Alaska Medicaid

ORAL NIZORAL®(ketoconazole)

Available 200mg tablet

INDICATIONS and USAGE:

NIZORAL® Tablets should be used only when other effective antifungal therapy is not available or tolerated and the potential benefits are considered to outweigh the potential risks.

NIZORAL® (ketoconazole) Tablets are indicated for the treatment of the following systemic fungal infections in patients who have failed or who are intolerant to other therapies: blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, and paracoccidioidomycosis. NIZORAL® Tablets should not be used for fungal meningitis because it penetrates poorly into the cerebrospinal fluid.

Criteria for Approval:

1. Diagnosis from the 'Indication and Usage' section and must be supported by documentation from the patient's medical record; **AND**
2. Submit dates of trial from at least one alternative antifungal medication; **AND**
3. Appropriate baseline laboratory test for liver assessment; **AND**
4. No history of acute or chronic liver disease; **AND**
5. Box Warnings discussed with recipient.

Length of Authorization:

Coverage may be approved for 1 month.

Dispensing Limit: The dispensing limit is a 30 day supply of medication with a **Quantity Limit of 2 per day.**

Reminder: You are encouraged to report negative side effects of prescription drugs to the FDA. Visit http://www.fda.gov/Safety/MedWatch/default.htm or call 1-800-FDA-1088

References:

Nizoral® package insert is available at: < http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/018533s040lbl.pdf > Accessed 12/11/13

FDA Drug Safety Communication < http://www.fda.gov/Drugs/DrugSafety/ucm362415.htm >

Nizoral (oral) criteria
Version 1
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