



POLICY AND PROCEDURE

POLICY NUMBER: *RX.PA.018.E*

REVISION DATE: *5/13*

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POLICY TITLE: Itraconazole (Sporanox and Onmel)
DEPARTMENT: Clinical Pharmacy Services- Utilization Management
ORIGINAL DATE: April 1999 (as adopted from UPMC Health Plan)

Last P & T Committee Approval Date: February 2018

Product Applicability: mark all applicable products below:

COMMERCIAL	<input type="checkbox"/> HMO <input type="checkbox"/> PPO	Products: <input type="checkbox"/> Small <input type="checkbox"/> Indiv. <input type="checkbox"/> Large	Exchange: <input type="checkbox"/> Shop <input type="checkbox"/> Indiv.	<input checked="" type="checkbox"/> All
OTHER	<input checked="" type="checkbox"/> Self-funded/ASO			

PURPOSE

The purpose of this policy is to define the prior authorization process for oral dosage forms of itraconazole (Sporanox and Onmel).

Itraconazole capsule/solution (Sporanox) is indicated for the treatment of the following fungal infections in immunocompromised and non-immunocompromised patients:

- Blastomycosis, pulmonary and extrapulmonary
- Histoplasmosis, including cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis
- Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or refractory to amphotericin B therapy

Itraconazole capsule/solution (Sporanox) also is indicated for the treatment of the following fungal infections in non-immunocompromised patients:

- Onychomycosis of the toenail, with or without fingernail involvement, due to dermatophytes (tinea unguium)
- Onychomycosis of the fingernail due to dermatophytes (tinea unguium)

Itraconazole tablet (Onmel) is indicated for the treatment of the following fungal infections in non-immunocompromised patients:

- Onychomycosis of the toenail due to *Trichophyton rubrum* or *T. mentagrophytes*

The Health Plan does not cover itraconazole for reasons determined to be cosmetic.



DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drugs, itraconazole capsule and solution (Sporanox) and itraconazole tablet (Onmel), are subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

1. For itraconazole (Sporanox) capsule

- For treatment of fungal infections must have one of the following:
 - Onychomycosis in a diabetic, transplant, or immunocompromised member
 - Onychomycosis causing severe debilitating foot pain (supported by chart documentation) after trial and failure of 1 course (3 months) of oral terbinafine (Lamisil®)
 - Fungal infections on trunk of body such as tinea that are too large to treat with topical cream
 - Oral thrush that has not responded to oral nystatin
 - Esophageal candidiasis
- For prophylactic treatment:
 - Must submit documentation of the type of infection, other therapeutic alternatives, and supporting literature for the purposes of coverage

If the above criteria are met, itraconazole (Sporanox) capsule is approved for a timeframe dependent upon the diagnosis.

2. For itraconazole (Sporanox) oral solution:

- Must meet above criteria for itraconazole (Sporanox) capsule
- Must have an adequate trial and failure of generic itraconazole capsules or a contraindication to this formulation
- **An exception for the oral solution is made if the member has a diagnosis of oral and/or esophageal candidiasis.**

If the above criteria are met, itraconazole (Sporanox) oral solution is approved for a timeframe dependent upon the diagnosis.

3. For itraconazole tablet (Onmel)

- For treatment of fungal infections must have one of the following:



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- Onychomycosis of the toenail due to *Trichophyton rubrum* or *T. mentagrophytes* causing severe, debilitating foot pain (supported by chart documentation) in a non-immunocompromised member
 - Must provide documentation of laboratory testing of nail specimen [such as potassium hydroxide (KOH) preparation, fungal culture, or nail biopsy]
 - Must have documentation of trial and failure of itraconazole capsules for at least 1 full course of treatment (3 months)

If the above criteria are met, itraconazole tablet (Onmel) is approved for 3 months.

Reauthorization Criteria:

All prior authorization renewals are reviewed on a case-by-case basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at case-by-case intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to case-by-case or duration of member's membership with plan
Reauthorization	Same as initial
Quantity Level Limit	
Onmel	30 tablets per 30 days
Sporanox	60 capsules per 30 days

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Elewski BE. Tinea capitis: A current perspective. *J Am Acad Dermatol.* 2000; 42:1-20.
2. Crawford F, Hart R, Bell-Syer SE, et al. Athlete's foot and fungally infected toe nails. *Clinical Evidence.* 2000; 4:939.
3. Drake LA, Dinehard SM, Farmer ER, et al. Guidelines of care for superficial mycotic infections of the skin: Tinea corporis, tinea cruris, tinea faciei, tinea manuum, and tinea pedis (American Academy of Dermatology). *J Am Acad Dermatol.* 1996; 34:282-6.
4. SporanoX [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. ; June 2011.
5. Drake LA, Dinehart SM, Farmer ER, et al. Guidelines of care for superficial mycotic infections of the skin: Onychomycosis. *J Am Acad Dermatol.* 1996; 34:116-21.
6. Elewski BE. Onychomycosis: Treatment, quality of life, and economic issues. *Am J Clin Dermatol.* 2000; 1(1):19-26.
7. Lamisil tablets [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2012.
8. Onmel [Prescribing Information]. Greensboro, NC: Merz Pharmaceuticals, LLC; November 2012.



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RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
<i>Annual Review</i>	<i>02/17, 02/18</i>

