



## ORAL ANTIFUNGALS AND TOPICAL CICLOPIROX PA SUMMARY

<b>PREFERRED</b>	ciclopirox 8% nail lacquer (solution), clotrimazole oral troche, fluconazole (tablets, oral suspension, injection), flucytosine (generic Ancobon), itraconazole capsules, Gris-PEG (brand), terbinafine tablets
<b>NON-PREFERRED</b>	Ciclodan Kit (brand only; generic is not covered), CNL8 Nail Kit, Grifulvin V, Griseofulvin Microsize (generic), Griseofulvin Ultramicrosize (generic), Lamisil oral granules, Noxafil DR and suspension, Onmel, Pedipirox-4 Nail, 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 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 8% generic, 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.



*For itraconazole capsules*

- ❖ 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 Noxafil (solution or DR tablets)*

- ❖ Noxafil 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
- ❖ Noxafil 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.
- ❖ Noxafil 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 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 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**.

**PA and APPEAL PROCESS:**

- ❖ For online access to the PA process please go to [www.mmis.georgia.gov/portal](http://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](http://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.