PROVIDER NOTICE:
Ketoconazole

On July 26, 2013, the U.S. Food & Drug Administration (FDA) released new warnings for the oral antifungal drug, ketoconazole. Warnings of severe liver injuries, adrenal gland problems and multiple harmful drug interactions have been added to the drug's label. As a result of these new warnings, it is recommended that ketoconazole tablets only be used to treat endemic mycoses when alternative antifungal therapies are not available or tolerated. While the FDA has strengthened the warnings contained within the medication guide, the European Medicines Agency took one step further and recommended that use oral ketoconazole products be suspended throughout the European Union. For your easy reference, the FDA's warning, attached to this email, can be located at http://www.fda.gov/Drugs/DrugSafety/ucm362415.htm.

In response to these new warnings, the Mississippi Division of Medicaid has elected to change the Preferred Drug List (PDL) status of ketoconazole tablets from preferred to non-preferred. Patients currently taking ketoconazole will be allowed a two week transition period to switch to an alternative, preferred oral antifungal product. Prescribers, whose patients are currently on ketoconazole and wish for them to receive the 14 day transition provision, are requested to call the Pharmacy PA unit at 1-877-537-0722. Otherwise, prescribers are to submit prior authorization requests for the on-going use of ketoconazole tablets. This will allow the DOM pharmacy staff and its clinical contractors to evaluate the risks and benefits of using ketoconazole tablets within the Mississippi Medicaid population. Be advised that this change in PDL status will be effective immediately. The revised PDL will be posted to DOM's website by COB, August 2, 2013.