Effective Date **12/15/2024**
Coverage Policy Number **IP0513**

Oteseconazole

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for oteseconazole (**Vivjoa**™).

Medical Necessity Criteria

Oteseconazole (Vivjoa) is considered medically necessary when the following are met:

Recurrent vulvovaginal candidiasis. Individual meets ALL of the following criteria:

A. Is ≥ 18 years of age
B. Has had at least three episodes of vulvovaginal candidiasis in a 12-month period
Note: A patient who has had two or more previous episodes of vulvovaginal candidiasis in the previous 12 months (prior to the current infection) would meet this requirement.

C. Not of reproductive potential (persons who are postmenopausal or have another reason for permanent infertility such as tubal ligation, hysterectomy, salpingo-oophorectomy)

D. Not pregnant
E. Not lactating (for example, breastfeeding)
F. **ONE** of the following:
    i. Documentation of failure, contraindication, or intolerance to oral fluconazole maintenance therapy (fluconazole 100 mg, 150 mg or 200 mg once weekly for 6 months)
    ii. **ONE** of the following:
        a. Documentation that oral fluconazole is not clinically appropriate for the individual due to drug-drug interactions
        b. Has documented fluconazole allergy
        c. Is being treated for a Candida species that is not susceptible to fluconazole
    iii. Has already started on Vivjoa therapy and is continuing in order to complete the course of therapy

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Reauthorization Criteria

Not applicable for continuation beyond initial approval duration.

Authorization Duration

Initial approval duration: 3 months
Reauthorization approval duration: not applicable

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (criteria will be updated as new published data are available).

Background

OVERVIEW
Vivjoa, an azole antifungal, is indicated to reduce the incidence of **recurrent vulvovaginal candidiasis** (RVVC) in females with a history of RVVC who are not of reproductive potential.[1] 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 is contraindicated in females of reproductive potential and in pregnant and lactating women.

The Vivjoa pivotal studies enrolled females with RVVC, which was defined as three or more episodes of vulvovaginal candidiasis in a 12-month period; this definition aligns with the Centers for Disease Control and Prevention's (CDC) definition of RVVC.[1,2]

References

1. Vivjoa™ capsules [prescribing information]. Durham, NC: Mycovia; April 2024.
2. Workowski KA, Bachmann LH, Chan PA, et al. Sexually transmitted infections treatment guidelines 2021. MMWR Recomm Rep. 2021;70(4):1-187.

Revision Details

Type of Revision	Summary of Changes	Date
Selected Revision	**Recurrent Vulvovaginal Candidiasis.** **Added** "Is ≥ 18 years of age" **Added** "Has had at least three episodes of vulvovaginal candidiasis in a 12-month period; Note: A patient who has had two or more previous episodes of vulvovaginal candidiasis in the previous 12 months (prior to the current infection) would meet this requirement." **Added** "Not pregnant"	12/15/2024

The policy effective date is in force until updated or retired.