

Clinical Policy Title:	neomycin/fluocinolone
Policy Number:	RxA.236
Drug(s) Applied:	Neo-Synalar®
Original Policy Date:	02/07/2020
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of Business

Background

Neomycin/fluocinolone cream (Neo-Synalar®) is a combination antibacterial and corticosteroid topical cream. It 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
neomycin/fluocinolone Cream (Neo-Synalar®)	Dermatoses with secondary infection	Apply a thin film to affected area 2 to 4 times daily	4 applications/day

Dosage Forms

- Cream (15 g, 60 g): 0.5% neomycin/0.025% fluocinolone acetamide

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Dermatoses (must meet all):

1. Diagnosis of a corticosteroid-responsive dermatoses (e.g., eczema, psoriasis, poison ivy, oak, or sumac, insect bites, atopic dermatitis, seborrheic dermatitis);
2. Failure of Neomycin/polymyxin B/hydrocortisone cream at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
3. Dose does not exceed two tubes (120 g) per treatment course.

Approval Duration

Commercial: 14 days

Medicaid: 14 days

II. Continued Therapy Approval

A. Dermatoses

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval Duration

Not Applicable

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
bacitracin, neomycin, polymyxin b, and hydrocortisone ointment	Apply sparingly to affected area 2 to 4 times daily for up to 7 days	Varies

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
 - Hypersensitivity to any components of the preparation, use in the external auditory canal if the eardrum is perforated.
- Boxed Warning(s):
 - None reported.

APPENDIX D: General Information

- If local infection should continue or become severe, or in the presence of systemic infection, appropriate systemic antibacterial therapy, based on susceptibility testing, should be considered. Because of the concern of nephrotoxicity and ototoxicity associated with neomycin, this combination product should not be used over a wide area or for extended periods of time. There are articles in the current medical literature that indicate an increase in the prevalence of persons sensitive to neomycin.

References

1. Neo-Synalar® Prescribing Information. Buena, NJ: Medimetriks Pharmaceuticals Inc.; September 2016. Available at: https://www.medimetriks.com/sites/default/files/pi-files/neosynalar_pi_website.pdf . Accessed July 12, 2021.
2. Neo-Synalar®. Micromedex Solutions. Truven Health Analytics Inc. Ann Arbor, MI. Available at: <http://www.micromedexsolutions.com>. Accessed July 12, 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Policy title table was updated.	6/23/2020	09/14/2020

<ol style="list-style-type: none"> 2. Line of Business Policy Applies to was update to all lines of business. 3. Initial and Continued Approval Duration was updated to include Medicaid approval duration. 4. Reference was updated. 		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Statement about provider sample “The provision of provider samples does not guarantee coverage...” was added to Clinical Policy. 2. Therapeutic Alternatives verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..". 3. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 4. Appendix D was updated to include “If local infection should continue or become severe....”. 5. References were reviewed and updated. 6. 	<p>07/12/2021</p>	<p>09/14/2021</p>