

## Office of Pharmacy Service Prior Authorization Criteria

## Ketoconazole

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

- 1. Diagnosis of one of the following fungal infections: blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, or paracoccidioidomycosis
- 2. No history of acute or chronic liver disease
- 3. 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 treatment (If ALT values increase to a level above the upper limit of normal or 30% above baseline, or if the patient develops symptoms of abnormal liver function, treatment should be interrupted and a full set of liver tests be obtained. Liver tests should be repeated to ensure normalization of values.)
- 5. Assessment of all concomitant medications for potential adverse drug interactions with ketoconazole

US Food and Drug Administration July 26, 2013