blue of california

ITRACONAZOLE AGENTS

Applies to:

- **itraconazole (SPORANOX) 10 mg/ml oral solution**
- **SPORANOX 10 mg/ml oral solution**
- **TOLSURA (itraconazole) 65 mg oral solid dispersion capsule**
- **SPORANOX (itraconazole) PULSEPAK 100 mg capsule**

Diagnoses Considered for Coverage:

FDA-approved indications:

Aspergillosis, Invasive, salvage therapy Tolsura and Sporanox capsules
Blastomycosis – *Tolsura and Sporanox Capsules*
Candidiasis of the esophagus sporanox solution
Candidiasis of the esophagus - HIV infection
Histoplasmosis, Disseminated Sporanox Capsulesand Tolsura
Histoplasmosis, Disseminated, nonmeningeal - HIV infection - *Tolsura*
HIV infection - Oropharyngeal candidiasis
Onychomycosis due to dermatophyte – sporanox capsules non-immunocompromised
Oropharyngeal candidiasis – sporanox solution
Pulmonary histoplasmosis – *Tolsura and sporanox capsules*

Compendia or IDSA supported indications:

Allergic bronchopulmonary aspergillosis (ABPA)
Aspergillosis, Invasive, in high-risk patients; Prophylaxis
Aspergillosis, Invasive; Prophylaxis - Hemopoietic stem cell transplant
Coccidioidomycosis
Coccidioidomycosis; Prophylaxis - HIV infection
Coccidioidomycosis - HIV infection
Cryptococcal meningitis - HIV infection
Cryptococcosis
Histoplasmosis, Central Nervous System
Histoplasmosis, Central Nervous System - HIV infection
Histoplasmosis; Prophylaxis - HIV infection
Histoplasmosis; Prophylaxis - Patient immunosuppressed
Infection due to Penicillium marneffei
Invasive fungal infection; Prophylaxis
Pulmonary aspergillosis, Chronic (cavitary or necrotizing)
Sporotrichosis
Tinea corporis, cruris, pedis, manuum, capitis, versicolor, or unguium (onychomycosis)

Coverage Criteria:

FOR PROPHYLAXIS

1. **For fungal prophylaxis against aspergillosis or histoplasmosis:**
   - ***For Tolsura request only***: Patient is unable to use generic itraconazole capsule and solution (Sporanox), **and**
   - Dose does not exceed FDA label maximum or compendia support, **and**
   - One of the following:
     - Patient with HIV infection, or

- Patient is currently neutropenic, or
- Patient recently had a recent bone marrow transplant, or
- Patient has cancer and is currently undergoing myelosuppressive (immunosuppressive) chemotherapy, or
- Patient has GVHD and currently on corticosteroid or other immunosuppressant therapy.

2. **For prophylaxis (primary or secondary) or maintenance treatment of talaromycosis (Talaromyces marneffei, formerly Penicillium marneffei):**
   - Patient with HIV infection, **and**
   - Dose does not exceed FDA label maximum or compendia support.
   - ***For Tolsura request:*** Patient is unable to use generic itraconazole capsule and solution (Sporanox)

FOR ACTIVE INFECTION:

3. **For treatment of pulmonary aspergillosis, chronic (cavitary or necrotizing):**
   - ***For Tolsura request:*** Patient is unable to use generic itraconazole capsule and solution (Sporanox)
   - Dose does not exceed FDA label maximum or compendia support.

4. **For treatment of systemic fungal infection:**
   - Culture positive evidence of Aspergillosis, Blastomycosis, Cryptococcosis, Histoplasmosis, or Sporotrichosis, **and**
   - ***For Tolsura request***: Patient is unable to use generic itraconazole capsule and solution (Sporanox), **and**
   - Dose does not exceed FDA label maximum or compendia support.

5. **For treatment of ABPA:**
   - ***For Tolsura request***: Patient is unable to use generic itraconazole capsule and solution (Sporanox)
   - Dose does not exceed FDA label maximum or compendia support.

6. **For treatment of coccidioidomycosis:**
   - Culture positive evidence of coccidioidomycosis, **and**
   - One of the following:
     a. Inadequate response, intolerable side effect, or contraindication with fluconazole, or
     b. Patient with HIV infection and bone or joint infection, **and**
   - ***For Tolsura request***: Patient is unable to use generic itraconazole capsule and solution (Sporanox), **and**
   - Dose does not exceed FDA label maximum or compendia support.

7. **For treatment of esophageal or oropharyngeal candidiasis:**
   - Inadequate response, intolerable side effect, or contraindication with fluconazole, **and**
   - ***For Tolsura request***: Patient is unable to use generic itraconazole solution (Sporanox), **and**
   - Dose does not exceed FDA label maximum or compendia support.

8. **For treatment of tinea capitis:**
   - Inadequate response, intolerable side effect, or contraindication with oral terbinafine **and**
   - ***For Tolsura request***: Patient is unable to use generic itraconazole capsule and solution (Sporanox), **and**
   - Dose does not exceed FDA label maximum or compendia support.

