Pharmacy Policy Bulletin: J-1231 Vivjoa (oteseconazole) - Commercial and Healthcare Reform	
Number: J-1231	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Other Managed Prior Authorization = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1231-004	**Original Date:** 06/01/2022
Effective Date: 07/18/2025	**Review Date:** 06/25/2025

Drugs Product(s):	• Vivjoa (oteseconazole)
FDA-Approved Indication(s):	• To reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are NOT of reproductive potential

Background:	• Vivjoa is an azole antifungal. Vivjoa targets the fungal sterol required for fungal cell membrane formation and integrity, resulting in the accumulation of sterols that are toxic to fungi. • Vulvovaginal candidiasis (VVC), also known as a yeast infection, is a fungal vaginal infection usually caused by Candida albicans. Typical symptoms include pruritis, vaginal soreness, dyspareunia, external dysuria, and abnormal vaginal discharge. RVVC is defined as three or more episodes of symptomatic VVC in less than one year. RVVC affects less than 5% of women. RVVC can be idiopathic or secondary (related to frequent antibiotic use, diabetes, or other underlying host factors). • The 2021 Centers for Disease Control and Prevention (CDC) Sexually Transmitted Infections (STI) Treatment Guidelines state short-course topical formulations effectively treat uncomplicated VVC. For RVVC, a longer duration of initial therapy with an oral or topical azole (e.g., 7–14 days of topical therapy or a 100-mg, 150-mg, or 200-mg oral dose of fluconazole every third day for a total of 3 doses [days 1, 4, and 7]) is recommended, to attempt mycologic remission, before initiating a maintenance antifungal regimen. Oral fluconazole weekly for 6 months is the recommended maintenance regimen. • The 2016 Infectious Diseases Society of America (IDSA) guidelines for uncomplicated VVC recommend topical antifungal agents, with no one agent superior to another. Alternatively, a single 150 mg oral dose of oral fluconazole is recommended. For RVVC, the recommendation is 10-14 days of induction therapy with a topical agent or oral fluconazole, followed by fluconazole 150 mg weekly for 6 months. • Prescribing Considerations:

	○ Vivjoa must be taken with food. Capsules must be swallowed whole and not chewed, crushed, dissolved, or opened. ○ Vivjoa is contraindicated in females of reproductive potential as well as pregnant and lactating women due to the risk of embryo-fetal toxicity. According to the FDA package insert, females who are not of reproductive potential are defined as: persons who are biological females who are postmenopausal or have another reason for permanent infertility (e.g., tubal ligation, hysterectomy, salpingo-oophorectomy). ○ Vivjoa may increase the exposure of breast cancer resistance protein substrates, which may increase the risk of adverse reactions associated with these drugs. ○ There are two recommended Vivjoa dosage regimens: ▪ Vivjoa-only dosage regimen • On Day 1: Administer Vivjoa 600 mg (as a single dose), then • On Day 2: Administer Vivjoa 450 mg (as a single dose), then • Beginning on Day 14: Administer Vivjoa 150 mg once a week (every 7 days) for 11 weeks (Weeks 2 through 12). ▪ Fluconazole/Vivjoa dosage regimen • On Day 1, Day 4, and Day 7: Administer fluconazole 150 mg orally, then • On Days 14 through 20: Administer Vivjoa 150 mg once daily for 7 days, then • Beginning on Day 28: Administer Vivjoa 150 mg once a week (every 7 days) for 11 weeks (Weeks 4 through 14).

Approval Criteria

I. Approval Criteria
When a benefit, coverage of Vivjoa may be approved when all of the following criteria are met **(A. through D.)**:
- **A.** The member has a diagnosis of RVVC (no ICD-10 code).
- **B.** The member has experienced ≥ 3 episodes of VVC in less than one year.
- **C.** The prescriber attests that the member is not of reproductive potential defined as one (1) of the following **(1. or 2.):**
  - **1.** Postmenopausal
  - **2.** Another reason for permanent infertility (e.g., tubal ligation, hysterectomy, salpingo-oophorectomy)
- **D.** The member has experienced therapeutic failure, contraindication, or intolerance to a six-month maintenance course of oral fluconazole.

II. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 13-week authorization may be granted.

Automatic Approval Criteria

None

References:

1. Vivjoa [package insert]. Durham, NC: Mycovia Pharmaceuticals, Inc.; April 2024.
2. Centers for Disease Control and Prevention. Vulvovaginal Candidiasis (VVC). Available at: https://www.cdc.gov/std/treatment-guidelines/candidiasis.htm. Accessed May 14, 2025.
3. Pappas PG, Kauffman CA, Andes DR, et al. Clinical Practice Guideline for the Management of Candidiasis: 2016 Update by the Infectious Diseases Society of America. CID 2016:62(4):e1-50.

Pharmacy policies do not constitute medical advice, nor are they intended to govern physicians' prescribing or the practice of medicine. They are intended to reflect the plan's coverage and reimbursement guidelines. Coverage may vary for individual members, based on the terms of the benefit contract.

The plan retains the right to review and update its pharmacy policy at its sole discretion. These guidelines are the proprietary information of the plan. Any sale, copying or dissemination of the pharmacy policies is prohibited; however, limited copying of pharmacy policies is permitted for individual use.