Clinical Policy Title:	oteseconazole
Policy Number:	RxA.760
Drug(s) Applied:	Vivjoa™
Original Policy Date:	07/18/2022
Last Review Date:	07/13/2023
Line of Business Policy Applies to:	All lines of business

Background

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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
oteseconazole (Vivjoa™)	Vulvovaginal candidiasis, recurrent	**Vivjoa™ only regimen** • On Day 1: 600 mg as a single dose. • On Day 2: 450 mg as a single dose. • Beginning on Day 14: 150 mg once a week (every 7 days) for 11 weeks (Weeks 2 through 12). **Fluconazole/ Vivjoa™:** • On Day 1, Day 4, and Day 7: fluconazole 150 mg orally. • On Days 14 through 20: Vivjoa™ 150 mg once daily for 7 days. • Beginning on Day 28: Vivjoa™ 150 mg once a week (every 7 days) for 11 weeks (Weeks 4 through 14).	Varies

Dosage Forms

- Capsules: 150 mg of oteseconazole.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Recurrent Vulvovaginal candidiasis (must meet all):

1. Diagnosis of recurrent vulvovaginal candidiasis;
2. Prescribed by or in consultation with an obstetrician, gynecologist, or infectious disease physician;
3. Age ≥ 12 years;
4. History of RVVC (≥ 3 acute VVC episodes within 12 months)
5. Member must meet one of the following (a or b):
   a. Member is postmenopausal;
   b. Age ≥ 12 years and postmenarchal, but not of reproductive potential (i.e. history of tubal ligation, salpingo-oophorectomy, or hysterectomy);
6. Request meets one of the following (a or b):
   a. For Vivjoa™ only dosing regimen: On day 1, 600 mg as a single dose; on day 2, 450 mg as a single dose and beginning on day 14, 150 mg once a week (every 7 days) for 11 weeks (Weeks 2 through 12).
   b. Fluconazole/ Vivjoa™: On Day 1, Day 4, and Day 7 fluconazole 150 mg orally; on days 14 through 20 Vivjoa™ 150 mg once daily for 7 days and beginning on day 28 Vivjoa™ 150 mg once a week (every 7 days) for 11 weeks (Weeks 4 through 14).

Approval Duration
Commercial: 4 months
Medicaid: 4 months

II. Continued Therapy Approval

A. Recurrent Vulvovaginal candidiasis (must meet all):

1. Re-authorization is not permitted. Vivjoa™ is not indicated for continuous use for this indication. Members must meet the initial approval criteria.

Approval Duration
Not applicable.

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
RVVC: recurrent vulvovaginal candidiasis

APPENDIX B: Therapeutic Alternatives
Not Applicable

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s)*:
  - Females of reproductive potential;
  - Pregnant and lactating women;
  - Patients with known hypersensitivity to oteseconazole.

  *Contraindications listed reflect direct statements made in the manufacturer's package insert; for additional uses, warnings, and precautions, please refer to clinical guidelines.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- Embryo-Fetal Toxicity Vivjoa™ is contraindicated in females of reproductive potential, and in pregnant and lactating women.

- Vivjoa™ is not recommended for use in patients with moderate or severe hepatic impairment.
- Vivjoa™ is not recommended for use in patients with severe renal impairment or ESRD (with or without dialysis).

References

1. Vivjoa™ Prescribing Information. Durham, NC: Mycovia Pharmaceuticals, Inc; April 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215888s000lbl.pdf. Accessed May 31, 2023.
2. IPD Analytics Rx Insights_New Drug Review_ Vivjoa™ 05.2022. Available at: https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=Vivjoa. Accessed May 31, 2023.
3. Vulvovaginal Candidiasis (VVC). Sexually Transmitted Infections Treatment Guidelines, 2021. Centers for Disease Control and Prevention. Updated July 2021. Available at: https://www.cdc.gov/std/treatment-guidelines/candidiasis.htm. Accessed May 31, 2023.
4. Mycovia Pharmaceuticals Inc. A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Oteseconazole (VT-1161) Oral Capsules in the Treatment of Subjects with Recurrent Vulvovaginal Candidiasis. clinicaltrials.gov; 2021. Available at: https://clinicaltrials.gov/ct2/show/NCT03561701. Accessed May 31, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	06/03/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria I.A.2: Updated prescriber criteria from " Prescribed by or in consultation with an obstetrician, gynaecologist" to "Prescribed by or in consultation with an obstetrician, gynecologist, or infectious disease physician". 2. Initial Approval Criteria, I.A.6: Updated to remove prior trial and failure criteria "Trial and failure of oral fluconazole maintenance treatment for at least 6 months unless contraindicated or adverse effects are experienced (such as hypersensitivity or drug-drug interaction". 3. Initial Approval Criteria, I.A.7: Updated to remove criteria pertaining to indication "positive KOH (potassium hydroxide) test or gram stain test". 4. Initial Approval Criteria: Approval duration updated from "12 months" to "4 months". 5. Appendix B, Drug Name: Updated to remove therapeutic alternative	05/31/2023	07/13/2023

fluconazole (Diflucan®). 6. Appendix D, General Information: Updated to include new information regarding Hepatic, renal impairment dosing recommendation. 7. References were reviewed and updated.		