

Office of Pharmacy Service Prior Authorization Criteria

Ketoconazole (Oral)

Prior authorization requests for ketoconazole will be approved if each of the following criteria are met:

- 1. Diagnosis of one of the following fungal infections: blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, or paracoccidioidomycosis
- 2. Documented failure or intolerance of all other diagnosis-appropriate antifungal therapies, i.e. itraconazole, fluconazole, flucytosine, etc
- Baseline assessment of the liver status including alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, alkaline phosphatase, prothrombin time, and international normalized ration (INR) before starting treatment
- 4. Weekly monitoring of serum ALT for the duration of the treatment
- 5. Ketaconazole will **not** be approved for treatment for fungal infections of the skin and nails

US Food and Drug Administration July 26, 2013