

Vivjoa (oteseconazole)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Vivjoa is indicated to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are NOT of reproductive potential.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR APPROVAL

An authorization of 4 months for one treatment course (18 capsules) per year may be granted when all of the following criteria are met:

1. The requested drug is being prescribed for the treatment of recurrent vulvovaginal candidiasis (RVVC), defined as 3 or more episodes of symptomatic VVC in a 12-month period.
2. The patient is not of reproductive potential (i.e. persons who are biological females who are postmenopausal or have another reason for permanent infertility [e.g., tubal ligation, hysterectomy, salpingo-oophorectomy]). Documentation must be provided.
Note: The drug exposure window of approximately 690 days (based on 5 times the half-life of oteseconazole) precludes adequate mitigation of the embryo-fetal toxicity risks.
3. Vivjoa is prescribed by, or in consultation with, an infectious disease physician or obstetrician/gynecologist.
4. Patient meets one of the following criteria, with documentation provided:
 - a. The patient has experienced treatment failure to a 6-month maintenance course of weekly oral fluconazole (100 mg, 150 mg, or 200 mg) [e.g., acute VVC episode while on fluconazole therapy, acute VVC episode within 14 days of completing 6-month fluconazole course, acute VVC episode after two 6-month courses of fluconazole within 2 years]
 - b. The patient has experienced an intolerance to fluconazole
 - c. The patient has a contraindication or documented resistance that would prohibit a trial of fluconazole
5. Other causes, such as bacterial vaginosis or trichomoniasis, have been ruled out.
6. The requested drug is not being used in a footbath.

III. QUANTITY LIMIT

Vivjoa has a quantity limit of 18 capsules every 365 days (1 treatment course per year).

Indication	Dose
RVVC	<p><i>Vivjoa-only Dosage Regimen:</i></p> <ul style="list-style-type: none"> • Day 1: 600 mg (4 x 150 mg capsules as a single dose), then • Day 2: 450 mg (3 x 150 mg capsules as a single dose), then • Beginning on Day 14: 150 mg once weekly (every 7 days) for 11 weeks (Weeks 2-12) <p><i>Fluconazole/Vivjoa Dosage Regimen:</i></p> <ul style="list-style-type: none"> • Day 1, Day 4, and Day 7: fluconazole 150 mg orally (prescribed separately), then

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	<ul style="list-style-type: none">• Days 14 through 20: Vivjoa 150 mg once daily for 7 days, then• Beginning on Day 28: Vivjoa 150 mg once weekly (every 7 days) for 11 weeks (Weeks 4-14)
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IV. REFERENCES

1. Vivjoa [package insert]. Durham, NC: Mycovia Pharmaceuticals, Inc.; April 2021.
2. Sexually Transmitted Infections Treatment Guidelines, 2021. Vulvovaginal Candidiasis (VVC). Centers for Disease Control and Prevention. <https://www.cdc.gov/std/treatment-guidelines/candidiasis.htm>. Accessed December 2022.