

STEP THERAPY POLICY

- POLICY:** Antifungals for Vulvovaginal Candidiasis Step Therapy Policy
- Brexafemme[®] (ibrexafungerp tablets – Scynexis)
 - Diflucan[®] (fluconazole tablets – Pfizer, generic)
 - Miconazole vaginal suppository (100 mg, 200 mg, or 1,200 mg) [over-the-counter]
 - Terconazole vaginal cream 0.4% (generic only)
 - Terconazole vaginal cream 0.8% (generic only)
 - Terconazole vaginal suppository 80 mg (generic only)

REVIEW DATE: 09/07/2022

OVERVIEW

The listed vaginal antifungals, oral fluconazole, and Brexafemme are indicated for the **treatment of vulvovaginal candidiasis**.¹⁻⁴ Brexafemme is also indicated to reduce the incidence of recurrent vulvovaginal candidiasis in adults and post-menarchal pediatric females.¹ Many of the vaginal antifungals are available as over-the-counter (OTC) products.^{3,4}

Guidelines

Brexafemme is not addressed in the guidelines. The Centers for Disease Control and Prevention (CDC) Sexually Transmitted Infections Treatment Guidelines (2021) recommend an intravaginal product (e.g., miconazole, tioconazole) or oral fluconazole for the treatment of vulvovaginal candidiasis.⁵ Treatment with an azole antifungal typically results in relief of symptoms and negative cultures in 80% to 90% of patients who complete treatment. There are no data to show superiority of one intravaginal product over another.⁶ The efficacy of oral fluconazole and intravaginal antifungals is similar.

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1: fluconazole 150 mg tablets, miconazole vaginal suppository (over-the-counter kits that include miconazole vaginal suppository are also included), terconazole vaginal cream, terconazole vaginal suppository

Step 2: Brexafemme

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. No other exceptions are recommended.

REFERENCES

1. Brexafemme® tablets [prescribing information]. Jersey City, NJ: Scynexis; November 2022.
2. Diflucan® tablets and powder for oral suspension [prescribing information]. New York, NY: Pfizer, March 2020.
3. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2022. Available at: <http://online.factsandcomparisons.com/login.aspx?url=/index.aspx&q>. Accessed on September 2, 2022. Search terms: fluconazole, miconazole, terconazole.
4. Clinical Pharmacology © 2022. Available at <http://www.clinicalpharmacology-ip.com/Default.aspx>. Accessed on September 2, 2022. Search terms: fluconazole, miconazole, terconazole.
5. Workowski KA, Bachmann LH, Chan PA, et al. Sexually transmitted infections treatment guidelines 2021. *MMWR Recomm Rep*. 2021;70(4):1-187.
6. Pappas PG, Kauffman CA, Andes D, et al. Clinical practice guidelines for the management of candidiasis: 2016 update by the Infectious Diseases Society of America. *Clin Infect Dis*. 2006;62(4):e1-50.