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## **ORIGINAL ARTICLE**

### **Poor Antifungal Coverage for Onychomycosis in a Cross-Sectional Analysis of Medicaid Formularies**

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**Background:** Onychomycosis is the most common nail disease seen in clinical practice.

Medication safety, severity of disease, co-morbidities, concomitant medications, patient age, and cost are all important considerations when treating onychomycosis. Since cost may affect treatment decisions, we sought to analyze Medicaid formulary coverage of onychomycosis antifungals.

**Methods:** Public state Medicaid formularies were searched for coverage of FDA approved onychomycosis medications and off-label oral fluconazole. Total drug cost for a single great toenail was calculated using National Average Drug Acquisition Cost. Pearson correlation

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coefficients were calculated to compare coverage and cost, mycological cure rate, and complete cure rate.

**Results:** Oral terbinafine and off-label fluconazole were widely covered for onychomycosis treatment. There was poor coverage of oral itraconazole and topical ciclopirox, and no coverage of topical efinaconazole and tavaborole without step-edits or prior authorization.

There was a significant negative correlation between medication coverage and cost ( $r = -0.758$ ,  $p = 0.040$ ). There was no correlation between medication coverage and mycologic ( $r = 0.548$ ,  $p = 0.339$ ) and complete ( $r = 0.768$ ,  $p = 0.130$ ) cure rates.

**Conclusions:** There is poor Medicaid coverage of antifungals for the treatment of onychomycosis, with step-edits and prior authorization based on cost rather than treatment safety and efficacy. We recommend involving podiatrists and dermatologists in developing criteria for insurance approval of onychomycosis treatments.

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Onychomycosis is a fungal infection of the nail by dermatophytes, nondermatophytes, and yeast and is the most commonly encountered nail disorder in clinical practice [1, 2]. It is important to promptly diagnosis and treat onychomycosis because it may result in pain, paresthesias, and impaired social interactions and activities of daily life [3]. Toenails are involved more often than fingernails, with the great or second toenails being the most common locations [4]. Onychomycosis does not resolve without treatment, and can spread to other nails

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and skin if left untreated [5]. Given the nail plate thickness and slow growth rate of the toenail, treatment often requires prolonged and recurrent therapy [6]. Although debridement decreases toenail thickness, alleviates discomfort, and improves cosmetic appearance, it does not eradicate the fungal infection and therefore should be used with an oral or topical antifungal [7, 8]. Antifungals can be costly, with overall costs expected to rise with an aging population [9].

Onychomycosis management considerations include disease severity, quality of life impact, co-morbidities, potential adverse events, drug-drug interactions and cost [1, 10]. Therefore, it is important for podiatrists and dermatologists to understand costs and insurance coverage for prescribed onychomycosis medications. Currently, oral terbinafine, an allylamine, and itraconazole, a triazole, are approved by the US Food and Drug Administration (FDA) for treatment of onychomycosis. The triazole fluconazole is used off-label with broad-spectrum antifungal coverage. Topical ciclopirox, a hydroxypyridone, efinaconazole, a triazole, and tavaborole, a benzoxaborole, are also FDA approved [8, 10]. Our objectives were to analyze Medicaid formulary coverage of onychomycosis antifungals.

## **Materials and Methods**

Public state Medicaid formularies were searched for FDA approved onychomycosis medications and fluconazole using Google searches of “Medicaid formulary” with state name. Coverage was

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classified as covered, not covered, requiring prior authorization (PA) and/or step-edits, or lacking public data. Total drug cost for a single great toenail was calculated using National Average Drug Acquisition Cost (NADAC) [11]. Mycologic and complete cure rates were recorded from medication package inserts. Pearson correlation coefficients were calculated using Excel Data Analysis Toolpak (Microsoft Corporation, Redmond, WA) with significance set at  $P < .05$ .

