RATIONALE 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 (1-3).

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 (1-3).

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