

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Antifungal (Onychomycosis/Candidiasis) Agents, Oral PDL Edit
<b>First Implementation Date:</b>	November 9, 2005
<b>Proposed Date:</b>	March 18, 2021
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

**Why Issue Selected:** Onychomycosis is a fungal infection of the nails usually caused by trichophyton rubrum and trichophyton mentagrophytes. These dermatophytes feed on keratinized nail tissue and are normally confined to the nails; but occasionally spread to surrounding skin. The hallmarks of the disease are thickening, scaling, discoloration, and splitting of the nail bed. Without treatment, however, the nails can become so thick they press against the inside of the shoes, causing pressure, irritation, and pain. Onychomycosis is difficult to treat because nails grow slowly and receive very little blood supply. However, there have been recent advances in treatment options, including oral and topical medications. These medications are usually administered over a 3-month period, but because the nails grow very slowly it will typically take 6 months to a year for the nail to regain a healthy, clear, thin appearance. This class of oral antifungals includes agents for oropharyngeal candidiasis in adults and children. Effective therapy usually requires treatment for 7-14 days. Fluconazole is the agent of choice for prevention of oropharyngeal candidiasis in immunocompromised adults and children. At this time, this PDL Therapeutic Class does not include the oral antifungals that are used to treat serious fungal infections, including invasive aspergillosis.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	<ul style="list-style-type: none"> <li>• Clotrimazole Troche</li> <li>• Fluconazole Susp/Tabs</li> <li>• Griseofulvin Susp</li> <li>• Nystatin Susp/Tabs</li> <li>• Terbinafine Tabs</li> </ul>	<ul style="list-style-type: none"> <li>• Diflucan®</li> <li>• Griseofulvin Micro/Ultramicronsize Tabs</li> <li>• Gris-PEG®</li> <li>• Itraconazole</li> <li>• Onmel®</li> <li>• Oravig®</li> <li>• Sporanox®</li> </ul>

**Type of Criteria:**  Increased risk of ADE  
 Appropriate Indications  
 Preferred Drug List  
 Clinical Edit

**Data Sources:**  Only Administrative Databases  
 Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Antifungal (Onychomycosis/Candidiasis) Agents, Oral
- Age range: All appropriate MO HealthNet participants

## Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial of 1 preferred agent
  - Documented trial period of preferred agents
  - Documented ADE/ADR to preferred agents
- For terbinafine or itraconazole:
  - Documented diagnosis of proximal or distal, white, subungual onychomycosis, identified through:
    - KOH microscopic exam **OR**
    - Periodic Acid Schiff (PAS) **OR**
    - Fungal culture **OR**
    - Nail biopsy **AND**
  - > 30% nail plate involvement
- See Appendix A for maximum approvable durations of therapy for onychomycosis

## Denial Criteria

- Lack of adequate trial on required preferred agents
- For itraconazole: left ventricular dysfunction, such as congestive heart failure
- Therapy will be denied if all approval criteria are not met

## Required Documentation

Laboratory Results:  
MedWatch Form:

X

Progress Notes:  
Other:

X

## Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)  
Rule Type: PDL

## Default Approval Period

6 months

## Appendix A

Product	Strength/Dose	Duration of Therapy	Anatomic Location of Infection
Terbinafine	250mg once daily	6 weeks	Fingernails
Terbinafine	250mg once daily	12 weeks	Toenails
Itraconazole	200mg twice daily	1 week (3 weeks no therapy) for 3 cycles (pulse)	Fingernails
Itraconazole	200mg once daily	12 weeks (or pulse)	Toenails

## References

1. Evidence-Based Medicine and Fiscal Analysis: "Oral Antifungals – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; March 2021.
2. Evidence-Based Medicine Analysis: "Onychomycosis Antifungals", UMKC-DIC; February 2021.
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2021.
4. USPDI, Micromedex; 2021.
5. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.