Effective Date 05/01/2022
Reviewed: 02/2022, 12/2022, 01/2023
Scope: Medicaid

Brexafemme (ibrexafungerp)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Brexafemme is indicated in adult and post-menarchal pediatric females for:
1. The treatment of vulvovaginal candidiasis (VVC).
2. The reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC).

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR APPROVAL

1. Brexafemme is prescribed by, or in consultation with, an infectious disease physician or obstetrician/gynecologist.
2. Other causes, such as bacterial vaginosis or trichomoniasis, have been ruled out.
3. Documentation provided of assessment of pregnancy status prior to each treatment course and effective contraception throughout and at least 4 days after the last dose.
   Note: Brexafemme is contraindicated and has a black box warning for pregnancy.
4. The requested drug is not being used in a footbath.

Vulvovaginal candidiasis (VVC)

If the requested drug is being prescribed for the treatment of vulvovaginal candidiasis (VVC) in an adult or post-menarchal pediatric patient, an authorization of one month for one treatment course (4 tablets) may be granted when all the following criteria is met:
a. The member has experienced a failure, contraindication or intolerance to a topical agent for VVC (e.g., clotrimazole vaginal cream, miconazole vaginal cream or suppository, terconazole vaginal cream or suppository)
b. The member has experienced a failure, contraindication or intolerance to oral fluconazole.

Recurrent vulvovaginal candidiasis (RVVC)

If the requested drug is being prescribed for the treatment of recurrent vulvovaginal candidiasis (RVVC) in an adult or post-menarchal pediatric patient, an authorization of six months (24 tablets total) may be granted when all the following criteria is met, with documentation provided:
a. The member has had 3 or more episodes of symptomatic VVC in a 12-month period.
b. The member meets one of the following, with documentation provided:
   i. The member has experienced treatment failure to a 6-month maintenance course of weekly oral fluconazole (100 mg, 150 mg, or 200 mg) [e.g., acute VVC episode while on fluconazole therapy, acute VVC episode within 14 days of completing 6-month fluconazole course, acute VVC episode after two 6-month courses of fluconazole within 2 years]
   ii. The member has experienced an intolerance to fluconazole
   iii. The member has a contraindication or documented resistance that would prohibit a trial of fluconazole
c. The member has experienced a treatment failure, contraindication or intolerance to Vivjoa, with documentation provided.

III. QUANTITY LIMIT

Brexafemme 150mg tablets have a quantity limit of 4 tablets per day.
For RVVC, Brexafemme will be approved for 4 tablets per month for 6 months with a yearly limit of 24 tablets.

Indication	Dose
VVC	Brexafemme 300 mg (two tablets of 150 mg) administered approximately 12 hours apart (e.g., in the morning and in the evening) for one day, for a total daily dosage of 600 mg (four 150 mg tablets)
RVVC	Brexafemme 300 mg (two tablets of 150 mg) administered approximately 12 hours apart (e.g., in the morning and in the evening) for one day, for a total daily dosage of 600 mg (four 150 mg tablets) monthly for six months

IV. REFERENCES

1. Brexafemme [package insert]. Jersey City, NJ: SCYNEXIS, Inc.; June 2021.
2. Workowski, KA, Bachmann, LH, Chan, PA, et al. Sexually Transmitted Infections Treatment Guidelines, 2021. MMWR Recomm Rep 2021;70.(No. RR-4)