BlueCross BlueShield
Federal Employee Program

ITRACONAZOLE
SPORANOX, TOLSURA*

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

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Itraconazole is an oral azole antifungal agent indicated for the treatment of blastomycosis, histoplasmosis, aspergillosis, onychomycosis and oropharyngeal or esophageal candidiasis. FDA-approved indications vary by dosage form, and dosage forms are not interchangeable. Itraconazole works by inhibiting the production of ergosterol (principal sterol in fungal cell membrane) and inhibiting cell membrane formation (1).

Regulatory Status

FDA-approved indications: Sporanox oral solution is indicated for the treatment of oropharyngeal and esophageal candidiasis. Only the oral solution has demonstrated effective for oral and/or esophageal candidiasis (2).

Sporanox capsules and 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 (2-3).

Sporanox capsules are also indicated for the treatment of onychomycosis in non-immunocompromised patients (3).

<u>Tolsura Limitations of Use:</u> (4)
Tolsura is not indicated for the treatment of onychomycosis and it is not interchangeable or substitutable with other itraconazole products.

Itraconazole has a boxed warning for congestive heart failure, cardiac effects and drug interactions. Do not administer itraconazole in patients with evidence of ventricular dysfunction, such as congestive heart failure (CHF) or a history of CHF. Coadministration of a number of CYP3A4 substrates are contraindicated with itraconazole (2-4).

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Itraconazole has warnings regarding hepatic effects, cardiac dysrhythmias, cardiac disease, interaction potential, interchangeability, hydroxypropyl-β-cyclodextrin, and treatment of severely neutropenic patients (2-4)

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 (2-4)

Summary

Itraconazole is an oral azole antifungal agent indicated for the treatment of blastomycosis, histoplasmosis, aspergillosis, onychomycosis and oropharyngeal or esophageal candidiasis. FDA-approved indications vary by dosage form, and dosage forms are not interchangeable. Itraconazole works by inhibiting the production of ergosterol (principal sterol in fungal cell membrane) and inhibiting cell membrane formation. Itraconazole has a boxed warning for congestive heart failure, cardiac effects and drug interactions. Itraconazole has warnings regarding hepatic effects, interchangeability, hydroxypropyl-β-cyclodextrin, and treatment of severely neutropenic patients. 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 Itraconazole while maintaining optimal therapeutic outcomes.

References

1. Itraconazole. Clinical Pharmacology [database online]. Tampa, FL: Elsevier; Revision year 2018. Available from: http://www.clinicalkey.com.
2. Sporanox oral solution [package insert]. Titusville, NJ: Janssen Pharmaceuticals; September

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3. Sporanox capsules [package insert]. Titusville, NJ: Janssen Pharmaceuticals; December 2019.
4. Tolsura [package insert]. Greenville, NC: Mayne Pharma International Pty Ltd; April 2022.
5. Patterson TF, Thompson GR, Denning DW, et al. Practice Guidelines for the Diagnosis and Management of Aspergillosis: 2016 Update by the Infectious Diseases Society of America. *Clinical Infectious Diseases.* 2016; 63:112-146.