

QUANTITY LIMIT PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	DERMATOLOGICAL TOPICAL ANTIFUNGAL COMBINATIONS
	BRAND AND GENERIC
	ALL DOSAGE FORMS
BRAND NAME	
(generic)	(clotrimazole and betamethasone dipropionate)
	(nystatin and triamcinolone acetonide)
Status: CVS Caremark® Criteria	
Type: Quantity Limit; Post Limit Prior Authorization	

POLICY

FDA-APPROVED INDICATIONS

Clotrimazole and Betamethasone Dipropionate Lotion

Clotrimazole and betamethasone dipropionate lotion is indicated in patients 17 years and older for the topical treatment of symptomatic inflammatory tinea pedis, tinea cruris, and tinea corporis due to *Epidermophyton floccosum*, *Trichophyton mentagrophytes*, and *Trichophyton rubrum*. Effective treatment without the risks associated with topical corticosteroid use may be obtained using a topical antifungal agent that does not contain a corticosteroid, especially for noninflammatory tinea infections. The efficacy of clotrimazole and betamethasone dipropionate lotion for the treatment of infections caused by zoophilic dermatophytes (e.g., *Microsporum canis*) has not been established.

Clotrimazole and Betamethasone Dipropionate Cream

Clotrimazole and betamethasone dipropionate cream is a combination of an azole antifungal and corticosteroid and is indicated for the topical treatment of symptomatic inflammatory tinea pedis, tinea cruris, and tinea corporis due to *Epidermophyton floccosum*, *Trichophyton mentagrophytes*, and *Trichophyton rubrum* in patients 17 years and older.

Nystatin and Triamcinolone Cream and Ointment

Nystatin and triamcinolone acetonide cream and ointment are indicated for the treatment of cutaneous candidiasis; it has been demonstrated that the nystatin-steroid combination provides greater benefit than the nystatin component alone during the first few days of treatment.

INITIAL QUANTITY LIMIT**

INITIAL LIMIT QUANTITY

Limits should accumulate across same chemical entity up to highest quantity listed depending on the order the claims are processed. Accumulation does not apply if limit is coded for daily dose.

PLEASE NOTE: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

<u>Drug</u>	<u>1 Month Limit*</u>	<u>3 Month Limit*</u>
clotrimazole and betamethasone dipropionate lotion	60 mL / 25 days	Does Not Apply*
clotrimazole and betamethasone dipropionate cream	60 gm / 25 days	Does Not Apply*

nystatin and triamcinolone acetonide cream and ointment

60 gm / 25 days Does Not Apply*

* The duration of 25 days is used for a 30-day fill period to allow time for refill processing.

* **These drugs are for short-term acute use; therefore, the intent is for prescriptions of the requested drug to be filled one month at a time; there should be no 3 month supplies filled.**

**If the patient is requesting more than the initial quantity limit, the claim will reject with a message indicating that a prior authorization is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

COVERAGE CRITERIA

Cutaneous Candidiasis

Authorization may be granted for the treatment of cutaneous candidiasis when ALL of the following criteria are met:

- The requested drug is NOT being used in a footbath
- The request is for nystatin/triamcinolone

Tinea Corporis, Tinea Cruris, Tinea Pedis

Authorization may be granted for the treatment of tinea corporis, tinea cruris or tinea pedis when ALL of the following criteria are met:

- The requested drug is NOT being used in a footbath
- The request is for clotrimazole/betamethasone

QUANTITY LIMITS APPLY

90 gm or 90 mL per 25 days* for clotrimazole/betamethasone, 120 gm per 25 days* for nystatin/triamcinolone, 3 month limit does not apply

* The duration of 25 days is used for a 30-day fill period to allow time for refill processing. These drugs are for short-term acute use; therefore, the intent is for prescriptions of the requested drug to be filled one month at a time; there should be no 3 month supplies filled.

DURATION OF APPROVAL (DOA)

- 2912-HJ: DOA: 3 months

REFERENCES

1. Clotrimazole/Betamethasone dipropionate lotion [package insert]. Hawthorne, NY: Taro Pharmaceuticals Inc.; May 2016.
2. Clotrimazole/Betamethasone dipropionate cream [package insert]. Hawthorne, NY: Taro Pharmaceuticals Inc.; October 2019.
3. Nystatin/Triamcinolone [package insert]. Hawthorne, NY: Taro Pharmaceuticals Inc.; September 2004.
4. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed February 20, 2024.
5. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 02/20/2024).
6. Vyas JM. National Library of Medicine. Candida Infection of the skin. MedlinePlus. December 24, 2020. Available at: <https://medlineplus.gov/ency/article/000880.htm>. Accessed February 19, 2024.
7. Eichenfield L, Tom W, Berger T, et al. Guidelines of Care for the Management of Atopic Dermatitis Section 2. Management and Treatment of Atopic Dermatitis with Topical Therapies. *J Am Acad Dermatol*. 2014; 71:116-32.
8. U.S. Department of Health & Human Services. Burn Triage and Treatment – Thermal Injuries. Chemical Hazards Emergency Medical Management. February 12, 2024. Available at: <https://chemm.hhs.gov/burns.htm>. Accessed February 19, 2024.