Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

Oral Antifungals

Override(s)	Approval Duration
Prior Authorization^ Quantity Limit	• 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)	
Tolsura (SUBA-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);

Market Applicability							
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Applicable	X	X	X	X	X	X	NA

OR

II. Requests for **Sporanox, Tolsura (SUBA-itraconazole capsules) or Onmel** may be approved for the following **non-onychomycosis** indications:

A. Blastomycosis, pulmonary and extrapulmonary (capsules); **OR**
B. Histoplasmosis, including chronic cavitary 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. Primary prophylaxis to prevent first episode of histoplasmosis in HIV infected adults or adolescents with CD4 T-cell counts less than 150/mm^3 who reside in areas where histoplasmosis is highly endemic (itraconazole 100mg, 200mg capsules/tablets) (AHFS, CDC/NIH/IDSA); **OR**
K. Prevention of recurrence (secondary prophylaxis) of histoplasmosis in HIV-infected adults, adolescents and children who have been adequately treated for histoplasmosis (itraconazole 100mg, 200mg capsules/tablets) (AHFS, CDC/NIH/IDSA); **OR**
L. Basidiobolomycosis (all oral dosage forms) (AHFS); **OR**
M. 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**
N. Allergic bronchopulmonary aspergillosis (all oral dosage forms) (DrugPoints, B IIa); **OR**
O. Prophylaxis of invasive fungal infection (all oral dosage forms) (DrugPoints, B IIa); **OR**
P. Chronic pulmonary aspergillosis (cavitary or necrotizing) (all oral dosage forms) (DrugPoints, B IIa); **OR**
Q. Chromomycosis caused by various dematiaceous fungi (such as *Cladosporium, Exophiala, Fonsecaea, Phialophora)* (all oral dosage forms) (AHFS); **OR**
R. Penicilliosis caused by *Penicillium marneffei* (all oral dosage forms) (AHFS, CDC/NIH/IDSA); **OR**
S. Microsporidosis (all oral dosage forms) (AHFS, CDC/NIH/IDSA);

AND

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

III. Requests is for Tolsura (SUBA-itraconazole) must also meet the following step therapy criteria in addition to the prior authorization criteria above for **non-onychomycosis** indications:
   A. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to generic itraconazole capsules.

OR

IV. 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:
      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.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.