

Market Applicability															
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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Oral Antifungals

Override(s)	Approval Duration
Prior Authorization Quantity Limit	<ul style="list-style-type: none"> For Onychomycosis: 12 weeks or 3x 1 month fills per rolling calendar year per incidence of onychomycosis For all other indications: 1 year

Medications	Quantity Limit
Sporanox (itraconazole)	May be subject to quantity limit
Terbinex (terbinafine HCl)	
Onmel (itraconazole)	

For the following drugs: itraconazole, terbinafine

if the reject is **Product Service Not Covered** due to *benefit exclusion (nail bed [finger/toe] fungus or onychomycosis)*, may approve all non onychomycosis diagnoses without regard to the below criteria.

APPROVAL CRITERIA

- I. Requests for Sporanox (itraconazole capsules), Onmel (itraconazole tablets), or Terbinex (terbinafine HCl) **for the treatment of onychomycosis** may be approved based on the following criteria:
 - A. Individual has **no relevant comorbidity** (normal immune system, and no disorder which predisposes to infection in the extremities); **AND**
 - B. Evidence of functional impairment (such as loss of one or more toenails, pain, or swelling) is present; **AND**
 - C. Individual has a confirmed fungal infection (such as, potassium hydroxide [KOH] preparation, fungal culture, nail biopsy or physical exam);

OR

 - D. Individual has **a relevant comorbidity** (abnormal immune system [such as, HIV positive, on immunosuppressant drugs] and/or disorder which predisposes to infection in the extremities [such as, Diabetes]); **AND**
 - E. Individual has confirmed fungal infection (such as, potassium hydroxide [KOH] preparation, fungal culture, nail biopsy or physical exam);

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OR

II. Requests for **Sporanox or Onmel** may be approved for the following **non-onychomycosis** indications:

- A. Blastomycosis, pulmonary and extrapulmonary (capsules); **OR**
- B. Histoplasmosis, including chronic cavitory pulmonary disease and disseminated, non-meningeal histoplasmosis (capsules); **OR**
- C. Invasive Aspergillosis, pulmonary and extrapulmonary, in individuals refractory to or intolerant or contraindicated to treatment with amphotericin B (capsules); **OR**
- D. Oropharyngeal and esophageal candidiasis (oral solution); **OR**
- E. Uncomplicated vulvovaginal candidiasis (AHFS); **OR**
- F. Paracoccidioidomycosis (all oral dosage forms)(AHFS); **OR**
- G. Sporotrichosis (all oral dosage forms) (AHFS, Kauffmann 2007); **OR**
- H. Cryptococcus (all oral dosage forms) if other alternative regimens have failed or are not available or are contraindicated(AHFS, CDC/NIH/IDSA); **OR**
- I. Treatment and prevention of coccidioidomycosis caused by *Coccidioides immitis* or *C. posadasii* (all oral dosage forms) (AHFS, Galgiani 2016); **OR**
- J. Basidiobolomycosis (all oral dosage forms) (AHFS); **OR**
- K. Alternative to fluconazole for long-term suppressive or maintenance therapy (second prophylaxis) to prevent recurrence or relapse of mucocutaneous candidiasis (esophagel, oropharyngeal, vaginal) in HIV-infected infants (oral solution) (AHFS, CDC/NIH/IDSA); **OR**
- L. Allergic bronchopulmonary aspergillosis (all oral dosage forms) (DrugPoints, B IIa); **OR**
- M. Prophylaxis of invasive fungal infection (all oral dosage forms) (DrugPoints, B IIa); **OR**
- N. Chronic pulmonary aspergillosis (cavitory or necrotizing) (all oral dosage forms) (DrugPoints, B IIa); **OR**
- O. Chromomycosis caused by various dematiaceous fungi (such as *Cladosporium*, *Exophiala*, *Fonsecaea*, *Phialophora*) (all oral dosage forms) (AHFS); **OR**
- P. Penicilliosis caused by *Penicillium marneffeii* (all oral dosage forms) (AHFS, CDC/NIH/IDSA); **OR**
- Q. Microsporidiosis (all oral dosage forms) (AHFS, CDC/NIH/IDSA);

OR

III. Requests for Sporanox (itraconazole capsules) may be approved for the following:

- A. Tinea infections (**EXCEPT** for Tinea unguium*) (DrugPoints, B IIa) where the individual has received at least one prior topical antifungal therapy including, but not limited to:

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1. Miconazole; **OR**
2. Tolnaftate; **OR**
3. Clotrimazole; **OR**
4. Ketoconazole; **OR**
5. Econazole; **OR**
6. Nystatin; **OR**
7. Butenafine; **OR**
8. Terbinafine

*Note: Tinea unguium = onychomycosis

Note: Onychomycosis is also known as tinea unguium, nail fungus, and dermatophytosis of the nails. Itraconazole (Sporanox, Onmel) has black box warnings for congestive heart failure, cardiac effects, and drug interactions. Sporanox capsules and tablets should not be administered for the treatment of onychomycosis in individuals with evidence of ventricular dysfunction such as congestive heart failure (CHF) or a history of CHF. If signs or symptoms of CHF occur during administration, continued utilization should be reassessed for intravenous and oral solution dose forms and therapy discontinued in tablet/capsule dose forms.

Coadministration of methadone, disopyramide, dofetilide, dronedarone, quinidine, ergot alkaloids (such as dihydroergotamine, ergometrine (ergonovine), ergotamine, methylergometrine (methylergonovine)), irinotecan, lurasidone, oral midazolam, pimozide, triazolam, felodipine, nisoldipine, ranolazine, eplerenone, cisapride, lovastatin, simvastatin, ticagrelor and, in subjects with varying degrees of renal or hepatic impairment, colchicine, fesoterodine, telithromycin and solifenacin with itraconazole is contraindicated.

Coadministration of these agents with itraconazole can cause elevated plasma concentrations of these drugs which may increase or prolong both the pharmacologic effects and/or adverse reactions to these drugs. One example is increased plasma concentrations of some of these drugs leading to QT prolongation and ventricular tachyarrhythmias including torsades de pointes, a potentially fatal arrhythmia.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed January 30, 2017.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

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Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2017; Updated periodically.

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