Select Topical Antibiotics/Combinations

Policy # 00717
Original Effective Date: 01/01/2021
Current Effective Date: 10/14/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider select topical antibiotic/combination products, including, but not limited to Altabax®‡ (retapamulin) ointment and Neo-Synalar®‡ (neomycin/fluocinolone) cream to be **eligible for coverage**** when the below patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for select topical antibiotic/combination products, including, but not limited to Altabax (retapamulin) ointment and Neo-Synalar (neomycin/fluocinolone) cream will be considered when the following patient selection criteria are met for the requested drug:

- For Altabax ointment requests:
  - Patient has a diagnosis of impetigo; AND
  - Patient is 9 months of age or older; AND
  - Area to treat is less than or equal to 100 cm^2 total area in adults OR less than or equal to 2% total body surface area in pediatrics; AND
  - Patient has tried and failed (e.g., intolerance or inadequate response) GENERIC mupirocin (ointment or cream) for the CURRENT infection AND Xepi™‡ (ozenoxacin) cream for the CURRENT infection unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.
    *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

- For Neo-Synalar cream requests:
  - Requested drug is being utilized for the treatment of corticosteroid-responsive dermatoses with secondary infection; AND
  - Patient has tried and failed (e.g., intolerance or inadequate response) over the counter (OTC) triple antibiotic ointment PLUS GENERIC fluocinolone 0.025% cream after at least 7 days of therapy for the CURRENT infection unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
    *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
  - Patient has tried and failed (e.g., intolerance or inadequate response) a Cortisporin®‡ (neomycin/polymyxin/bacitracin/hydrocortisone) 0.5% cream or 1% ointment after at least 7 days of therapy for the CURRENT infection unless there is clinical evidence or patient history that suggests the use of this product will be ineffective or cause an adverse reaction to the patient.
    *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of select topical antibiotic/combination products, including, but not limited to Altabax (retapamulin) ointment and Neo-Synalar (neomycin/fluocinolone) cream when the patient has not tried and failed the specified alternative products for the specified amount of time (where applicable) to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of select topical antibiotic/combination products, including, but not limited to Altabax (retapamulin) ointment and Neo-Synalar (neomycin/fluocinolone) cream when the patient selection criteria are not met (except those noted to be **not medically necessary****) to be **investigational.***

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Background/Overview

Altabax ointment is indicated for the topical treatment of impetigo due to *Staphylococcus aureus* (methicillin-susceptible isolates only) or *Streptococcus pyogenes* in patients aged 9 months or older. Both generic mupirocin (ointment and cream) and Xepi carry similar indications to Altabax. All of these products were evaluated versus placebo in their respective clinical studies. Therefore, claims of superiority amongst the products cannot be made. The alternative products offer a more cost effective, yet efficacious option for treatment as compared to Altabax.

Neo-Synalar is indicated for the treatment of corticosteroid-responsive dermatoses with secondary infection. It has not been demonstrated that Neo-Synalar provides greater benefit than the steroid component alone after 7 days of treatment. Cortisporin (neomycin/polymyxin/bacitracin/hydrocortisone) carries the same indication as Neo-Synalar. An alternative option for treatment would be use of an OTC triple antibiotic ointment plus a generic fluocinolone 0.025% cream (similar ingredients as Neo-Synalar). These products were evaluated versus placebo, so claims of superiority amongst the products cannot be made. Cortisporin, as well as the combination of an OTC triple antibiotic plus generic fluocinolone 0.025% cream, offers a more cost effective, yet efficacious option for treatment as compared to Neo-Synalar.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Altabax ointment is indicated for the topical treatment of impetigo due to *Staphylococcus aureus* (methicillin-susceptible isolates only) or *Streptococcus pyogenes* in patients aged 9 months or older. Neo-Synalar is indicated for the treatment of corticosteroid-responsive dermatoses with secondary infection. It has not been demonstrated that Neo-Synalar provides greater benefit than the steroid component alone after 7 days of treatment.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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This policy is intended to ensure that these products are used per their FDA package inserts. None of the products mentioned in this policy have been studied head to head, so no superiority claims can be made among these products. The alternative products mentioned in the policy offer a more cost effective, yet efficacious option for treatment as compared to the targeted medications.

References

1. Altabax [package insert]. Almirall, LLC. Exton, Pennsylvania. Updated September 2019.
2. Neo-Synalar [package insert]. Medimetriks Pharmaceuticals, Inc. West Fairfield, New Jersey. Updated September 2016.
3. UpToDate. Impetigo. Updated April 2019. Accessed August 2020.
4. Xepi [package insert]. Biofrontera, Inc. Woburn, Massachusetts. Updated January 2020.
5. mupirocin [package insert]. Various manufacturers.
6. Cortisporin [package insert]. Pfizer. New York, New York. Updated April 2018.

Policy History

Original Effective Date: 01/01/2021
Current Effective Date: 10/14/2024

09/03/2020	Medical Policy Committee review
09/09/2020	Medical Policy Implementation Committee approval. New policy.
09/02/2021	Medical Policy Committee review
09/08/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/01/2022	Medical Policy Committee review
09/14/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/07/2023	Medical Policy Committee review
09/13/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/05/2024	Medical Policy Committee review
09/11/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 09/2025

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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.