RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	neomycin/fluocinolone
Policy Number:	RxA.236
Drug(s) Applied:	Neo-Synalar®
Original Policy Date:	02/07/2020
Last Review Date:	09/14/2020
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 acetonide

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.

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 Cortisporin® 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

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

Approval Duration
Commercial: Not Applicable
Medicaid: Not Applicable

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Cortisporin (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 Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic

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

- Not Applicable

References

1. Neo-Synalar Prescribing Information. Buena, NJ: Medimetriks Pharmaceuticals Inc.; September 2016. Available at: http://www.medimetriks.com/. Accessed June 23, 2020.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed June 23, 2020.

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. 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.	6/23/2020	09/14/2020