Antifungal Agents for Onychomycosis

### Covered Medications
- Terbinafine (Lamisil®, Terbinex™), Itraconazole (Sporanox®, generic), Fluconazole (Diflucan®, various generic)

### What they do and how they are used
- Onychomycosis is a localized infection of the nail or nail bed characterized by thickened, brittle, yellow nails. Onychomycosis is often treated to avoid irritation, swelling, pain and discomfort. In severe cases, the infection can lead to disfigurement and loss of mobility. If the fungal infection remains untreated, the affected nails can act as a reservoir for other infection (e.g., bacterial infection).
- Dermatophytes (fungal parasites) cause 90% of all cases. Yeast (candida species) cause 7% of infections and nondermatophyte molds 3% of infections. These nondermatophyte infections are difficult to eradicate using antifungal agents.
- Antifungal agents exhibit the "reservoir effect" whereby therapeutic concentrations of the medications remain in the nail plate for several months after therapy has stopped. Following the completion of a course of antifungal therapy, the nail may still appear abnormal until healthy nail tissue begins to appear. Toenail onychomycosis requires a longer treatment regimen than fingernail onychomycosis because of inherent slower growth of toenails.
- To treat toenail onychomycosis, Lamisil®, Terbinex™, and Sporanox® are administered for 3 months and Diflucan® is administered for 6 months.

<table>
<thead>
<tr>
<th>Antifungal Product</th>
<th>Full dosage regimen for treatment of toenail onychomycosis</th>
<th>Covered quantity of antifungal agent per 6 month time period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluconazole (Diflucan®)</td>
<td>300 mg per week for 6 months</td>
<td>7,200 mg</td>
</tr>
<tr>
<td>Itraconazole (Sporanox®)</td>
<td>200 mg daily for 3 months</td>
<td>18,000 mg</td>
</tr>
<tr>
<td>Terbinafine (Lamisil®)</td>
<td>250 mg daily for 3 months</td>
<td>22,500 mg</td>
</tr>
<tr>
<td>Terbinafine (Terbinex™)</td>
<td>250 mg daily for 3 months</td>
<td>21,000 mg</td>
</tr>
</tbody>
</table>

### Rationale for coverage authorization
To limit coverage to an amount sufficient to treat onychomycosis and provide coverage for additional quantities (when needed for a longer course of treatment) through a coverage authorization process.

### Benefit design
Coverage is provided immediately (without generating a coverage review process) in the presence of drugs indicating HIV disease, cancer, or organ transplantation. Otherwise, coverage is provided for a drug quantity sufficient to treat onychomycosis in any 6-month period. Requests for coverage of greater quantities of medication (when necessary for a longer duration of treatment) are determined through a coverage authorization process.

### Coverage authorization criteria
Benefit coverage provided for 12 months for the treatment of conditions other than onychomycosis.

### References
- Product Information: Fluconazole tablets (Diflucan® - Pfizer) 2004.
- Product Information: Terbinafine tablets (Terbinex™) – JSJ Pharmaceuticals) 2009.