Pharmacy Policy Bulletin

Title: Retapamulin (Altabax®)
Policy #: Rx.01.79

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

**Intent:**
The intent of this policy is to communicate the medical necessity criteria for retapamulin (Altabax®) as provided under the member’s prescription drug benefit.

**Description:**
Impetigo is a contagious, superficial bacterial infection most commonly observed in children. The primary pathogen associated with impetigo is Staphylococcus aureus. Beta hemolytic streptococci account for the minority of cases. Topical treatment is used for patients with limited skin involvement. Oral therapy is reserved for cases in which numerous lesions are present. Topical treatments include mupirocin and retapamulin. Over the counter topical treatments (ie bacitracin, neomycin, polymyxin B) are not recommended as they are not as effective as mupirocin or retapamulin.

Retapamulin is a semisynthetic derivative of pleuromutilin which inhibits bacterial protein synthesis by interacting with the 50S subunit of the bacterial ribosome. Retapamulin is bacteriostatic against Staphylococcus aureus and Streptococcus pyogenes.

**Retapamulin (Altabax®)** is a topical antibiotic indicated for the treatment of impetigo due to Staphylococcus aureus (methicillin-susceptible isolates only) or Streptococcus pyogenes in individuals nine months of age and older.

**Policy:**
Retapamulin (Altabax®) is approved when ALL of the following are met:

1. Diagnosis of impetigo; and
2. Member is 9 months of age or older; and
3. Inadequate response or inability to tolerate mupirocin ointment

**Black Box Warning:**
Guidelines:
Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:


Applicable Drugs:
Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tbody>
<tr>
<td>Altabax®</td>
<td>retapamulin</td>
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Cross References:
N/A

Policy Version Number: 8.00
P&T Approval Date: January 11, 2018
Policy Effective Date: April 1, 2018
Next Required Review Date: January 11, 2019

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