STEP THERAPY POLICY

POLICY: Topical Antibacterials Step Therapy Policy

- Altabax® (repatamulin ointment – Almirall)
- Centany® (mupirocin ointment – Medimetriks)
- Centany® AT (mupirocin ointment – Medimetriks)
- Mupirocin cream (generic only)
- Mupirocin ointment (generic only)
- Xepi™ (ozenoxacin cream – Biofrontera)

REVIEW DATE: 11/15/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

These topical antibacterials are generally indicated for the treatment of **dermatologic infections** caused by *Staphylococcus aureus* or *Streptococcus pyogenes*.[1-6]

The approved indications for these products are as follows:

- Altabax is indicated for use in adults and **pediatric patients ≥ 9 months of age** for the topical **treatment of impetigo** (up to 100 cm^2 in total area in adults or 2% total body surface area in pediatric patients ≥ 9 months of age) due to *S. aureus* (methicillin-susceptible isolates only) or *S. pyogenes.*
- Centany/Centany AT/mupirocin ointment are indicated for the topical **treatment of impetigo** due to *S. aureus* and *S. pyogenes*. The safety and effectiveness of Centany/mupirocin ointment have been established in **pediatric patients 2 months to 16 years of age**. Centany AT differs from Centany in that it is packaged with gauze pads and cloth tape strips.
- Mupirocin cream is indicated for the treatment of **secondarily infected traumatic skin lesions** (up to 10 cm in length or 100 cm^2 in area) due to susceptible isolates of *S. aureus* and *S. pyogenes*. The safety and effectiveness

of mupirocin cream have been established in **pediatric patients 3 months to 16 years of age**.
- Xepi, a topical quinolone antimicrobial, is indicated for the topical **treatment of impetigo** due to *S. aureus* or *S. pyogenes* in adults and **pediatric patients ≥ 2 months of age**.

Guidelines

The Infectious Diseases Society of America (IDSA) updated their practice guidelines for the diagnosis and management of skin and soft tissue infections in 2014.[7] (Note: The guidelines were released prior to the approval of Xepi). The IDSA notes that either topical mupirocin or Altabax should be used for 5 days for the treatment of bullous and nonbullous impetigo. Topical treatment with mupirocin or Altabax is as effective as oral antimicrobials for impetigo. However, systemic therapy is preferred in patients with numerous lesions or in outbreaks affecting several people, to decrease transmission of infection. A 7-day regimen of an oral agent active against *S. aureus* is recommended unless cultures show streptococci alone (and oral penicillin is the recommended agent).

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Topical Antibacterials product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.

Step 1: generic mupirocin ointment

Step 2: Altabax, Centany, Centany AT, generic mupirocin cream, Xepi

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.

REFERENCES

1. Altabax® ointment [prescribing information]. Exton PA: Almirall; June 2023
2. Centany® ointment [prescribing information]. Fairfield, NJ: Medimetriks; May 2017.
3. Centany® AT ointment [prescribing information]. Fairfield NJ: Medimetriks; May 2017.
4. Mupirocin cream [prescribing information]. Mahwah, NJ: Glenmark; March 2020.
5. Xepi™ cream [prescribing information]. Woburn, MA: Biofrontera; January 2020.
6. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2023. Available at: http://online.factsandcomparisons.com/login.aspx?url=/index.aspx&qs=. Accessed on November 8, 2023. Search terms: mupirocin.

7. 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	11/09/2022
Annual Revision	No criteria changes.	11/15/2023