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Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Anti-infective Agents	**Original Policy Date:**	May 27, 2022
Subject:	Vivjoa	**Page:**	1 of 4

Last Review Date: June 13, 2024

Vivjoa

Description

Vivjoa (oteseconazole)

Background
Vivjoa (oteseconazole) is an antifungal drug. It targets the fungal sterol, 14α demethylase (CYP51), an enzyme that catalyzes an early step in the biosynthetic pathway of ergosterol, a sterol required for fungal cell membrane formation and integrity. Inhibition of CYP51 results in the accumulation of 14-methylated sterols, some of which are toxic to fungi (1).

Regulatory Status
FDA-approved indication: 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 (1).

Vivjoa is contraindicated in females of reproductive potential, and in pregnant and lactating women. Vivjoa may cause fetal harm. The drug exposure window of approximately 690 days (based on 5 times the half-life of oteseconazole) precludes adequate mitigation of the embryo-fetal toxicity risks associated with Vivjoa use (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) (1).

The safety and effectiveness of Vivjoa in pre-menarchal pediatric females have not been established (1).

Related policies
Brexafemme

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Vivjoa may be considered **medically necessary** if the conditions indicated below are met.

Vivjoa may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age Post onset of menses

Diagnosis

Patient must have the following:

Recurrent vulvovaginal candidiasis (RVVC)

AND ALL of the following:

1. Positive fungal culture for *Candida* species
2. Patient has a history of RVVC, defined as ≥3 episodes of vulvovaginal candidiasis (VVC) in a 12-month period
3. Inadequate treatment response, intolerance, or contraindication to fluconazole
4. Patient is **NOT** of reproductive potential

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 18 capsules

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Vivjoa is an azole antifungal that is indicated to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC. Vivjoa may only be used in females who are not of reproductive potential (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Vivjoa while maintaining optimal therapeutic outcomes.

References

1. Vivjoa [package insert]. Durham, NC: Mycovia Pharmaceuticals, Inc.; April 2022.

Policy History

Date	Action
May 2022	Addition to PA
June 2022	Annual review
September 2022	Per FEP, addition of requirement to t/f fluconazole
December 2022	Annual review
June 2023	Annual review
June 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.