PRIOR AUTHORIZATION POLICY

POLICY: Antifungals – Flucytosine Prior Authorization Policy
- Ancobon® (flucytosine capsules – Bausch Health, generic)

REVIEW DATE: 05/03/2023

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. 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

Flucytosine, an antifungal, is indicated for the treatment of serious infections caused by susceptible strains of *Candida* and/or *Cryptococcus*:[1]

- ***Candida* infections:** Septicemia, endocarditis, and urinary system infections have been effectively treated with flucytosine. Limited trials in pulmonary infections justify the use of flucytosine.
- ***Cryptococcus* infections:** Meningitis and pulmonary infections have been treated effectively. Studies in septicemias and urinary tract infections are limited, but good responses have been reported.

Flucytosine should be used in combination with amphotericin B for the treatment of systemic candidiasis and cryptococcosis due to emergence of resistance to flucytosine.

Treatment duration is varied; patients are treated until infection has cleared.[2-4]

There have been reports of flucytosine capsules being compounded for use as foot baths. There are no data to support the use of flucytosine capsules in this manner and coverage of flucytosine capsules for this use is not recommended.

Guidelines/Recommendations

Infectious Diseases Society of America (IDSA) guidelines for treatment of *Candida* infections (2016) and *Cryptococcus* infections (2010) are available and guidelines address use of flucytosine for these infections.[2,3] Guidelines note that flucytosine can be used as monotherapy or in combination with other antifungals for these infections.

Flucytosine capsules may be extemporaneously compounded for vaginal use for patients with vulvovaginal candidiasis.[2,4] IDSA guidelines for the management of candidiasis (2016) note 17% flucytosine cream to be an option, as monotherapy or in combination with 3% amphotericin B cream, for the treatment of *C. glabrata* vulvovaginitis unresponsive to oral azole antifungals (weak recommendation; low quality evidence); duration of treatment is 14 days.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of flucytosine capsules. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

- **Ancobon® (flucytosine capsules (Bausch Health, generic)**

is(are) covered as medically necessary when the following criteria is(are) met for fda-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. ***Candida* Infection (Systemic) – Treatment.** Approve for 3 months.

2. ***Cryptococcus* Infection (Systemic) – Treatment.** Approve for 3 months.

Other Uses with Supportive Evidence

3. **Fungal Infection (Systemic) That Is Susceptible to Flucytosine – Treatment.** Approve for 3 months.

4. **Vulvovaginal candidiasis.** Approve for 14 days if the patient has previously tried at least one other antifungal therapy.

5. **Patient is Currently Receiving Flucytosine For a Systemic Fungal Infection.** Approve for 3 months to complete the course of therapy.

CONDITIONS NOT COVERED

- **Ancobon® (flucytosine capsules (Bausch Health, generic)**

is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Foot baths.** There are no data to support the use of flucytosine capsules for use as foot baths.

REFERENCES

1. Ancobon® capsules [prescribing information]. Bridgewater, NJ: Bausch Health; February 2022.
2. 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:e1-50.
3. 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.
4. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2023. Available at: https://fco.factsandcomparisons.com/lco/action/home. Accessed on April 26, 2023. Search term: flucytosine.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	05/03/2023