RATIONAL FOR INCLUSION IN PA PROGRAM

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).

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 (1-3).

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 (4).

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

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.

Itraconazole may be considered medically necessary in patients 18 years of age or older for the treatment of onychomycosis, not immunocompromised, and no evidence of ventricular dysfunction, such as congestive heart failure or a history of CHF; for the treatment of candidiasis, must be
unresponsive to fluconazole, and include oropharyngeal and esophageal candidiasis; for the
treatment of aspergillosis – invasive or saprophytic and must be refractory or intolerant to
amphotericin B; for the treatment of aspergillosis – allergic bronchopulmonary; for the treatment of
blastomycosis, coccidioidomycosis, histoplasmosis, sporotrichosis, or other diagnosed fungal
infection and diabetic or immune compromised.

Itraconazole may be considered investi gational in patients below 18 years of age or for all other
indications.

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

References
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