaceuticals Inc; November 2023.
6. Xepi (ozenoxacin) cream, for topical use [prescribing information]. Woburn, MA: Biofrontera Inc; January

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Drug and Biologic Coverage Criteria
2020.

7. Stevens DL, et al. Practice Guidelines for the Diagnosis and Management of Skin and Soft- Tissue Infections: 2014 Updated by the Infectious Disease Society of America. Clin Infect Dis. 2014 Jul 15;59(2):e10-52.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION-Notable Revisions: FDA-Approved Uses References Policy Name Change	Q2 2024
REVISION-Notable Revisions: Required Medical Information FDA-Approved Uses Contraindications/Exclusions/Discontinuation Available Dosage Forms References	Q2 2023
REVISION-Notable Revisions: Quantity References	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file