

## DRUG QUANTITY MANAGEMENT POLICY – PER RX

**POLICY:** fluconazole tablets (Diflucan<sup>®</sup> – Pfizer, generics) Dispensing Limit

**DATE REVIEWED:** 03/02/2016

### DESCRIPTION

#### **Diflucan 150 mg tablet (generic)**

Maximum quantity per RX = 2 tablets

The manufacturer recommended dosing for treatment of vaginal candidiasis is one 150-mg tablet, as a single dose. Hence, two tablets should be sufficient for two episodes of vaginal candidiasis. If additional medication is needed, the participant will need to pay additional copayments. For longer duration of therapy (several days in a row), the participant could use other strengths of Diflucan (50 mg, 100 mg, or 200 mg) or other formulary or OTC vaginal antifungals. For recurrent vulvovaginal candidiasis, use of 150 mg of fluconazole weekly for 6 months was found to statistically significantly reduce the rate of recurrence compared with placebo. Also, the Centers for Disease Control and Prevention guidelines for sexually transmitted diseases recommended that for maintenance regimens for recurrent vulvovaginal candidiasis, one option is fluconazole dosed 100 mg to 200 mg once weekly. Diflucan 150 mg once weekly has been used (but is not FDA approved) to treat various tinea infections (e.g., tinea pedis, tinea cruris, tinea corporis, cutaneous candidiasis). Exceptions can be made for these conditions if necessary. For other indications, patients should use the 50 mg, 100 mg, or 200 mg tablets.

### CRITERIA

All approvals are provided for 12 months in duration unless otherwise noted below.

1. Vaginal candidiasis or vulvovaginal candidiasis (non-recurrent): Express Scripts recommends not to override this quantity limit.
2. Treatment of the following:
  - tinea pedis, tinea cruris, tinea corporis, tinea manuum, tinea faciei
  - cutaneous candidiasis
  - maintenance therapy for recurrent vaginal/vulvovaginal candidiasisApprove 5 tablets per dispensing (1 tablet weekly).
3. Treatment of recurrent vaginal/vulvovaginal candidiasis before initiating maintenance therapy: Approve a one-time override for a quantity of 3 tablets.
4. Express Scripts recommends not to override this quantity limit for any other conditions. The following list is examples of conditions:
  - a. pityriasis (tinea) versicolor
  - b. tinea capitis
  - c. tinea barba
  - d. onychomycosis
  - e. coccidioidomycosis
  - f. cryptococcal meningitis
  - g. candida urinary tract infections
  - h. histoplasmosis
  - i. oropharyngeal or esophageal candidiasis
  - j. immunocompromised patients (e.g., bone marrow transplant recipients, cancer chemotherapy and/or radiation therapy patients)

### REFERENCES

1. Diflucan® [prescribing information]. New York, NY: Pfizer, Inc; January 2016.
2. Sobel JD, Wiesenfeld HC, Martens M, et al. Maintenance fluconazole therapy for recurrent vulvovaginal candidiasis. *N Engl J Med.* 2004;351:876-883.
3. Pappas PG, Kauffman CA, Andes DR, et al. Clinical practice guidelines for the management of Candidiasis: 2016 update by the Infectious Diseases Society of America. *Clin Infect Dis.* 2015;civ933v1-civ933.
4. Kauffman CA, Bustamante B, Chapman SW, Pappas PG. Clinical practice guidelines for the management of Sporotrichosis: 2007 update by the Infectious Diseases Society of America. *Clin Infect Dis.* 2007;45:1255-1265.
5. Galgiani JN, Ampel NM, Blair JE, et al. Clinical Practice Guidelines for the Treatment of Coccidioidomycosis; *Clin Infect Dis.* 2005;41:1217-1223.
6. Perfect JR, Dismukes WE, Dromer F, et al. Clinical Practice Guidelines for the Management of Cryptococcal Disease: 2010 Update by the Infectious Diseases Society of America. *Clin Infect Dis.* 2010; 50:291-322.
7. Wheat LJ, Freifeld AG, Kleiman MB, et al. Clinical Practice Guidelines for the Management of Patients with Histoplasmosis: 2007 Update by the Infectious Diseases Society of America. *Clin Infect Dis.* 2007; 45:807-825.
8. Treatment Guidelines from The Medical Letter – Antifungal Drugs. *The Medical Letter.* 2012; 10(120):61-68.
9. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc; 2016. Available at <http://www.clinicalpharmacology-ip.com/Default.aspx>. Accessed on: March 2, 2016. Search term: fluconazole.

## **HISTORY**

Reviewed and approved by Clinical Criteria Committee on 8/14/01.

Reviewed and approved by Express Scripts Therapeutic Assessment Committee (TAC) on 8/14/02 & 10/1/03.

Reviewed and approved by the Express Scripts Drug Evaluation Unit (DEU) on 10/27/04 and 02/01/06.

Reviewed and approved by TAC on 03/07/07.

Reviewed by Clinical Specialists on 03/28/08, 04/21/09, 05/21/10, 06/16/11, and 06/12/12.

Integrated policy reviewed and approved by TAC, changed days supply from 34 days to 30 days, on 11/14/2012.

Reviewed by Clinical Specialists on 07/19/2013, 12/08/2014 and 03/02/2016.