## Results

Medicaid formularies were accessible for 49 states and Washington D.C. (Table 1). For systemics, off-label fluconazole (82.4%) and terbinafine (78.4%) were most often covered without PA. Ciclopirox (37.3%) was the only covered topical without PA (Table 2). Two states required step-edits and 84% of states (42/50) required PA for at least one non-preferred medication (Table 3). Four percent (2/50) of states required mycology for approval of any antifungal and 10% (5/50) for efinaconazole and tavaborole only. There was a significant negative correlation between medication coverage and cost ( $r = -0.758$ ,  $p = 0.040$ ). There was no correlation between medication coverage and mycologic ( $r = 0.548$ ,  $p = 0.339$ ) and complete ( $r = 0.768$ ,  $p = 0.130$ ) cure rates (Table 2).

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## Discussion

Our study showed that oral terbinafine and off-label fluconazole were widely covered, with poor coverage of oral itraconazole and topical ciclopirox, and no coverage of topical efinaconazole and tavaborole without step-edits or PA. Furthermore, there was a significant negative correlation between medication coverage and cost, and no correlations between medication coverage and cure rates, suggesting that Medicaid formularies base medication coverage on cost rather than efficacy.

We also found that only a minority of states required mycological confirmation for approval of antifungals. Although history and physical examination aid in the diagnosis of onychomycosis [12], clinical diagnosis of onychomycosis is largely unreliable, and corroboration is necessary to avoid misdiagnosis, disease progression, and potential treatment associated adverse events. Confirmatory testing prior to treatment initiation is essential to exclude other causes of nail dystrophy, especially since other nail diseases such as lichen planus, psoriasis, and traumatic onychodystrophies can present similar to onychomycosis [4, 8]. Confirmatory testing with potassium hydroxide and microscopy, fungal culture, or periodic acid–Schiff staining has also been shown to decrease treatment costs for both topical and oral antifungals [13]. Therefore, we advocate for replacing step-edits and strict PA criteria with mycological testing, with dual benefits of having a positive impact on patient care and being cost saving.

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Our study is subject to several limitations. Griseofulvin is FDA approved for onychomycosis treatment, but was excluded from our analysis because it is rarely used. We analyzed generic medications when both generic and brands were available. The South Dakota formulary was inaccessible.

### **Conclusions**

There is poor Medicaid coverage of antifungals for onychomycosis treatment, with step-edits and PAs based on cost rather than treatment safety and efficacy. Therefore, we recommend recruiting podiatrists and dermatologists to develop more reasonable criteria for insurance approval of onychomycosis treatments, which would result in better patient outcomes and reduce costs for insurance companies.

**Financial Disclosure:** None reported.

**Conflict of Interest:** Dr. Lipner has served as a consultant for Ortho-Dermatologics, Verrica, and Hoth Therapeutics.

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**Table 1: Medicaid Onychomycosis Medication Coverage per State**

State	Medications covered, n (%)	Medications without specified coverage, n (%)	Medications requiring prior authorization, n (%)	Medications without published data, n (%)
Alabama	4 (66.7)	0 (0)	2 (33.3)	0 (0)
Alaska	3 (50)	0 (0)	3 (50)	0 (0)
Arizona	3 (50)	3 (50)	0 (0)	0 (0)
Arkansas	0 (0)	0 (0)	3 (50)	3 (50)
California	2 (33.3)	0 (0)	4 (66.7)	0 (0)
Colorado	0 (0)	0 (0)	0 (0)	6 (100)
Connecticut	2 (33.3)	4 (66.7)	0 (0)	0 (0)
Delaware	3 (50)	0 (0)	3 (50)	0 (0)
Florida	3 (50)	1 (16.7)	2 (33.3)	0 (0)
Georgia	2 (33.3)	0 (0)	4 (66.7)	0 (0)
Hawaii	4 (66.7)	2 (33.3)	0 (0)	0 (0)
Idaho	2 (33.3)	0 (0)	4 (66.7)	0 (0)
Illinois	2 (33.3)	0 (0)	4 (66.7)	0 (0)
Indiana	4 (66.7)	0 (0)	2 (33.3)	0 (0)
Iowa	3 (50)	0 (0)	3 (50)	0 (0)
Kansas	0 (0)	0 (0)	0 (0)	6 (100)
Kentucky	2 (33.3)	0 (0)	4 (66.7)	0 (0)
Louisiana	2 (33.3)	0 (0)	4 (66.7)	0 (0)
Maine	2 (33.3)	0 (0)	4 (66.7)	0 (0)
Maryland	2 (33.3)	0 (0)	4 (66.7)	0 (0)
Massachusetts	4 (66.7)	0 (0)	2 (33.3)	0 (0)
Michigan	2 (33.3)	0 (0)	4 (66.7)	0 (0)
Minnesota	3 (50)	0 (0)	3 (50)	0 (0)
Mississippi	3 (50)	0 (0)	3 (50)	0 (0)
Missouri	2 (33.3)	0 (0)	4 (66.7)	0 (0)
Montana	3 (50)	0 (0)	3 (50)	0 (0)
Nebraska	2 (33.3)	0 (0)	4 (66.7)	0 (0)
Nevada	0 (0)	0 (0)	0 (0)	6 (100)
New Hampshire	0 (0)	1 (16.7)	5 (83.3)	0 (0)

