BlueCross BlueShield
Federal Employee Program

VIVJOA
(oteseconazole)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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.

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References

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