BlueCross BlueShield
Federal Employee Program

BREXAFEMME
(ibrexafungerp)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Brexafemme (ibrexafungerp) is a triterpenoid antifungal drug indicated for the treatment of vulvovaginal candidiasis (VVC) or the reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC). VVC is a common condition characterized by vulvovaginal inflammation in the presence of yeast (primarily *Candida* species). Brexafemme targets glucan synthase, an essential enzyme responsible for the formation of the fungal cell wall and exhibits fungicidal activity (1).

Regulatory Status

FDA-approved indications: Brexafemme is a triterpenoid antifungal indicated in adult and post-menarchal pediatric females for: (1)

- Treatment of vulvovaginal candidiasis (VVC).
- Reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC).

Brexafemme contains a boxed warning for the risk of embryo-fetal toxicity. Brexafemme is contraindicated in pregnant females. For females of reproductive potential, it should be verified that the patient is not pregnant prior to initiating Brexafemme treatment. Pregnancy status should be reassessed prior to each dose when Brexafemme is used monthly for 6 months for reduction in the incidence of RVVC. Females of reproductive potential should be advised to use effective contraception during treatment with Brexafemme and for 4 days after the last dose (1).

The most common adverse events of Brexafemme include diarrhea, nausea, abdominal pain, dizziness, and vomiting (1).

The safety and effectiveness of Brexafemme in pre-menarchal pediatric patients have not been established (1).

Summary

Brexafemme (ibrexafungerp) is an antifungal medication indicated for the treatment of vulvovaginal candidiasis (VVC) or the reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC). VVC is a common fungal infection that results in irritation, burning, redness and excoriation in the presence of yeast. Brexafemme is fungicidal via inhibition of an enzyme, glucan synthase, which is

essential to fungal cell wall synthesis. The safety and effectiveness of Brexafemme in pre-menarchal pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Brexafemme while maintaining optimal therapeutic outcomes.

References

1. Brexafemme [package insert]. Jersey City, NJ: Scynexis, Inc.; November 2022.