Executive Summary

**Purpose:** Ensure appropriate utilization and control of systemic antifungal therapies

**Why Issue Selected:** Systemic antifungals include amphotericin B, variousazole 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:**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Quantity</th>
<th>Cost per Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cressema 186 mg cap</td>
<td>7</td>
<td>$34,861.89 per cap NADAC</td>
</tr>
<tr>
<td>Cressema 372 mg vial</td>
<td>0</td>
<td>- per cap MAC</td>
</tr>
<tr>
<td>Noxafil 300 mg/16.7 ml vial</td>
<td>14</td>
<td>$73,933.73 per vial WAC</td>
</tr>
<tr>
<td>Noxafil 40 mg/ml susp</td>
<td>12</td>
<td>$17,697.79 per ml WAC</td>
</tr>
<tr>
<td>Noxafil DR 100 mg tab</td>
<td>92</td>
<td>$522,854.93 per tab MAC</td>
</tr>
<tr>
<td>Tolsura 65 mg cap</td>
<td>0</td>
<td>- per tab MAC</td>
</tr>
<tr>
<td>Vfend 200 mg tab</td>
<td>114</td>
<td>$42,984.97 per tab NADAC</td>
</tr>
<tr>
<td>Vfend 40 mg/ml susp</td>
<td>59</td>
<td>$53,323.85 per ml MAC</td>
</tr>
<tr>
<td>Vfend 50 mg tablet</td>
<td>40</td>
<td>$36,260.11 per tab MAC</td>
</tr>
<tr>
<td>Vfend IV 200 mg vial</td>
<td>23</td>
<td>$7,304.31 per vial MAC</td>
</tr>
</tbody>
</table>

**Type of Criteria:**

- □ Increased risk of ADE
- ☒ Preferred Drug List
- ☒ Appropriate Indications
- ☒ Clinical Edit
- ☒ Databases + Prescriber-Supplied

**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 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

<table>
<thead>
<tr>
<th>Laboratory Results:</th>
<th>Progress Notes:</th>
<th>MedWatch Form:</th>
<th>Other:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

### Disposition of Edit

- Denial: Exception code “0682” (Clinical Edit)
- Rule type: CE

### Default Approval Period

- 90 Days

### References