

Medical Affairs Policy & Procedure

Title/Service: Antifungal Medications – Oral (Diflucan, Lamisil, Sporanox)

Revised	11/18/2011
Reviewed	02/25/00, 04/19/00, 05/05/00, 01/26/01, 03/22/02, 06/21/02, 08/23/02, 03/28/03, 02/24/06, 04/20/07, 11/21/08
Developed	
Policy Committee Approval	11/18/11

Description:

Antifungal medications are used for the treatment fungal infections, including onychomycosis (a fungal infection of the fingernails or toenails). Onychomycosis may cause thickening, discoloration, and disfigurement of the nails and may result in irritation or pain in the affected digit. Antifungal medications can be administered orally or topically

Indications of Coverage:

Antifungal medications are considered medically necessary in the following situations:

For the treatment of one of the fungal infections listed below (not including onychomycosis) that have been confirmed by a fungal culture, positive KOH (potassium hydroxide) stain, or positive PAS (para-aminosalicylic acid) stain.

Aspergillosis (including allergic bronchopulmonary aspergillosis)

Coccidiomycosis

Blastomycosis

Histoplasmosis

Ringworm in children ages four through twelve. Lamisil oral granules for a six week course of treatment may be allowed.

Fungal skin conditions, after the failure of a one month trial of topical antifungal agents. A two week course of oral antifungal treatment may be allowed once per rolling year.

Fungal sinus infections

Esophageal or oropharyngeal candidiasis with itraconazole when treatment with agents such as nystatin, ketoconazole, or clotrimazole troches have failed and

proper oral hygiene with use of steroid inhalers has been addressed (when applicable). A fourteen day course of treatment may be allowed.

For the treatment of onychomycosis of the toenails when one of the following is documented:

The patient's immune system is currently compromised due to disease (for example, cancer, bone marrow or organ transplant, or HIV)

Diabetes with impaired peripheral circulation and symptomatic complications from the nail infection

Severe heart disease with impairment of peripheral circulation

The treatment is ordered in conjunction with surgical nail removal

For the treatment of onychomycosis of the fingernails when all of the following are documented:

The infection causes pain affecting the activities of daily living and has been confirmed by culture, positive KOH (potassium hydroxide) stain, or positive PAS (para-aminosalicylic acid) stain.

In all onychomycosis situations, terbinafine (generic Lamisil) must have been tried/failed before itraconazole (Sporanox) will be eligible for coverage.

If the criteria are met, oral antifungal agents for the treatment of onychomycosis of the toenails can be approved for twelve weeks, or six weeks for onychomycosis of the fingernails.

Other uses for antifungal medications require physician or pharmacist review.

Limitations of Coverage:

Review contract and endorsements for exclusions and prior authorization or benefit requirements.

If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental or investigative.

If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria is not met, deny as not medically necessary.

The use of antifungal medications for the treatment of Candida Related Complex (CRC), Yeast Allergy Syndrome (YAS) and related conditions is considered not medically necessary.

The use of Penlac lacquer for more than forty-eight weeks has not been established and is considered investigative.

Documentation Required:

- Office notes
- Test results (if necessary)

Rationale:

The criteria above are from the US Food and Drug Administration approved package inserts.

References:

1. Diflucan (Fluconazole tablets, Fluconazole injection - for intravenous infusion only, Fluconazole for oral suspension). New York, New York: Roerig, Division of Pfizer Inc., Revised Aug 2004. Available at: www.pfizer.com/pfizer/download/uspi_diflucan.pdf. Accessed: 11 Feb 08.
2. Higgins EM, Fuller LC, Smith CH. Guidelines for the management of tinea capitis. British Association of Dermatologists. Br J Dermatol. 2000 Jul; 143(1): 53-8.
3. Itraconazole. Drug Facts and Comparisons monograph. 2007.
4. Lamisil (terbinafine hydrochloride). East Hanover, New Jersey: Novartis Pharmaceuticals Corp, Revised Nov 2005. Available at: www.lamisil.com/hcp/tools/pi.jsp. Accessed: 2011.
5. Rushing M. Tinea corporis. 29 Jan 2006. Available at: www.emedicine.com/DERM/topic421.htm. Accessed: 11 Feb 08.
6. US Food and Drug Administration. Lamisil granules prescribing information. Updated September 2007. Available at: www.fda.gov/consumer/updates/lamisil100907.html. Accessed: 11 Feb 08.

Approved by the Medical Director