MEDICAL MUTUAL®

Drug Policy

Policy:	Vivjoa (oteseconazole)	Annual Review Date: 08/24/2023 Last Revised Date: 08/24/2023

OVERVIEW

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

POLICY STATEMENT

This policy involves the use of Vivjoa. Prior authorization is recommended for pharmacy benefit coverage of Vivjoa. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Vivjoa as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Vivjoa be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

Automation:

- When available, ICD-10 code B37.3 AND claims history for fluconazole within the previous 180 days AND zero claims history for Vivjoa OR less than 12 weeks of claims history for Vivjoa within the previous 180 days will be used for automation to allow approval of the requested medication.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Vivjoa is recommended in those who meet the following criteria:

1. Recurrent Vulvovaginal Candidiasis

Criteria. *Patient must meet the following criteria (A, B, and C):*

A. The patient has experienced three or more episodes of symptomatic vulvovaginal candidiasis within a one-year period; AND

B. The patient meets one of the following (a, b, or c):

   a. The patient has tried oral fluconazole as maintenance therapy AND had inadequate efficacy; OR
   Note: Maintenance dosing for fluconazole (100 mg, 150 mg or 200 mg) is once weekly for 6 months.

b. Patient meets one of the following (i, ii, or iii):
    i. Oral fluconazole is not clinically appropriate for the patient due to drug-drug interactions, as determined by the prescriber; OR
    ii. The patient has a fluconazole allergy or intolerance, as determined by the prescriber; OR
    iii. The patient is being treated for a Candida species that is not susceptible to fluconazole, as determined by the prescriber; OR
c. The patient has already started on Vivjoa therapy (to complete the course of treatment).

Initial Approval/ Extended Approval.
Approval duration: 90 days

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Vivjoa has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Use in patients of reproductive potential.** Vivjoa is contraindicated in females of reproductive potential, and in pregnant and lactating women. Based on animal studies, Vivjoa may cause fetal harm.

2. **Use in patients who are lactating (i.e. breastfeeding).** Vivjoa is contraindicated in females of reproductive potential, and in pregnant and lactating women. Based on animal studies, Vivjoa may cause fetal harm.

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Vivjoa capsules [prescribing information]. Durham, NC: Mycovia Pharmaceuticals, Inc; Apr 2022.