Neo-Synalar® (neomycin sulfate and fluocinolone acetonide) external cream (kit is an exclusion)

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.

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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.

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.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. 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. Incomplete forms or forms without the chart notes will be returned.
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.

Dermatosis is defined as a disorder involving lesions or eruptions of the skin that are acute, than may last a few days to weeks, or chronic, than may last for months. Acute lesions are common and are the result of a wide range of clinical conditions. Any condition that affects the skin can be categorized as a dermatosis. Common causes of dermatosis include autoimmune disorders, bacteria, fungi, viruses, and others. Treatment will depend on the specific cause.

Normal skin bacteria include gram positive organisms Staphylococcus epidermidis, Staphylococcus aureus, Micrococi, Diptheroids (coryneforms), Propionibacterium spp, and Streptococci (especially beta-hemolytic), and gram negative bacteria Acinetobacter spp, Enterobacter, Klebsiella, Escherichia coli, and Proteus spp. that are the predominant gram-negative organisms found on the skin. Infections involving the skin are usually due to Staphylococci or Streptococci. Antibiotics active against these organism should be used unless there are risk factors for other organisms.

Corticosteroid

- 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

Aminoglycoside

- 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 antimicrobial agents

- Other topical antimicrobial agents include polymyxin B sulfate and bacitracin
- Polymyxin B sulfate is a basic polypeptide antibiotic that has bactericidal activity against many 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
Neo-Synalar (neomycin sulfate-fluocinolone acetate)

Medication class:
Aminoglycoside antibiotic-Corticosteroid

FDA-approved indication(s):
- 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

Recommended Dose:
- Apply to the affected area as a thin film from two to four times daily depending on the severity of the condition

Maximum dosage
- Not stated

Available Dosage Forms:
- 0.5% neomycin sulfate with 0.025% fluocinolone acetate cream in 15 g and 60 g tubes

Warnings and Precautions:
- Children may absorb proportionally larger amounts of topical preparations and thus be more susceptible to systemic toxicity such as HPA axis suppression, Cushing’s syndrome, & intracranial hypertension
- Topical use of neomycin may cause nephrotoxicity and ototoxicity it should not be used over a wide area or for extended periods of time
- Patients receiving a large dose of a potent topical corticosteroid applied to a large surface area should be evaluated periodically for evidence of HPA axis suppression
- Prolonged use of topical corticosteroid may produce atrophy of the skin and subcutaneous tissues. When used on intertriginous or flexor areas, or on the face, this may occur even with short-term use
- Avoid use of occlusive dressings

Criteria:

Criteria for initial therapy: Neo-Synalar (neomycin sulfate and fluocinolone acetonide) is considered medically necessary and will be approved when ALL of the following criteria are met:

1. A confirmed diagnosis of corticosteroid-responsive dermatoses with secondary infection

2. Failure, contraindication or intolerance to Bacitracin-Polymyxin B-Neomycin simultaneously with any two of the preferred corticosteroids or the provider submitted clinical rationale why the preferred step therapy agents cannot be used:
   - Preferred corticosteroids include:
     - amcinonide 0.1% cream
     - betamethasone dipropionate augmented 0.05% cream

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NEO-SYNALAR® (neomycin sulfate and fluocinolone acetonide) external cream (kit is an exclusion) (cont.)

- betamethasone dipropionate 0.05% cream
- betamethasone valerate 0.1% cream
- clobetasol propionate 0.05% cream
- clobetasol propionate 0.1% cream
- clocortolone pivalate 0.1% cream
- desoximetasone 0.25% cream
- diflorasone diacetate 0.05% cream
- fluocinolone acetonide 0.1% cream
- fluticasone propionate 0.05% cream
- halobetasol propionate 0.05% cream
- hydrocortisone valerate 0.2% cream
- mometasone furoate 0.1% cream
- prednicarbate 0.1% cream
- triamcinolone acetonide 0.1% cream

