**ORAL ANTIFUNGALS AND TOPICAL CICLOPIROX PA SUMMARY**

**PREFERRED**
ciclopirox 8% nail lacquer (solution), clotrimazole oral troche, fluconazole (tablets, oral suspension, injection), fluconazole (generic Ancobon), itraconazole capsules, Gris-PEG (brand), terbinafine tablets

**NON-PREFERRED**
Ciclodan Kit (brand only; generic is not covered), CNL8 Nail Kit, Grifulvin V, Griseofulvin Microsize (generic), Griseofulvin Ultramicrosize (generic), Lamisil tablets, Lamisil oral granules, Noxafil, Oravig, Pedipirox-4 Nail, Penlac nail lacquer, Sporanox capsules and pulsepak, Sporanox oral solution, Terbinex kit, Vfend (suspension, IV), voriconazole (suspension, tablets, IV)

**LENGTH OF AUTHORIZATION:** Varies based on drug and diagnosis

**NOTE:** If Grifulvin V is approved, the PA will be entered for generic griseofulvin microsize. If Penlac is approved, the PA will be entered for generic ciclopirox 8%. If Lamisil tablets are approved, the PA will be entered for generic terbinafine tablets. If Sporanox capsules or pulsepak is approved, the PA will be entered for generic itraconazole capsules. If voriconazole suspension is approved, the PA will be entered for brand-name Vfend suspension. PA criteria for ciclopirox gel and shampoo are listed in a separate document titled "Topical Antifungals".

**PA CRITERIA:**

*For ciclopirox (Penlac), CNL8, Ciclodan Kit, or Pedipirox-4 Nail*

- Approvable for the treatment of mild to moderate onychomycosis or white superficial onychomycosis in members with diabetes mellitus or peripheral vascular disease. Member must have a positive fungal culture result.
- Approvable for the treatment of moderate to severe onychomycosis in members with diabetes mellitus, peripheral vascular disease, or immunocompromised status. Member must have a positive fungal culture result AND must have experienced ineffectiveness, allergies, drug-drug interactions, contraindications, or a history of intolerable side effects to terbinafine (Lamisil).
- CNL8, Ciclodan Kit, and Pedipirox-4 Nail also require a written letter of medical necessity stating the reason(s) that generic ciclopirox nail lacquer cannot be used.

*For fluconazole injection*

- Medication must be administered in member’s home by home health or in a long-term care facility.

*For Grifulvin V, griseofulvin microsize (generic), griseofulvin ultramicrosize (generic)*

- Submit a written letter of medical necessity stating the reason(s) that brand-name Gris-PEG (preferred product) is not appropriate for the member.

Revised 1/17/2014
For itraconazole capsules or Sporanox capsules or pulsepak

- Approvable for the treatment of onychomycosis. Member must have experienced ineffectiveness, allergies, drug-drug interactions, contraindications, or a history of intolerable side effects to terbinafine (Lamisil) AND must have a positive KOH preparation, fungal culture, or nail biopsy.
- Approvable for the diagnosis of aspergillus, blastomycosis, or histoplasmosis.
- Approvable for the diagnosis of tinea versicolor, tinea cruris, tinea corporis, or tinea pedis when infections involve a large area of the body or the member is immunocompromised or when member has tried and failed at least one OTC or prescription topical antifungal agent.

For Lamisil oral granules

- Approvable for the treatment of tinea capitis in members 4-12 years of age. Member must have experienced ineffectiveness, allergies, drug-drug interactions, contraindications, or a history of intolerable side effects to griseofulvin.

For Noxfail

- Noxfail is approvable for the following diagnoses:
  - Preventative therapy for invasive aspergillus and/or candida in immunocompromised members
  - Invasive aspergillosis, zygomycosis, fusariosis, or other moulds that are resistant to previous systemic antifungal therapy
- Noxfail is also approvable for oropharyngeal candidiasis refractory to itraconazole or fluconazole OR for members with allergies, contraindications, drug-drug interactions, or a history of intolerable side effects to itraconazole or fluconazole.
- Noxfail is also approvable for continuation of therapy following discharge from a hospital for certain diagnoses.

For Onmel

- Approvable for the treatment of onychomycosis.
- Prescriber should submit a written letter of medical necessity stating the reason(s) the preferred product (itraconazole capsules which also requires PA) is not appropriate for the member.

For Oravig

- Approvable for members 16 years of age or older for the treatment of oropharyngeal candidiasis
  
  AND
  
  - Was started as part of an inpatient hospital regimen
  
  OR
  
  - When the member is refractory to at least two of the following: clotrimazole troches, nystatin oral suspension, or fluconazole

Revised 1/17/2014
When the member has allergies, contraindications, drug-drug interactions, or a history of intolerable side effects to at least two of the following: clotrimazole troches, nystatin oral suspension, or fluconazole.

For Sporanox oral solution
- Approvable for the diagnosis of oropharyngeal candidiasis (thrush), esophageal candidiasis, or empiric febrile neutropenia.
- Approvable in patients meeting Sporanox capsules or pulsepak criteria who are unable to swallow capsules.

For terbinafine (Lamisil) tablets
- Approvable for the treatment of onychomycosis. Member must have a positive KOH preparation, fungal culture, or nail biopsy.

For Terbinex Kit
- Terbinafine tablets are preferred and also require PA. If terbinafine tablets cannot be used, submit a written letter of medical necessity detailing reason(s).

For Vfend ( suspension or IV) or voriconazole ( suspension, tablets, IV)
- Approvable for members using oral Vfend (voriconazole) for continuation of therapy after being started on IV Vfend therapy.
- Approvable for members who have tried one other systemic antifungal agent and who have one of the following diagnoses:
  - Esophageal candidiasis
  - Candidemia in nonneutropenic patient
  - Disseminated Candida skin infection
  - Candida infection in abdomen, kidney, bladder wall, or wound
- Approvable for members with invasive aspergillus, fungal infection caused by Scedosporium apiospermum, or fungal infection caused by Fusarium species.
- Approvable for prophylaxis of aspergillosis or candida in severely immunocompromised patients.
- Approvable for CNS blastomycosis. Member must have experienced ineffectiveness, allergies, contraindications, drug-drug interactions, or a history of intolerable side effects to itraconazole.
- Additionally, Vfend IV must be administered in a member’s home by home health or in a long-term care facility and must require IV Vfend therapy versus oral Vfend therapy.

QLL CRITERIA FOR SPORANOX (ITRACONAZOLE) CAPSULES OR PULSEPACK (QLL IS SET AT 60/30 DAYS):
- An authorization to exceed the QLL may be granted for members with aspergillus, blastomycosis, or histoplasmosis.

EXCEPTIONS:
- Exceptions to these conditions of coverage are considered through the prior authorization process.
- The Prior Authorization process may be initiated by calling Catamaran at 1-866-525-5827.

Revised 1/17/2014
PA and APPEAL PROCESS:
- For online access to the PA process please go to www.mmis.georgia.gov/portal, highlight the pharmacy link on the top right side of the page, and click on “prior approval process”.

QUANTITY LEVEL LIMITATIONS:
- For online access to the current Quantity Level Limit please go to www.mmis.georgia.gov/portal, highlight Provider Information and click on Provider Manuals. Scroll to the page with Pharmacy Services Part II and select that manual.