

oteseconazole capsule (VIVJOA)

Diagnoses Considered for Coverage:

- Recurrent vulvovaginal candidiasis (RVVC)

Coverage Criteria:

For diagnosis of vulvovaginal candidiasis:

- Patient is NOT of reproductive potential (e.g. postmenopausal, history of tubal ligation, hysterectomy, or salpingo-oophorectomy), **and**
- Patient has a history of at least 3 yeast infections within 12 months, **and**
- Inadequate response, intolerable side effect, or contraindication to fluconazole maintenance therapy (i.e. weekly fluconazole dosing for 6 months), **and**
- Dose does not exceed FDA labeled maximum:
 - Single agent: 600 mg orally on day 1 as a single dose followed by 450 mg orally on day 2 as a single dose; On day 14 administer 150 mg orally once every 7 days for 11 weeks, or
 - With fluconazole: fluconazole 150 mg orally on days 1, 4, and 7, then oteseconazole 150 mg once daily on days 14 to 20, then on day 28 administer 150 mg oteseconazole once every 7 days for 11 weeks.

Coverage Duration: one time

References:

1. Prescribing Information. VIVJOA(TM) oral capsules, oteseconazole oral capsules. Mycovia Pharmaceuticals Inc. 2022.
2. Pappas PG, Kauffman CA, Andes DR, Clancy CJ, Marr KA, Ostrosky-Zeichner L, Reboli AC, Schuster MG, Vazquez JA, Walsh TJ, Zaoutis TE, Sobel JD. Clinical Practice Guideline for the Management of Candidiasis: 2016 Update by the Infectious Diseases Society of America. Clin Infect Dis. 2016 Feb 15;62(4):e1-50. doi: 10.1093/cid/civ933. Epub 2015 Dec 16. PMID: 26679628; PMCID: PMC4725385.
3. Workowski KA, Bachmann LH, Chan PA, Johnston CM, Muzny CA, Park I, Reno H, Zenilman JM, Bolan GA. Sexually Transmitted Infections Treatment Guidelines, 2021. MMWR Recomm Rep. 2021 Jul 23;70(4):1-187. doi: 10.15585/mmwr.rr7004a1. PMID: 34292926; PMCID: PMC8344968.

Effective Date: 11/02/2023