3. There are NO contraindications:
   - Contraindications include:
     - History of hypersensitivity to any of the components of the preparation

Initial approval duration: 1 month

Criteria for continuation of coverage (renewal request): Neo-Synalar (neomycin sulfate and fluocinolone acetonide) is considered medically necessary and will be approved when ALL of the following criteria are met:

1. Individual’s condition has worsened or has not responded while on therapy
   - Worsening is defined as:
     - Secondary infection is still evident

2. Individual has been adherent with the medication

3. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
   - Contraindications as listed in the criteria for initial therapy section

Renewal duration: 1 month

Resources:

Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com. Call 866-325-1794 to check the status of a request. All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.** Pharmacy Coverage Guidelines are available at [www.azblue.com/pharmacy](http://www.azblue.com/pharmacy).

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**Pharmacy Prior Authorization Request Form**

Do not copy for future use. Forms are updated frequently. **REQUIRED:** Office notes, labs, and medical testing relevant to the request that show medical justification are required.

### Member Information

<table>
<thead>
<tr>
<th>Member Information</th>
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<tbody>
<tr>
<td><strong>Member Name (first &amp; last):</strong></td>
<td><strong>Date of Birth:</strong></td>
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<tr>
<td><strong>Address:</strong></td>
<td><strong>Gender:</strong></td>
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<td><strong>City:</strong></td>
<td><strong>BCBSAZ ID#:</strong></td>
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<tr>
<td><strong>State:</strong></td>
<td><strong>Zip Code:</strong></td>
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### Prescribing Provider Information

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<th>Prescribing Provider Information</th>
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<tr>
<td><strong>Provider Name (first &amp; last):</strong></td>
<td><strong>Specialty:</strong></td>
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<tr>
<td><strong>Office Address:</strong></td>
<td><strong>NPI#:</strong></td>
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<td><strong>City:</strong></td>
<td><strong>DEA#:</strong></td>
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<tr>
<td><strong>State:</strong></td>
<td><strong>Zip Code:</strong></td>
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<td><strong>Office Contact:</strong></td>
<td><strong>Office Phone:</strong></td>
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<td><strong>Office Fax:</strong></td>
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### Dispensing Pharmacy Information

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<tr>
<td><strong>Pharmacy Name:</strong></td>
<td><strong>Pharmacy Phone:</strong></td>
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### Requested Medication Information

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<tr>
<td><strong>Medication Name:</strong></td>
<td><strong>Strength:</strong></td>
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<td><strong>Dosage Form:</strong></td>
<td><strong>Directions for Use:</strong></td>
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<tr>
<td><strong>Quantity:</strong></td>
<td><strong>Refills:</strong></td>
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<td><strong>Duration of Therapy/Use:</strong></td>
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- Check if requesting **brand** only
- Check if requesting **generic**
- Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

### Turn-Around Time For Review

- **Standard**
- **Urgent. Sign here:**
- **Exigent (requires prescriber to include a written statement)**

### Clinical Information

1. **What is the diagnosis? Please specify below.**
   - **ICD-10 Code:**
   - **Diagnosis Description:**

2. - **Yes**
   - **No**
   - **Was this medication started on a recent hospital discharge or emergency room visit?**

3. - **Yes**
   - **No**
   - **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
   - Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

<table>
<thead>
<tr>
<th>Medication Name, Strength, Frequency</th>
<th>Dates started and stopped or Approximate Duration</th>
<th>Describe response, reason for failure, or allergy</th>
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5. **Are there any supporting labs or test results? Please specify below.**

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<thead>
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<th>Date</th>
<th>Test</th>
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6. Is there any additional information the prescribing provider feels is important to this review? Please specify below. For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

| Signature affirms that information given on this form is true and accurate and reflects office notes |
|---|---|
| Prescribing Provider’s Signature: | Date: |

**Please note:** Some medications may require completion of a drug-specific request form.

**Incomplete forms or forms without the chart notes will be returned.**

Office notes, labs, and medical testing relevant to the request that show medical justification are required.