Itraconazole

Description

Onmel (itraconazole); Sporanox (itraconazole); Tolsura* (itraconazole)

*Prior authorization for the brand formulation applies only to formulary exceptions due to being a non-covered medication.

Background

Itraconazole is an antifungal agent used to treat certain fungal infections which include the following: infections of the nails, skin, hands, feet or groin; candida (yeast) infections of the vagina; eye infections which have not responded to other treatment or which may be affecting vision; candida (yeast) infections of the mouth or throat in patients with lower resistance to disease; Itraconazole inhibits the production of ergosterol, which is a vital component of fungal cell membranes and without it causes cell death stopping the growth of the fungus (1).

Regulatory Status

FDA-approved indication: Sporanox (itraconazole) oral solution is indicated for the treatment of oropharyngeal and esophageal candidiasis (1).

Sporanox capsules are indicated for the treatment of Blastomycosis, Histoplasmosis and Aspergillosis in immunocompromised and non-immunocompromised patients. The capsules are also indicated for the treatment of onychomycosis in non-immunocompromised patients (2).

Tolsura capsules are indicated for the treatment of Blastomycosis, pulmonary and extrapulmonary; Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis; and Aspergillosis, pulmonary and
extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy (4).

Do not administer itraconazole for the treatment of onychomycosis in patients with evidence of ventricular dysfunction, such as congestive heart failure (CHF) or a history of CHF (1-4).

There are three major forms of aspergillosis: invasive, saprophytic and allergic. The Infectious Disease Society of America (IDSA) recommends the use of itraconazole and corticosteroids for the treatment of allergic bronchopulmonary aspergillosis (5).

The safety and efficacy of itraconazole in patients less than 18 years of age have not been established (1-4).

**Related policies**

**Policy**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Itraconazole may be considered **medically necessary** in patients 18 years of age and older for the treatment of susceptible fungal infections and if the conditions indicated below are met.

Itraconazole may be considered **investigational** for patients below 18 years of age and for all other indications.

**Prior-Approval Requirements**

**Age**

18 years of age or older

**Diagnoses**

Patient must have **ONE** of the following

**Sporanox and Onmel ONLY**

1. Onychomycosis
   a. Not immunocompromised
   b. Not have evidence of ventricular dysfunction, such as congestive heart failure or a history of CHF
Sporanox, Onmel, and Tolsura

1. Candidiasis
   a. Must be unresponsive to Fluconazole
   b. Includes oropharyngeal and esophageal candidiasis
2. Aspergillosis – invasive or saprophytic
   a. Must be refractory or intolerant to amphotericin B
3. Aspergillosis - allergic bronchopulmonary
4. Blastomycosis
5. Coccidioidomycosis
6. Histoplasmosis
7. Sporotrichosis

AND ALL of the following for ALL diagnoses:
   a. Prescriber agrees to monitor for QTc prolongation

Prior – Approval **Renewal Requirements**
Same as above

**Policy Guidelines**

**Pre - PA Allowance**
None

**Prior - Approval Limits**

**Duration**
6 months for a diagnosis of Onychomycosis or Candidiasis
1 year for all other diagnoses

**Prior – Approval **Renewal Limits**
Same as above

**Rationale**

**Summary**
Sporanox (itraconazole) is an antifungal agent. Itraconazole inhibits the production of ergosterol, which is a vital component of fungal cell membranes. The safety and efficacy of itraconazole in patients less than 18 years of age have not been established (1-4).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Sporanox while maintaining optimal therapeutic outcomes.

References

Policy History

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<td>December 2012</td>
<td>Annual editorial review and reference update.</td>
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<tr>
<td>March 2013</td>
<td>Addition of age and contraindication for CHF</td>
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<td>Addition of Onmel as a line extension</td>
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<tr>
<td>September 2014</td>
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<td>September 2015</td>
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<td>Addition of identified types of aspergillosis- allergic bronchopulmonary and aspergillosis – invasive or saprophytic</td>
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<td>March 2016</td>
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<td>Policy number changed from 5.03.18 to 5.01.18</td>
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<td>December 2017</td>
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<tr>
<td>January 2019</td>
<td>Addition of Tolsura. Policy renamed Itraconazole</td>
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<tr>
<td>March 2019</td>
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<td>June 2019</td>
<td>Annual review. Added requirement to monitor for QTc prolongation per SME</td>
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<td>September 2019</td>
<td>Removed diagnosis of other fungal infection if patient is diabetic or immune compromised</td>
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December 2019  Annual review. Moved Tolsura to MFE with PA only

**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective January 1, 2020.