

## PRIOR AUTHORIZATION POLICY

**POLICY:** Antifungals – Flucytosine Prior Authorization Policy

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

**REVIEW DATE:** 05/29/2024

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### OVERVIEW

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

- ***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.<sup>2-4</sup>

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) note that flucytosine can be used as monotherapy or in combination with other antifungals for these infections. The European Confederation of Medical Mycology, the International Society for Human and Animal Mycology, and the American Society of Microbiology developed global guidelines for the diagnosis and management of *Cryptococcosis* (2024) and note that flucytosine should be used in combination with other antifungals for these infections.

Flucytosine capsules may be extemporaneously compounded for vaginal use for patients with vulvovaginal candidiasis.<sup>2,4</sup> 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.

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

05/29/2024

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Coverage of flucytosine capsules is recommended in those who meet one of the following criteria:

#### **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 RECOMMENDED FOR APPROVAL**

Coverage of flucytosine capsules is not recommended in the following situations:

1. **Foot baths.** There are no data to support the use of flucytosine capsules for use as foot baths.
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

#### **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. Chang CC, Harrison TS, Bicanic TA, et al. Global guideline for the diagnosis and management of cryptococcosis: an initiative of the ECMM and ISHAM in cooperation with the ASM. *Lancet Infect Dis*. Published online February 2024.
4. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2024. Available at: <https://fco.factsandcomparisons.com/lco/action/home>. Accessed on May 23, 2024. Search term: flucytosine.