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New Jersey	2 (33.3)	0 (0)	4 (66.7)	0 (0)
New Mexico	3 (50)	2 (33.3)	1 (16.7)	0 (0)
New York	1 (16.7)	1 (16.7)	4 (66.7)	0 (0)
North Carolina	3 (50)	0 (0)	3 (50)	0 (0)
North Dakota	4 (66.7)	0 (0)	2 (33.3)	0 (0)
Ohio	3 (50)	0 (0)	3 (50)	0 (0)
Oklahoma	1 (16.7)	0 (0)	3 (50)	2 (33.3)
Oregon	2 (33.3)	4 (66.7)	0 (0)	0 (0)
Pennsylvania	3 (50)	0 (0)	3 (50)	0 (0)
Rhode Island	2 (33.3)	0 (0)	4 (66.7)	0 (0)
South Carolina	2 (33.3)	2 (33.3)	2 (33.3)	0 (0)
South Dakota	0 (0)	0 (0)	0 (0)	6 (100)
Tennessee	1 (16.7)	0 (0)	5 (83.3)	0 (0)
Texas	2 (33.3)	0 (0)	4 (66.7)	0 (0)
Utah	3 (50)	0 (0)	3 (50)	0 (0)
Vermont	2 (33.3)	0 (0)	4 (66.7)	0 (0)
Virginia	3 (50)	0 (0)	3 (50)	0 (0)
Washington	3 (50)	0 (0)	3 (50)	0 (0)
Washington, D.C.	3 (50)	1 (16.7)	2 (33.3)	0 (0)
West Virginia	1 (16.7)	0 (0)	5 (83.3)	0 (0)
Wisconsin	3 (50)	0 (0)	3 (50)	0 (0)
Wyoming	0 (0)	0 (0)	0 (0)	6 (100)

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**Table 2: Medicaid Medication Coverage for Treatment of Onychomycosis**

Medication name	States (+D.C.) with coverage, n (%)	States (+D.C.) without specified coverage, n (%)	States (+D.C.) requiring prior authorization, n (%)	States (+D.C.) without public data, n (%)	Cost*	Mycologic cure rate**, % For toenails	Complete cure rate***, % For toenails
Systemic							
Terbinafine 250 mg	40 (78.4)	1 (2.0)	3 (5.9)	7 (13.7)	\$14.67	70	38
Itraconazole 100 mg	9 (17.6)	5 (9.8)	31 (60.8)	6 (11.8)	\$167.88	54	14
Fluconazole 150 mg (off-label)	42 (82.4)	2 (3.9)	0 (0)	7 (13.7)	\$45.91	N/A	N/A
Topical							
Ciclopirox 8% solution	19 (37.3)	2 (3.9)	25 (49.0)	5 (9.8)	\$115.96	29 and 36	5.5 and 8.5
Efinaconazole 10% solution	0 (0)	7 (13.7)	39 (76.5)	5 (9.8)	\$8,662.97	53.4 and 55.2	15.2 and 17.8
Tavaborole 5% solution	0 (0)	7 (13.7)	39 (76.5)	5 (9.8)	\$8,121.91	31.1 and 35.9	6.5 and 9.1

