

<b>Clinical Policy Title:</b>	oteseconazole
<b>Policy Number:</b>	RxA.760
<b>Drug(s) Applied:</b>	Vivjoa™
<b>Original Policy Date:</b>	07/18/2022
<b>Last Review Date:</b>	08/28/2024
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. Recurrent Vulvovaginal candidiasis (must meet all):

1. Diagnosis of recurrent vulvovaginal candidiasis (RVVC);
2. History of  $\geq 3$  acute VVC episodes within 12 months;
3. Member meets one of the following (a or b):
  - a. Member is postmenopausal;
  - b. Member is postmenarchal, but not of reproductive potential (i.e. history of tubal ligation, salpingo-oophorectomy, or hysterectomy).

#### Approval Duration

**All Lines of Business (except Medicare):** 4 months

### II. Continued Therapy Approval

#### A. Recurrent Vulvovaginal candidiasis (must meet all):

1. Re-authorization is not permitted. Vivjoa™ is not indicated for continuous use for this indication. Members must meet the initial approval criteria.

#### Approval Duration

Not applicable.

## References

1. Vulvovaginal Candidiasis (VVC). Sexually Transmitted Infections Treatment Guidelines, 2021. Centers for Disease Control and Prevention. Updated July 2021. Available at: <https://www.cdc.gov/std/treatment-guidelines/candidiasis.htm>. Accessed August 28, 2024.
2. Mycovia Pharmaceuticals Inc. A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Oteseconazole (VT-1161) Oral Capsules in the Treatment of Subjects with Recurrent Vulvovaginal Candidiasis. clinicaltrials.gov; 2021. Available at: <https://clinicaltrials.gov/ct2/show/NCT03561701>. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	06/03/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria I.A.2: Updated prescriber criteria from	05/31/2023	07/13/2023

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<p>“ Prescribed by or in consultation with an obstetrician, gynaecologist” to “Prescribed by or in consultation with an obstetrician, gynecologist, or infectious disease physician”.</p> <p>2. Initial Approval Criteria, I.A.6: Updated to remove prior trial and failure criteria “Trial and failure of oral fluconazole maintenance treatment for at least 6 months unless contraindicated or adverse effects are experienced (such as hypersensitivity or drug-drug interaction”.</p> <p>3. Initial Approval Criteria, I.A.7: Updated to remove criteria pertaining to indication “positive KOH (potassium hydroxide) test or gram stain test”.</p> <p>4. Initial Approval Criteria: Approval duration updated from “12 months” to “4 months”.</p> <p>5. References were reviewed and updated.</p>		
<p>Policy was reviewed.</p>	<p>10/19/2023</p>	<p>10/19/2023</p>
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Removed age restrictions.</li> <li>2. Removed prescriber restrictions.</li> <li>3. Removed dose restrictions.</li> <li>4. Updated approval duration verbiage.</li> <li>5. References were reviewed and updated.</li> </ol>	<p>8/28/2024</p>	<p>9/13/2024</p>