

Pharmacy Policy Bulletin

Title: Oteseconazole (Vivjoa™)

Policy #: Rx.01.272

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **oteseconazole (Vivjoa™)** as provided under the member's prescription drug benefit.

Description:

Vulvovaginal candidiasis (VVC) is one of the most common causes of vulvovaginal itching and discharge. The disorder is characterized by inflammation in the setting of *Candida* species. Treatment is indicated for the relief of symptoms. Recurrent vulvovaginal candidiasis (RVVC) is defined as three or more episodes of symptomatic infection within one year

Oteseconazole is an antifungal drug. It is an azole metalloenzyme inhibitor that inhibits the enzyme CYP51 (also known as 14 α demethylase). It demethylates the 14- α position of lanosterol to yield ergosterol, a compound that plays a key role in maintaining the integrity of cell membranes in yeast and fungi, thereby inhibiting fungal growth.

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.

Policy:

INITIAL CRITERIA: Oteseconazole (Vivjoa™) is approved when ALL of the following are met:

1. Diagnosis of recurrent vulvovaginal candidiasis (RVVC); and
2. Member is not of reproductive potential; and
3. Diagnosis of RVVC is confirmed by ONE of the following:
 - a. Positive potassium hydroxide (KOH) preparation; or
 - b. Vaginal fungal culture; and
4. Member has experienced 3 or more symptomatic episodes of vulvovaginal candidiasis (VVC) within the past 12 months; and
5. Inadequate response or inability to tolerate BOTH of the following:
 - a. One intravaginal product (e.g., clotrimazole, miconazole, terconazole); and
 - b. Oral fluconazole

Authorization duration: 4 months

Black Box Warning as shown in the drug Prescribing Information:

N/A

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Sobel J. Candida vulvovaginitis: Treatment. UpToDate. Revised December 2022. Available from: uptodate.com. Accessed February 24, 2023.

Vivjoa™ (oteseconazole) [package insert]. Durham, NC: Mycovia Pharmaceuticals, Inc; April 2022. Available at <https://vivjoa.com/pi/VIVJOA-Full-Prescribing-Information.pdf>. Accessed February 24, 2023.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Vivjoa™	oteseconazole

Cross References:

Rx.01.33 Off Label Use

Rx.01.76 Quantity Level Limits for Pharmaceuticals Covered Under the Prescription Drug Benefit

Policy Version Number:	1.00
P&T Approval Date:	December 08, 2022
Policy Effective Date:	April 01, 2023
Next Required Review Date:	December 08, 2023

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.

--	--