\*Costs calculated using October 2021 National Average Drug Acquisition Cost (NADAC). Systemic medication cost was calculated based on a single treatment course per adult patient for toenail onychomycosis: terbinafine (250-mg daily for 12 weeks), itraconazole (200-mg daily for 12 weeks), fluconazole (150-mg once per week for 12 months). Topical medication cost was calculated based on a 48-week treatment course of 1 great toenail requiring 56 ml[14]. Correlation between medication coverage and cost:  $r = -0.758$ ,  $p = 0.040$

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\*\*Correlation between medication coverage and mycologic cure rate:  $r = 0.548$ ,  $p = 0.339$   
(calculated using average mycologic cure rate from two clinical trials)

\*\*\*Correlation between medication coverage and complete cure rate:  $r = 0.768$ ,  $p = 0.130$   
(calculated using average complete cure rate from two clinical trials)

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<b>Table 3. States Requiring Specific Criteria for Approval of Non-preferred Drugs for Treatment of Onychomycosis</b>				
<b>State</b> Bolder states have step-edits	<b>Preferred drugs</b> Covered without PA unless indicated*	<b>Orals required before topicals</b>	<b>Fungal testing required</b>	<b>Specific criteria for approval of non-preferred medications</b> Trial failures apply to medications within same class (oral, topical) States not listed did not indicate specific PA criteria
Delaware	T, F, C	No	No	Failure of 2 preferred medications
Idaho	T, F	Yes	No	-Orals: Failure of 1 preferred medication in past 60 days -Topicals: diagnosis in past year, failure of I and T, non-cosmetic treatment
Iowa	T, F, C	No	Yes***	-Failure of 1 preferred agent; E and TA: contraindication to T and C
Louisiana	T, F,	No	No	Failure/contraindication to 1+ preferred medication
<b>Maine</b>	T, F	No	Yes**	-Failure of 1 preferred medication -Step edits: T and F tried first
Mississippi	T, F, C	No	No	Trial of 2 preferred medications within past 6 months
Nebraska	T, F	No	Yes***	-Failure of 2 preferred medications within past 6 months -C: contraindication to oral T -E: diagnosis of <i>Trichophyton rubrum/mentagrophytes</i>
New Hampshire	T, I, C	No	No	Failure of 2 preferred medications
<b>New York</b>	T	Yes	No	-Failure of 1 preferred drug -Step edits: oral medications before C, C before E and TA
North Carolina	T, F, C	No	No	Failure of 2 preferred medications
North Dakota	T, I, F, C	Yes	Yes***	Topicals: trial of 3 preferred medications (including 1 oral)
Oklahoma	I, C	Yes	Yes***	C: trial of oral antifungal; E and TA: trial of oral drug, contraindication to C, diagnosis of

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				<i>Trichophyton rubrum/mentagrophytes</i> , non-cosmetic treatment
Rhode Island	T, F	No	No	Trial of preferred medication in past 90 days
Tennessee	T*, F, C*	No	Yes**	-Failure of 2 preferred medications -T: underlying disease, non-cosmetic treatment -C: underlying disease, failure/contraindication to T
Utah	T, F, C	No	No	Failure of 1 preferred medication
Vermont	T, F, C	No	No	Failure of 1 preferred medication
Virginia	T, F	No	No	-Failure of 2+ preferred medications -E and TA: failure of T, F, or I
West Virginia	T, F	Yes	Yes***	-Oral: trial of 1 preferred drug; Topical: 14-day trial of 2 preferred drugs -E: non-cosmetic treatment of <i>Trichophyton rubrum/mentagrophytes</i> , failure of I and T

**PA:** prior authorization; **T:** terbinafine; **I:** itraconazole; **F:** fluconazole; **C:** ciclopirox solution; **E:** efinaconazole; **TA:** tavaborole

\*\*Fungal testing required for any antifungal medication

\*\*\*Fungal testing required for efinaconazole and tavaborole only