Effective Date 03/01/2023
Reviewed: 12/22/2022, 06/2024, 07/2025 Scope: Medicaid

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 orobstetrician/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	***Vivjoa-only Dosage Regimen*:** • **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)

	Fluconazole/Vivjoa Dosage Regimen: • **Day 1**, **Day 4**, and **Day 7**: fluconazole 150 mg orally (prescribed separately), then • **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)

IV. REFERENCES

1. Vivjoa [package insert]. Durham, NC: Mycovia Pharmaceuticals, Inc.; July 2022.
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.