PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 08/06/2025

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 WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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. This is a result of a drug exposure window of approximately 690 days (based on 5 times the half-life of oteseconazole), which precludes adequate mitigation of the embryo-fetal toxicity risks.

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]

There are two recommended Vivjoa dosage regimens: a Vivjoa-only regimen and a fluconazole/Vivjoa regimen.[1] The duration of treatment is 12 weeks and 14 weeks for the Vivjoa-only dosage regimen and the fluconazole/Vivjoa dosage regimen, respectively.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Vivjoa. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

- **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 for 4 months if the patient meets ALL of the following (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
     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 not medically necessary for ANY other use(s); criteria will be updated as new published data are available.

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
Annual Revision	**Policy Statement**: The policy statement was updated to "All approvals are provided for the duration below. In cases where the approval is authorized in months, 1 month is equal to 30 days." Previously, it read "All approvals are provided for 30 days, which is an adequate duration for the patient to receive one course of treatment." **Recurrent Vulvovaginal Candidiasis**: The approval duration for this condition was updated to state 4 months. Previously, it stated "one treatment course."	08/06/2025