

PRIOR AUTHORIZATION POLICY

POLICY: Antifungals – Vivjoa Prior Authorization Policy

- Vivjoa™ (oteseconazole capsules – Mycovia)

REVIEW DATE: 08/17/2022

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 is 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}

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Vivjoa. All approvals are provided for 30 days, which is an adequate duration for the patient to receive one course of treatment.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Vivjoa is recommended in those who meet the following criteria:

FDA-Approved Indication

- 1. Recurrent Vulvovaginal Candidiasis.** Approve one course of treatment if the patient meets ALL of the following criteria (A, B, C, D, and E):
 - A)** Patient is ≥ 18 years of age; AND
 - B)** Patient has had at least three episodes of vulvovaginal candidiasis in a 12-month period; AND
 - C)** Patient is NOT of reproductive potential; AND
Note: A person who is NOT of reproductive potential is defined as a person who is a biological female who is postmenopausal or has another reason for permanent infertility (e.g., tubal ligation, hysterectomy, salpingo-oophorectomy).
 - D)** Patient is NOT pregnant; AND
 - E)** Patient is NOT breastfeeding.
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CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Vivjoa is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Vivjoa™ capsules [prescribing information]. Durham, NC: Mycovia; April 2022.
2. Workowski KA, Bachmann LH, Chan PA, et al. Sexually transmitted infections treatment guidelines 2021. *MMWR Recomm Rep.* 2021;70(4):1-187.

History

Type of Revision	Summary of Changes	Review Date
New Policy	--	08/17/2022