

SmartPA Criteria Proposal

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|-----------------------------------|--|
| 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:

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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