



PRIOR AUTHORIZATION POLICY

- POLICY:** Antifungals – Vivjoa Prior Authorization Policy
- Vivjoa™ (oteseconazole capsules – Mycovia)

REVIEW DATE: 08/28/2024

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

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}

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.

- **Vivjoa™ (oteseconazole capsules (Mycovia))**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

- 1. Recurrent Vulvovaginal Candidiasis.** Approve one course of treatment if the patient meets ALL of the following (A, B, C, D, and E):
 - A) Patient is \geq 18 years of age; AND**
 - B) Patient has had at least three episodes of vulvovaginal candidiasis in a 12-month period; AND**
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) 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.**

CONDITIONS NOT COVERED

- **Vivjoa™ (oteseconazole capsules (Mycovia))**

is(are) considered experimental, investigational, or unproven for ANY other use(s).

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.

History

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	08/23/2023
Annual Revision	No criteria changes.	08/28/2024

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