



Clinical Edit Criteria

Drug/Drug Class: **Systemic Antifungals Clinical Edit**

Date: **August 22, 2019**

Prepared for:

Prepared by: **MO HealthNet**

New Criteria

Revision of Existing Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of systemic antifungal therapies

Why was this 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.

	Drug	Cost (WAC)
Program-specific information:	• Tolsura™ 65mg capsule	• \$34.47 per cap
	• Noxafil® DR 100mg tablet	• \$68.53 per tab
	• Noxafil® 40mg/ml suspension	• \$13.71 per ml
	• Noxafil® 300mg/16.7ml vial	• \$530.39 per vial
	• Cresmba® 186mg capsule	• \$92.56 per cap
	• Cresmba® 372mg vial	• \$315.39 per vial
	• Voriconazole (generic VFend®) 50mg tablet	• \$9.38 per tab
	• Voriconazole (generic VFend®) 200mg tablet	• \$37.52 per tab
	• Voriconazole (generic VFend®) 40mg/ml susp	• \$11.25 per ml
	• Voriconazole (generic VFend®) IV 200mg vial	• \$122.07 per vial

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

- For Tolsura:
 - Documented trial of generic itraconazole in the past 90 days **AND**
 - Documented diagnosis of aspergillosis, blastomycosis, or histoplasmosis in the past 2 years
- For Noxafil:
 - Documented diagnosis of aspergillosis in the past 2 years **OR**
 - Documented diagnosis of appropriate specified candidiasis in the past 2 years **AND** documented trial of itraconazole or fluconazole in the past 90 days
- For Cresemba: Documented diagnosis of aspergillosis or mucormycosis in the past 2 years
- For Vfend:
 - Documented diagnosis of aspergillosis, opportunistic mycoses, or mycosis NOS in the past 2 years **OR**
 - Documented diagnosis of appropriate specified candidiasis in the past 2 years **AND** documented trial of itraconazole or fluconazole in the past 90 days
- Documentation of a severely suppressed immune system
- Approval based on Clinical Review

Denial Criteria

- Therapy will be denied if no approval criteria are met

References

1. TOLSURA [package insert]. Greenville, NC: Mayne Pharma Inc.; Revised: 12/2018
2. NOXAFIL® [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; Revised: 2/2019
3. CRESEMBA® [package insert]. Northbrook, IL: Astellas Pharma Inc.; Revised: 4/2018
4. VFEND® [package insert]. New York, NY: Pfizer, Inc; Revised: 1/2019
5. Sanjay G. Revankar. Antifungal Drugs. Merck Manual. <https://www.merckmanuals.com/professional/infectious-diseases/fungi/antifungal-drugs>. Updated November 2017. Accessed March, 7, 2019.
6. AntiinfectiveMeds.com. Antifungal Agents. <https://www.antiinfectivemed.com/anti-infective-therapy/antifungal-agents/>. Updated July 20, 2018. Accessed March 7, 2019.