9. **For treatment of tinea corporis, cruris, pedis or manuum:**
   - Inadequate response or intolerable side effect with topical antifungal, **and**
   - Inadequate response, intolerable side effect, or contraindication with oral terbinafine, **and**
   - ***For Tolsura request***: Patient is unable to use generic itraconazole capsule and solution (Sporanox), **and**
   - Dose does not exceed FDA label maximum or compendia support.

10. **For treatment of tinea versicolor:**
   - Inadequate response, or intolerable side effect, or contraindication with topical ketoconazole, **and**
   - Inadequate response, intolerable side effect, or contraindication with oral fluconazole, **and**
   - ***For Tolsura request***: Patient is unable to use generic itraconazole capsule and solution (Sporanox), **and**
   - Dose does not exceed FDA label maximum or compendia support.

11. **For treatment of onychomycosis:**

Initial Treatment

- Dosing does not exceed recommended daily or pulse therapy *(see dosing table),* **and**
- One of the following:
  - Inadequate response, intolerable side effect, or contraindication with oral terbinafine, **or**
  - Positive culture evidence for nail *Candida* is provided

  and
- ***For Tolsura request***: Patient is unable to use generic itraconazole capsule and solution (Sporanox).

Coverage Duration:

Location	Daily Dosing	Pulse Dosing
Fingernails	itraconazole two 100 mg capsules QD x 6 weeks	itraconazole two 100 mg capsules BID x 1 week per month up to 2 courses
	itraconazole two 100 mg capsules QD x 12 weeks	itraconazole two 100 mg capsules BID x 1 week per month up to 3 courses†
Toenails	itraconazole two 100 mg capsules QD x 12 weeks	itraconazole two 100 mg capsules BID x 1 week per month up to 3 courses†

Reauthorization

- Patient completed a course of antifungal therapy for onychomycosis more than **3 months ago** (from the last day the medication was finished), **and**
- Dosing does not exceed recommended daily or pulse therapy.

Coverage Duration: see table above

Coverage Duration:

PROPHYLAXIS	
Aspergillosis	Transplant: 200 mg BID for at least 75 days GVHD: 200 mg BID for 16 weeks or until steroid dose is less than 10 mg prednisolone equivalent
Histoplasmosis	200 mg orally once daily (immunosuppressed patients and in patients who relapse despite appropriate therapy)
Talaromycosis	Long-term suppression dose: 200 mg orally daily until restoration of cellular immunity as assessed by provider
TREATMENT	
Talaromycosis	up to 600mg/d x 3 days followed by up to 400mg/d for up to 12 weeks
Pulmonary aspergillosis, chronic (cavitary or necrotizing)	200 mg orally twice daily; treat for at least 6 months in symptomatic patients with radiographic progression or progressive loss of lung function
Invasive Aspergillosis	200 mg BID for 12 weeks or until evidence of clinical and laboratory improvement
Blastomycosis	200 mg BID for 6 to 12 months† or until evidence of clinical and laboratory improvement
Cryptococcosis	200 mg/day ORALLY for 6 to 12 months Cryptococcal meningitis - HIV infection: 200 mg orally twice daily for 8 weeks
Histoplasmosis, Central Nervous System	200 mg 2 or 3 times daily for at least 1 year and until resolution of cerebrospinal fluid abnormalities
Disseminated histoplasmosis treatment	200 mg orally twice daily for at least 12 months†
ABPA	200 mg BID up to 4 months and then re-evaluate
Coccidioidomycosis	up to 800 mg ORALLY daily for disseminated infection
Coccidioidomycosis - HIV infection	Mild: 200 mg BID long-term suppression for at least 6 months Severe: 200mg BID twice daily Meningitis: 200 mg orally 2 to 3 times daily; continue lifelong suppression therapy
Candidal vulvovaginitis - HIV infection	200 mg orally daily for 3 to 7 days†
Candidiasis of the esophagus	100 to 200 mg daily for a minimum of 3 weeks and 2 weeks following symptom resolution Fluconazole-refractory disease - 200 mg daily for 14 to 21 days
Oropharyngeal candidiasis	200 mg daily for 1 to 2 weeks
Sporotrichosis	100 to 200 mg once daily (up to 200 mg twice) daily for 3 to 6 months
Tinea capitis	The optimum regimen for itraconazole for tinea capitis is unclear. Itraconazole is *commonly prescribed* at a dose of 3 to 5 mg/kg

	daily for four to six weeks. The maximum daily dose is 400 mg.
Tinea cruris /corporis	200 mg once daily for 7 days
Tinea pedis, or manuum	200 mg twice daily for 1 week
Tinea versicolor	200 mg once daily for 5 to 7† days
Onychomycosis	*See Coverage Criteria*

†Guideline-supported dosing regimen

Additional Information:

- Approved in December 2018, **Tolsura** is FDA indicated for blastomycosis, histoplasmosis, and aspergillosis. Tolsura is started at 130 mg per day and increased in 65 mg increments up to 260 mg per day. For life-threatening cases, 130 mg PO 3 times daily for the first 3 days and continue treatment for at least 3 months until clinical parameters and laboratory tests indicate the active fungal infection has subsided.[2]
- Onmel has been discontinued (obsolete date: 7/20/2020).

Effective Date: 01/03/2024