Mass General Brigham
Health Plan

# Itraconazole solution
# Itraconazole capsules
# Effective 11/26/2018

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| **Plan** | ☐ MassHealth UPPL<br>☒Commercial/Exchange | **Program Type** | ☒ Prior Authorization<br>☐ Quantity Limit<br>☐ Step Therapy |
| **Benefit** | ☒ Pharmacy Benefit<br>☐ Medical Benefit | | |
| **Specialty Limitations** | N/A | | |
| **Contact Information** | **Medical Benefit**<br>**Pharmacy Benefit** | Phone: 833-895-2611<br>Phone: 800-711-4555 | Fax: 888-656-6671<br>Fax: 844-403-1029 |
| **Exceptions** | N/A | | |

**Overview**
Itraconazole oral solution and itraconazole capsules are inhibitor of CYP450-dependent synthesis of ergosterol.

Itraconazole oral solution is indicated for the treatment of oral and/or oesophageal candidiasis in HIV-positive or other immunocompromised patients and prophylaxis of fungal infections in neutropenic patients.

Itraconazole capsules are indicated for the treatment of:

1. Superficial dermatomycoses not responding to topical treatment.
2. Fungal keratitis which has failed to respond to topical treatment or where the disease is either progressing rapidly or is immediately sight threatening.
3. Pityriasis versicolor not responding to any other treatment.
4. Vulvovaginal candidiasis not responding to topical treatment.
5. Oral candidiasis in immunocompromised patients.
6. Onychomycosis caused by dermatophytes.
7. Systemic mycoses, only in the following fungal infections:
    a. Systemic aspergillosis, histoplasmosis, lymphocutaneous/cutaneous sporotrichosis.
    b. Treatment and maintenance therapy in AIDS patients with disseminated or chronic pulmonary histoplasmosis infection.
    c. Treatment of oropharyngeal and/or esophageal candidiasis when first line systemic antifungal therapy is inappropriate or has proven ineffective.
    d. Treatment of non-invasive candidiasis in non-neutropenic patients when first-line systemic antifungal therapy is inappropriate or has proven ineffective. This may be due to underlying pathology, insensitivity of the pathogen or drug toxicity.

**Coverage Guidelines**

**Itraconazole oral solution 10 mg/mL**
Authorization may be granted for members when ALL the following criteria are met:

1. Member has required treatment of oropharyngeal candidiasis or esophageal candidiasis.
2. Prescriber has provided documentation of a treatment failure or contraindication with oral fluconazole 200mg daily or greater.

3. Prescriber has provided documentation of ONE of the following:
    a. Member is 6 years of age or younger.
    b. Member has an inability to swallow capsules (i.e. dysphagia).

**Itraconazole 100mg capsules**

Authorization may be granted for members when product is being used for the one of the following conditions **AND** documentation (clinical notes and diagnostic confirmations) have been submitted:

1. Allergic bronchopulmonary aspergillosis
2. Allergic aspergillus sinusitis
3. Treatment of onychomycosis/tinea unguium (toenail and/or fingernail infection) caused by candida species
4. Treatment of onychomycosis/tinea unguium (toenail and/or fingernail infection) caused by non-candida species in a patient who:
    a. Has tried and failed terbinafine **AND**
    b. Is immunocompromised, has diabetes or has pain/mobility issues
5. Treatment of vaginal candidiasis in a patient who has tried and failed a topical vaginal antifungal **AND** fluconazole single-dose 150 mg
6. Treatment of tinea versicolor (pityriasis versicolor) in a patient who has tried and failed a topical antifungal agent*, oral fluconazole **AND** oral ketoconazole
    a. Note: Trial of a topical antifungal agent may be bypassed if the infection involves a large area of the body that which would be difficult to treat with a topical agent*
7. Treatment of tinea capitis or tinea barbae (tinea sycosis) in a patient who has tried and failed oral griseofulvin
8. Treatment of tinea cruris, tinea faciei, or tinea manuum (tinea manus) in a patient who has tried and failed a topical antifungal agent
9. Treatment of tinea corporis (ring worm) in a patient who has tried and failed a topical antifungal agent* **AND** oral fluconazole
    a. Note: Trial of a topical antifungal agent may be bypassed if the infection involves a large area of the body that which would be difficult to treat with a topical agent*
10. Treatment of tinea imbricata in a patient who has tried and failed **either** oral griseofulvin **OR** terbinafine
11. Treatment of tinea pedis in a patient who either:
    a. Has tried and failed a topical antifungal agent **OR**
    b. Has plantar-type or moccasin-type dry chronic tinea pedis
12. Treatment of oropharyngeal candidiasis (oral thrush) in a patient who has tried and failed oral fluconazole at a daily dose ≥ 200 mg
13. Prevention of other systemic or superficial fungal infections in an immunocompromised patient who has tried and failed oral fluconazole (if appropriate for indication)
14. Treatment of other systemic or superficial fungal infections in a patient who has tried and failed oral fluconazole (if appropriate for indication)

**Limitations**

1. For itraconazole solution authorization will be for 450mL (200mg daily) for 21 days.
2. For itraconazole 100mg capsules, the plan allows a maximum of 170 capsules per 12 months.
    a. The following quantity and timeframe limits apply:

| Indication | Approved Quantity/Duration |
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| Allergic bronchopulmonary aspergillosis | 60 capsules per month for 180 days |
| Allergic aspergillus sinusitis | |

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| Prevention/treatment of other systemic or superficial fungal infections in an immunocompromised person | |
| Onychomycosis (fingernail) | 14 capsules per month for 2 months<br><br>Dosing: 200 mg twice daily for 1 week; repeat 1-week course after 3-week off-time |
| Onychomycosis (toenail involvement) | Pulse therapy: 14 capsules per month for 3 months<br><br>Dosing: 200 mg twice daily for 1 week; repeat 1-week course after 3-week off-time |
| | Standard therapy: 60 capsules per month for 12 consecutive weeks |
| Tinea versicolor (Pityriasis versicolor) | 14 capsules for 7 days |
| All other indications | 60 capsules per month |

**References**


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**Review History**

12/19/2005 – Reviewed
11/27/2006 – Reviewed
11/26/2007 – Reviewed and updated
11/24/2008 – Reviewed
11/23/2009 – Reviewed and updated (oral thrush criteria)
11/22/2010 – Reviewed and updated
11/28/2011 – Reviewed and updated
11/26/2012 – Reviewed and updated
12/01/2012 – Reviewed and updated (RxAuth)
01/09/2013 – Reviewed and updated (Onmel® plan exclusion; 12/31/12 file)
11/25/2013 – Reviewed
11/24/2014 – Reviewed and updated
11/23/2015 – Reviewed in P&T Meeting
11/26/2018 – Reviewed and updated in P&T Meeting
03/18/2020 – Reviewed P&T Mtg
08/21/2021 – Removed specialty wording and switched Sporanox to itraconazole solution.