

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Systemic Antifungals Clinical Edit
<b>First Implementation Date:</b>	2003
<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:** Ensure appropriate utilization and control of systemic antifungal therapies

**Why Issue Selected:** Systemic antifungals include amphotericin B, various azole derivatives, echinocandins, and flucytosine. The azoles that are available for systemic use can be classified into two groups: the triazoles (fluconazole, itraconazole, voriconazole, posaconazole, and isavuconazole) and the imidazoles (ketoconazole). Azole antifungals inhibit the synthesis of ergosterol, an important component of the fungal cell membrane, to treat chronic mycoses; lowered ergosterol levels result in the breakdown of the fungal membrane. The first azole, ketoconazole, has been supplanted by more effective, less toxic triazoles which are now often recommended as first-line drugs for many invasive fungal infections. These drugs have markedly changed the approach to antifungal therapy. Due to the high cost and specific approved indications, MO HealthNet will impose clinical criteria to ensure appropriate utilization of systemic antifungal therapies.

### Program-Specific Information:

Date Range FFS 1-1-2020 to 12-31-2020				
Drug	Claims	Spend	Avg Spend per Claim	
CRESEMBA 186 MG CAPSULE	33	\$124,717.73	\$3,779.32	
CRESEMBA 372 MG VIAL	5	\$13,265.25	\$2,653.05	
NOXAFIL 40 MG/ML SUSPENSION	17	\$97,664.78	\$5,744.98	
NOXAFIL DR 100 MG TABLET	137	\$519,742.78	\$3,793.74	
NOXAFIL 300 MG/16.7 ML VIAL	0	-	-	
TOLSURA 65 MG CAPSULE	2	\$4,368.54	\$2,184.27	
VFEND 40 MG/ML SUSPENSION	64	\$64,533.10	\$1,008.32	
VFEND 50 MG TABLET	30	\$17,250.22	\$575.00	
VFEND 200 MG TABLET	113	\$33,183.17	\$293.65	
VFEND IV 200 MG VIAL	1	\$61.80	\$61.80	

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

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

## Setting & Population

- Drug class for review: Systemic Antifungals
- Age range: All appropriate MO HealthNet participants

## Approval Criteria

- Documentation of a severely suppressed immune system **OR**
- Approval based on Clinical Consultant Review **OR**
- For Tolsura (itraconazole):
  - Documented trial of generic itraconazole in the past 90 days **AND**
  - Documented diagnosis of aspergillosis, blastomycosis, or histoplasmosis
- For Noxafil (posaconazole):
  - Documented diagnosis of aspergillosis **OR**
  - Documented diagnosis of appropriate specified candidiasis **AND** documented trial of generic itraconazole or fluconazole in the past 90 days
- For Cresemba (isavuconazonium sulfate): Documented diagnosis of aspergillosis or mucormycosis
- For Vfend (voriconazole):
  - Documented diagnosis of aspergillosis, opportunistic mycoses, or mycosis NOS **OR**
  - Documented diagnosis of appropriate specified candidiasis **AND** documented trial of itraconazole or fluconazole in the past 90 days

## Denial Criteria

- Therapy will be denied if all approval criteria are not met

## Required Documentation

Laboratory Results:  
MedWatch Form:

  

Progress Notes:  
Other:

  

## Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)  
Rule type: CE

## Default Approval Period

90 Days

## References

- TOLSURA® (itraconazole capsules) [package insert]. Greenville, NC: Mayne Pharma Inc.; June 2020.
- NOXAFIL® (posaconazole) [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; September 2020.
- CRESEMBA® (isavuconazonium sulfate) [package insert]. Northbrook, IL: Astellas Pharma Inc.; December 2019.
- VFEND® (voriconazole) [package insert]. New York, NY: Pfizer, Inc; January 2021.

*SmartPA Clinical Proposal Form*

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- Sanjay G. Revankar. Antifungal Drugs. Merck Manual. <https://www.merckmanuals.com/professional/infectious-diseases/fungi/antifungal-drugs>. Updated July 2019. Accessed February 12, 2021.
- Holtry, B. Antifungal Agents. <https://www.antiinfectivemed.com/anti-infective-therapy/antifungal-agents/>. Updated December 1, 2020. Accessed February 12, 2021.
- Clinical Pharmacology. Azole Antifungals (systemic). Accessed February 12, 2021.

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