SmartPA Criteria Proposal

Drug/Drug Class:	Antifungal (Onychomycosis/Candidiasis) Agents - Oral PDL Edit
First Implementation Date:	November 9, 2005
Proposed Date:	March 19, 2020
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: Onychomycosis is a fungal infection of the nails usually caused by trichophyton rubrum and trichophyton mentagrophytes. These dermatophytes feed on keratinized nail tissue and are normally confined to the nails; but occasionally spread to surrounding skin. The hallmarks of the disease are thickening, scaling, discoloration, and splitting of the nail bed. Without treatment, however, the nails can become so thick they press against the inside of the shoes, causing pressure, irritation, and pain. Onychomycosis is difficult to treat because nails grow slowly and receive very little blood supply. However, there have been recent advances in treatment options, including oral and topical medications. These medications are usually administered over a 3-month period, but because the nails grow very slowly it will typically take 6 months to a year for the nail to regain a healthy, clear, thin appearance. This class of oral antifungals includes agents for oropharyngeal candidiasis in adults and children. Effective therapy usually requires treatment for 7-14 days. Fluconazole is the agent of choice for prevention of oropharyngeal candidiasis in immunocompromised adults and children. At this time, this PDL Therapeutic Class does not include the oral antifungals that are used to treat serious fungal infections, including invasive aspergillosis.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Clotrimazole Troche • Fluconazole Susp/Tabs • Griseofulvin Susp • Nystatin Susp/Tabs • Terbinafine Tabs	• Diflucan® • Griseofulvin Micro/Ultramicrosize Tabs • Gris-PEG® • Itraconazole • Onmel® • Oravig® • Sporanox®

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: Antifungal (Onychomycosis/Candidiasis) Agents - Oral
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial of 1 preferred agent
    - Documented trial period of preferred agents
    - Documented ADE/ADR to preferred agents
- For terbinafine or itraconazole:
    - Documented diagnosis of proximal or distal, white, subungual onychomycosis, identified through:
        - KOH microscopic exam **OR**
        - Periodic Acid Schiff (PAS) **OR**
        - Fungal culture **OR**
        - Nail biopsy **AND**
    - > 30% nail plate involvement
- See Appendix A for maximum approvable durations of therapy for onychomycosis

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if no approval criteria are met
- For itraconazole:
    - Left ventricular dysfunction, such as congestive heart failure

Required Documentation

Laboratory Results:	☐	Progress Notes:	☐
MedWatch Form:	☐	Other:	☐

Disposition of Edit

Denial: Exception Code “0160” (Preferred Drug List)
Rule Type: PDL

Default Approval Period

6 months

Appendix A

Product	Strength/Dose	Duration of Therapy	Anatomic location of Infection
Terbinafine	250mg once daily	6 weeks	Fingernails
Terbinafine	250mg once daily	12 weeks	Toenails
Itraconazole	200mg twice daily	1 week (3 weeks no therapy) for 3 cycles (pulse)	Fingernails
Itraconazole	200mg once daily	12 weeks (or pulse)	Toenails

References

1. Evidence-Based Medicine and Fiscal Analysis: "Oral Antifungals – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; January 2020.
2. Evidence-Based Medicine Analysis: "Onychomycosis Antifungals", UMKC-DIC; January 2020.
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
4. USPDI, Micromedex; 2020.
5. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.