A letter of medical necessity is used to support coverage for treatment and contains all pertinent patient information. Payers' requirements vary for determining medical necessity. Please confirm with individual payers what additional information they require. Please note that this is an example only and should be personalized for your patient's specific situation and based on your medical judgement. This example does not guarantee coverage.

To Prescriber: **Please refer to the full Prescribing Information and Important Safety Information when determining whether therapy is medically appropriate for the individual patient.**

Example Letter of Medical Necessity

Patient Name: [Patient Name]
Date of Birth: [Patient date of birth]
Member ID: [Patient ID #]

[Date]

[Insurance Plan Name]

[Address]

To Whom It May Concern:

I am writing this letter on behalf of [Patient Name] with a diagnosis of [Diagnosis] to support the approval of treatment with VIVJOA™ (oteseconazole) capsules.

Treatment rationale:

[Provide a statement about the patient's medical history, diagnosis, and signs and symptoms to help support your rationale for treatment with VIVJOA].

Treatment history and patient response:

[Provide a statement listing current and previously used medications to treat this condition and response to treatments].

Based on the patient's medical history, current diagnosis, and treatment history, please consider coverage of VIVJOA for [Patient Name].

If you have any questions or require additional information, please do not hesitate to contact me at [Provider Phone #].

Sincerely,

[Provider Name and Signature]

[Provider NPI #]

[Phone #]

[Fax #]

To download an editable template of this letter, please go to VIVJOA.com.

INDICATION

VIVJOA™ (oteseconazole capsules) is indicated to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are NOT of reproductive potential.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Females of Reproductive Potential: VIVJOA is contraindicated in females of reproductive potential. 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).

Please see additional Important Safety Information on next page and accompanying full Prescribing Information.

vivjoa™
(oteseconazole capsules)
150 mg per capsule, for oral use

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS (cont'd)

Pregnant and Lactating Women: VIVJOA is contraindicated in pregnant and lactating women.

Hypersensitivity: VIVJOA is contraindicated in patients with known hypersensitivity to oteseconazole.

WARNINGS AND PRECAUTIONS

Embryo-Fetal Toxicity: Based on animal studies, 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. Advise patients that VIVJOA is contraindicated in females of reproductive potential, and in pregnant and lactating women because of potential risks to a fetus or breastfed infant.

ADVERSE REACTIONS

The most frequently reported adverse reactions among VIVJOA-treated patients in clinical studies included headache (7.4%) and nausea (3.6%).

DRUG INTERACTIONS

Effect of VIVJOA on Other Drugs: Oteseconazole is a Breast Cancer Resistance Protein (BCRP) inhibitor. Concomitant use of VIVJOA with BCRP substrates (e.g., rosuvastatin) may increase the exposure of BCRP substrates (e.g., rosuvastatin), which may increase the risk of adverse reactions associated with these drugs. Use the lowest possible starting dose of the BCRP substrate or consider reducing the dose of the substrate drug and monitor for adverse reactions.

USE IN SPECIFIC POPULATIONS

Pregnancy: VIVJOA is contraindicated in females of reproductive potential and in pregnant women. Based on animal studies, VIVJOA may cause fetal harm when administered to pregnant women. In addition, 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.

Lactation: VIVJOA is contraindicated in lactating women and females of reproductive potential. There are no data on the presence of oteseconazole in human or animal milk or data on the effects of oteseconazole on milk production. There were no reported adverse effects in breastfed infants following maternal exposure to oteseconazole during lactation; however, given the limited duration of follow-up of the oteseconazole-exposed infants during the post-natal period, no conclusions can be drawn from these data.

Females of Reproductive Potential: VIVJOA is contraindicated in females of reproductive potential based on data from rat studies.

Pediatric Use: The safety and effectiveness of VIVJOA have not been established in pre-menarchal pediatric females.

Geriatric Use: Clinical studies of VIVJOA did not include sufficient numbers of patients 65 years of age and older to determine whether they respond differently from younger adult patients.

Renal Impairment: No dosage adjustment of VIVJOA is recommended in patients with mild to moderate renal impairment. VIVJOA is not recommended for use in patients with severe renal impairment or end-stage renal disease, as clinical studies did not include sufficient numbers of these patients.

Hepatic Impairment: No dosage adjustment of VIVJOA is recommended in patients with mild hepatic impairment. VIVJOA is not recommended for use in patients with moderate or severe hepatic impairment, as there is insufficient information in these patients.

To report SUSPECTED ADVERSE REACTIONS, contact Mycovia Pharmaceuticals, Inc. at 1-855-299-0637 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see additional Important Safety Information on previous page and accompanying full Prescribing Information.

mycovia Pharmaceuticals

04/2022
MA-575-2022-v1

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(oteseconazole capsules)
150 mg per capsule, for oral use