Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member’s specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy 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 BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.

**Description:**

Neo-synalar (neomycin sulfate and fluocinolone acetonide) cream is indicated for the treatment of corticosteroid-responsive dermatoses with secondary infection. It has not been demonstrated that this steroid-antibiotic combination provides greater benefit than the steroid component alone after 7 days of treatment.

Fluocinolone acetonide is a low-to-medium potency synthetic corticosteroid that has anti-inflammatory, antipruritic, and vasoconstrictive properties. Its anti-inflammatory action is thought to be due to its ability to control biosynthesis of potent mediators of inflammation. It stimulates phospholipase A-2 inhibitory proteins (lipocortins) and subsequently blocks the release of arachidonic acid, which is a common precursor to prostaglandins and leukotrienes.
Neomycin sulfate is an aminoglycoside antibiotic that exerts its bactericidal effect by inhibiting protein synthesis in susceptible bacterial cells. It is effective against gram-negative bacilli and some strains of gram-positive microorganisms, but ineffective against anaerobic bowel flora. Other topical antimicrobial agents include polymyxin B sulfate and bacitracin. Polymyxin B sulfate is a basic polypeptide antibiotic that has bactericidal activity against nearly all strains of gram-negative bacilli, except those of the *Proteus* group. It exerts its effect by increasing bacterial cell membrane permeability leading to death of the cell. It is not effective against gram-positive bacteria, fungi, or gram-negative cocci. Bacitracin, an antibiotic derived from cultures of *Bacillus subtilis*, exhibits antibacterial activity against a variety of gram-positive and few gram-negative organisms, however its clinical usefulness is restricted to staphylococcal infections.

**Definitions:**

**Drug related events:**

**Ineffective / failure**

Use of a drug employing optimal doses (FDA-recommended doses) for optimal duration; where the condition being treated has not improved or worsened

A request for branded agent due to generic drug failure or ineffectiveness will be assessed for potential approval with documentation of use of optimal dose / duration of the generic product and meeting other criteria within the coverage guideline. When the drug in question is a combination product, there must be documentation of failure / ineffectiveness of concurrent use (each ingredient used at the same time) of individual generic components. When the drug in question is a low dose formulation, there must be documentation of failure / ineffectiveness of low dose generic formulation.

**Adverse Drug Event: Allergic reaction / Hypersensitivity / Intolerance**

Use of a drug produced a significant reaction where continued use of the drug places the individual at risk for either lack of improvement or worsening of the condition being treated or at risk for harm and the concern is documented in medical record. A significant adverse drug event is when an individual's outcome is death, life-threatening, hospitalization (initial or prolonged), disability resulting in a significant, persistent, or permanent change, impairment, damage or disruption in the individuals' body function/structure, physical activities or quality of life, or requires intervention to prevent permanent impairment or damage.

*Allergic reaction / hypersensitivity* – may or may not involve the active ingredient. When the active ingredient is involved, use of same or a chemically similar agent places the individual at risk for harm when the same or chemically similar agent is used. The subsequent reaction may be the same as the original reaction or a more exaggerated response may be seen, potentially placing the individual at even greater risk for harm.

If the reaction occurred from the active/main generic ingredient; request for branded agent with same active ingredient will not be considered unless it is proven (documented) that active ingredient did not cause reaction and the request meets other criteria within the coverage guideline.
NEO-SYNALAR® (neomycin sulfate and fluocinolone acetonide) external cream (kit is an exclusion) (cont.)

Intolerance – these events represent circumstance(s) where use of a drug produced a significant reaction and continued use may result in non-adherence to proposed therapy and this concern is documented in medical record.

Contraindication
Use of a drug that is not recommended by the manufacturer or FDA labelling
Use of any drug in the face of a contraindication is outside of the FDA and manufacturer’s labelled recommendation and is considered investigational or experimental.

Non-adherence
Individual does not follow prescribe regimen that places the individual at risk for lack of improvement or worsening of the condition being treated and this concern is documented in medical record.

Precertification:

Precertification (Prior Authorization) is required for members with a Blue Cross Blue Shield of Arizona (BCBSAZ) pharmacy benefit for medication(s) or product(s) indicated in this guideline.

This Pharmacy Coverage Guideline does not apply to FEP or other states’ Blues Plans.

Information about medications that require precertification is available at [www.azblue.com/pharmacy](http://www.azblue.com/pharmacy).

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Criteria:

See “Resources” section for FDA-approved dosage.

- Precertification for Neo-Synalar (neomycin sulfate and fluocinolone acetonide) requires completion of the specific request form in its entirety. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to [Pharmacyprecert@azblue.com](mailto:Pharmacyprecert@azblue.com). Incomplete forms will be returned.

- FDA-approved product labeling (indication, age, dosage, testing, contraindications, exclusions, etc.) of Neo-Synalar (neomycin sulfate and fluocinolone acetonide) is considered medically necessary when ALL of the following criteria are met:
  1. Medical record documentation of a confirmed diagnosis of corticosteroid-responsive dermatoses with secondary infection.
NEO-SYNALAR® (neomycin sulfate and fluocinolone acetonide) external cream (kit is an exclusion) (cont.)

2. Medical record documentation that the individual is unable to use ONE of the following regimens due to a failed response, significant adverse drug event, contraindication, or the provider submitted clinical rationale why the preferred products cannot be used:
   - Simultaneous use of topical antimicrobial with topical corticosteroid:
     - Bacitracin-Polymyxin B simultaneously with ALL corticosteroids listed below
     - Bacitracin-Polymyxin B-Neomycin simultaneously with ALL corticosteroids listed below
   - Use of ALL of the corticosteroids:
     - alclometasone dipropionate external cream
     - amcinonide external cream
     - betamethasone dipropionate aug external cream
     - betamethasone dipropionate external cream
     - betamethasone valerate external cream
     - clobetasol propionate e external cream
     - clobetasol propionate external cream
     - cloprednol pivalate external cream
     - Cordran external cream
     - desonide external cream
     - desoximetasone external cream
     - diflorasone diacetate external cream
     - fluocinolone acetonide external cream
     - fluocinonide external cream
     - fluocinonide-e external cream
     - fluticasone propionate external cream
     - halobetasol propionate external cream
     - hydrocortisone butyrate external cream
     - hydrocortisone external cream
     - hydrocortisone valerate external cream
     - mometasone furoate external cream
     - prednicarbate external cream
     - triamcinolone acetonide external cream

3. Absence of ALL of the following contraindications:
   - History of hypersensitivity to any of the components of the preparation

   Neo-Synalar (neomycin sulfate and fluocinolone acetonide) for all other indications not previously listed is considered experimental or investigational based upon:
   1. Lack of final approval from the Food and Drug Administration, and
   2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
   3. Insufficient evidence to support improvement of the net health outcome, and
   4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
   5. Insufficient evidence to support improvement outside the investigational setting.
NEO-SYNALAR® (neomycin sulfate and fluocinolone acetonide) external cream (kit is an exclusion) (cont.)

Resources:


FDA-approved indication and dosage:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Recommended Dose</th>
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<tbody>
<tr>
<td>Neo-Synalar cream is indicated for the treatment of corticosteroid-responsive dermatoses with secondary infection. It has not been demonstrated that this steroid-antibiotic combination provides greater benefit than the steroid component alone after 7 days of treatment.</td>
<td>Neo-Synalar cream is generally applied to the affected area as a thin film from two to four times daily depending on the severity of the condition.</td>
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