

SmartPA Criteria Proposal

Drug/Drug Class:	Systemic Antifungals Clinical Edit
First Implementation Date:	2003
Proposed Date:	March 19, 2020
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	<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.

Program-Specific Information:

Date Range FFS 1-1-2019 to 12-31-2019				
Drug	Claims	Spend	Cost per unit	
Cresamba 186 mg cap	7	\$34,861.89	\$88.83	per cap NADAC
Cresamba 372 mg vial	0	-	\$314.12	per vial MAC
Noxafil 300 mg/16.7 ml vial	14	\$73,933.73	\$530.39	per vial WAC
Noxafil 40 mg/ml susp	12	\$17,697.79	\$13.71	per ml WAC
Noxafil DR 100 mg tab	92	\$522,854.93	\$37.95	per tab MAC
Tolsura 65 mg cap	0	-	\$36.16	per cap WAC
Vfend 200 mg tab	114	\$42,984.97	\$4.63	per tab NADAC
Vfend 40 mg/ml susp	59	\$53,323.85	\$9.47	per ml MAC
Vfend 50 mg tablet	40	\$36,260.11	\$3.45	per tab MAC
Vfend IV 200 mg vial	23	\$7,304.31	\$29.55	per vial MAC

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: Systemic Antifungals

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- 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 in the past 2 years
- For Noxafil (posaconazole):
 - 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 generic itraconazole or fluconazole in the past 90 days
- For Cresemba (isavuconazonium sulfate): Documented diagnosis of aspergillosis or mucormycosis in the past 2 years
- For Vfend (voriconazole):
 - 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

Denial Criteria

- Therapy will be denied if no approval criteria are met

Required Documentation

Laboratory Results:
MedWatch Form:

Progress Notes:
Other:

X

Disposition of Edit

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

Default Approval Period

1 year

References

- TOLSURA (itraconazole capsules) [package insert]. Greenville, NC: Mayne Pharma Inc.; December 2018.
- NOXAFIL® (posaconazole) [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; March 2019.
- CRESEMBA® (isavuconazonium sulfate) [package insert]. Northbrook, IL: Astellas Pharma Inc.; December 2019.
- VFEND® (voriconazole) [package insert]. New York, NY: Pfizer, Inc; January 2019.
- Sanjay G. Revankar. Antifungal Drugs. Merck Manual. <https://www.merckmanuals.com/professional/infectious-diseases/fungi/antifungal-drugs>. Updated July 2019. Accessed 2/13/2020.
- AntiinfectiveMeds.com. Antifungal Agents. <https://www.antiinfectivemed.com/anti-infective-therapy/antifungal-agents/>. Updated July 20, 2018. Accessed 2/13/2020.
- Clinical Pharmacology. Azole Antifungals (systemic). Accessed 2/17/2020.

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