



## DRUG QUANTITY MANAGEMENT POLICY – PER RX

- POLICY:** Antifungals – Fluconazole (Oral) Drug Quantity Management Policy – Per Rx
- Diflucan® (fluconazole 150 mg tablets – Pfizer, generic)

**REVIEW DATE:** 06/12/2024

### INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

## CIGNA NATIONAL FORMULARY COVERAGE:

### OVERVIEW

Fluconazole (Diflucan, generic), a triazole antifungal, is indicated for the following uses:<sup>1</sup>

- **Vaginal candidiasis**, as a treatment for vaginal yeast infections due to *Candida*.
- **Oropharyngeal and esophageal candidiasis** as treatment.
- **Cryptococcal meningitis**.
- **Prophylaxis to decrease the incidence of candidiasis**, in patients undergoing bone marrow transplantation who receive cytotoxic chemotherapy and/or radiation therapy.

In small, non-comparative studies, fluconazole was also effective for the treatment of *Candida* urinary tract infections, peritonitis, and systemic *Candida* infections including candidemia, disseminated candidiasis, and pneumonia.<sup>1</sup>

### Dosing

For vaginal candidiasis, the recommended dose of fluconazole is 150 mg as a single, oral dose.<sup>1</sup> Therefore, two tablets (refer to Quantity Limit table below) are sufficient to treat two episodes of vaginal candidiasis.

The Centers for Disease Control and Prevention guidelines for sexually transmitted infections (2021) and the Infectious Diseases Society of America guidelines for the management of candidiasis (2016), recommend fluconazole 150 mg orally x 1 dose as a prescription treatment option for vulvovaginal candidiasis.<sup>2,3</sup> For severe vulvovaginal candidiasis (e.g., extensive vulvar erythema, edema, excoriation, and fissure formation), the recommended regimen is 150 mg of fluconazole given in two or three sequential doses (given 72 hours apart). Additionally, immunocompromised patients may require 7 to 14 days of therapy.<sup>2</sup> For recurrent vulvovaginal candidiasis, usually defined as three or more episodes of symptomatic vulvovaginal candidiasis in less than 1 year, guidelines recommend either fluconazole 100 mg, 150 mg, or 200 mg once every 72 hours (Days 1, 4, and 7) to attempt mycologic remission prior to initiating a maintenance antifungal regimen.<sup>2</sup> The indicated maintenance regimen is oral fluconazole 100 mg, 150 mg, or 200 mg once weekly (QW) for 6 months. Overrides to the standard quantity limit are provided for these situations.

Fluconazole has been used off-label, to treat various tinea infections (e.g., tinea pedis, tinea cruris, tinea corporis, tinea manuum, tinea capitis, onychomycosis, and pityriasis versicolor [formerly tinea versicolor]).<sup>4-6</sup> For most tinea infections, a dose of 150 mg QW is recommended. However, a dose of 300 mg QW has been used for pityriasis versicolor. The recommended duration of therapy also varies by specific indication, but generally, 2 to 6 weeks of therapy are required. For onychomycosis, 150 mg to 450 mg QW for 3 months (fingernail) or 6 to 12 months (toenail) is used.<sup>5</sup> Once weekly dosing at 150 mg for up to 4 weeks has also been used for intertrigo (also referred to as cutaneous candidiasis) and *Candida* folliculitis.<sup>4,5</sup>

Other FDA-approved and off-label indications for fluconazole, such as *Candida* urinary tract infections, Coccidioidomycosis, Cryptococcal meningitis, Histoplasmosis, and oropharyngeal/esophageal candidiasis require doses other than 150 mg and other strengths of fluconazole tablets (i.e., 50 mg, 100 mg, or 200 mg) or oral solution should be used. There are no quantity limits on the other strengths of the fluconazole tablets.

### **Availability**

Oral fluconazole (Diflucan, generic) is available as 50 mg, 100 mg, 150 mg, and 200 mg tablets.<sup>1</sup> A 10 mg/mL and 40 mg/mL oral suspension is also available. Of note, only the 150 mg tablets are targeted in this policy. No quantity limits apply to the other strengths/dosage forms of fluconazole.

