

Ibrexafungerp (BREXAFEMME)

Criteria for Use

Updated Aug 2023

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES. The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the [PBM INTRAnet](#) site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive ibrexafungerp.

- Concomitant administration of CYP3A inducing drugs
- Pregnancy or lactation

Inclusion Criteria

ONE of the following criteria must be met.

- Signs and symptoms consistent with vulvovaginal candidiasis (VVC) which has not responded to trials of both a topical azole preparation AND fluconazole (unless contraindicated or not tolerated)
- At least 3 episodes of recurrent symptomatic VVC in 12 months and has failed at least 6 months of maintenance fluconazole (unless contraindicated or not tolerated, or isolate is documented to be fluconazole-resistant)

Additional Inclusion Criteria: Select if applicable

- For patients who can become pregnant: Pregnancy MUST be excluded prior to receiving ibrexafungerp
- For patients who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for 4 days after stopping treatment

Other Justification

- ANY other indication (e.g. off-label for invasive candidiasis, invasive aspergillosis) should be restricted to Infectious Diseases or other facility authorized provider

Supplemental Information

- The CDC STI guidelines recommend vaginal culture or PCR be obtained from women with complicated VVC to confirm clinical diagnosis and identify non-*albicans Candida*. *C. albicans* azole resistance is becoming more common in vaginal isolates, and non-*albicans Candida* are often resistant to azoles; therefore, culture and susceptibility testing should be considered for patients who remain symptomatic.
- Normal dose for treatment of VVC 300mg twice daily for 1 day and should be decreased to 150mg twice daily for 1 day in those on strong CYP3A inhibitors
- Normal dose for prevention of recurrent VVC is 300mg administered 12 hours apart for 1 day monthly for 6 months