### **POLICY STATEMENT**

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of fluconazole 150 mg tablets (Diflucan, generic). If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration, unless otherwise noted below. Note: Only the

150 mg tablets are targeted in this policy. No quantity limits apply to the other strengths/dosage forms of fluconazole (Diflucan, generic).

### Drug Quantity Limits

Product	Strength/Package Size	Retail Maximum Quantity Per Rx	Home Delivery Maximum Quantity Per Rx
Diflucan® (fluconazole tablets, generic)	150 mg tablets* (single, unit-dose blister)	2 tablets	

\* Quantity limit applies only to the 150 mg tablets. Other strengths/dosage forms of fluconazole (Diflucan, generic) are not targeted by quantity limits.

**Antifungals – Fluconazole (Oral) Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.**

#### CRITERIA

1. If the patient is immunocompromised and requires treatment of vulvovaginal candidiasis, approve a one-time override for the requested quantity, not to exceed 5 tablets at retail or home delivery.
2. If the patient requires treatment for severe vulvovaginal candidiasis, approve a one-time override for the requested quantity, not to exceed 3 tablets at retail or home delivery.  
Note: Characteristics of severe disease may include extensive vulvar erythema, edema, excoriation, and fissure formation.
3. If the patient requires treatment of recurrent vulvovaginal candidiasis, approve a one-time override for the requested quantity, not to exceed 3 tablets at retail or home delivery.
4. If the patient requires maintenance treatment for recurrent vulvovaginal candidiasis, approve the requested quantity, not to exceed 4 tablets per dispensing at retail or home delivery.
5. If the patient requires treatment for onychomycosis, approve the requested quantity, not to exceed 12 tablets per dispensing at retail or 36 tablets per dispensing at home delivery.
6. If the patient requires treatment for ONE of the following conditions (A, B, C, D, E, F, G, or H), approve a one-time override for the requested quantity, not to exceed 6 tablets at retail or home delivery:
  - A)** Intertrigo (also referred to as cutaneous candidiasis).

- B)** *Candida* folliculitis.
- C)** Tinea capitis.
- D)** Tinea pedis.
- E)** Tinea cruris.
- F)** Tinea corporis (includes tinea faciei and tinea gladiatorum).
- G)** Tinea manuum.
- H)** Pityriasis versicolor (formerly tinea versicolor).

**EXCLUSIONS**

Approval of additional quantities of fluconazole 150 mg tablets (Diflucan, generic) is NOT recommended in the following situations:

1. *Candida* urinary tract infections.
2. Coccidioidomycosis.
3. Cryptococcal meningitis.
4. Histoplasmosis.
5. Oropharyngeal or esophageal candidiasis.

**REFERENCES**

1. Diflucan® tablets [prescribing information]. New York, NY: Pfizer; February 2024.
2. Workowski KA, Bachmann LH, Chan PA, et al. Sexually Transmitted Infections Treatment Guidelines, 2021. *MMWR Recomm Rep.* 2021;70(4):1-187.
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.* 2016;62(4):e1-50.
4. Facts and Comparisons® Online. Wolters Kluwer N.V.; 2023. Available at: <http://online.factsandcomparisons.com/lco/action/home>. Accessed on May 29, 2024. Search terms: fluconazole.
5. UpToDate® Online. Wolters Kluwer N.V.; 2024. Available at: <https://www.uptodate.com/contents/search>. Accessed on May 29, 2024. Search terms: fluconazole, tinea infections, fungal folliculitis.

**HISTORY**

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.  Fluconazole tablets (Diflucan, generic): Home delivery quantity limit changed from 6 tablets per dispensing to 2 tablets per dispensing.	06/07/2023
Annual Revision	Override criteria for the treatment of onychomycosis were updated to approve the requested quantity, not to exceed 12 tablets per dispensing at retail or 36 tablets per dispensing at home delivery.	06/12/2024

	Previously, this criteria approved a quantity of 4 tablets per dispensing at retail or home delivery.	
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