BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.01.072

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Anti-Infective Agents	**Original Policy Date:**	December 24, 2021
Subject:	Brexafemme	**Page:**	1 of 5

Last Review Date: March 7, 2025

Brexafemme

Description

Brexafemme (ibrexafungerp)

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).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Brexafemme may be considered **medically necessary** if the conditions indicated below are met.

Brexafemme may be considered **investigational** for all other indications.

Prior-Approval Requirements

Patients who have filled at least a 1-day supply of fluconazole in the last 30 days are exempt from these Prior Authorization (PA) requirements.

Age 18 years of age or older **OR** post onset of menses

Diagnoses

Patient must have **ONE** of the following:

1. Vulvovaginal candidiasis (VVC)
2. Recurrent vulvovaginal candidiasis (RVVC)
    a. Used to reduce the incidence of RVVC

AND ALL of the following:

1. Inadequate treatment response, intolerance, or contraindication to fluconazole
2. **NOT** being used in a footbath

3. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Brexafemme and for 4 days after the last dose

Prior–Approval *Renewal* Requirements

Each prior authorization (PA) request for Vulvovaginal candidiasis (VVC) is considered initiation of therapy due to the acute nature of the infection

Age 18 years of age or older **OR** post onset of menses

Diagnosis

Patient must have the following:
1. Recurrent vulvovaginal candidiasis (RVVC)
    a. Used to reduce the incidence of RVVC

AND ALL of the following:
1. Prescriber has determined that the patient will benefit from an additional 6 months of therapy for prevention of RVVC
2. **NOT** being used in a footbath
3. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Brexafemme and for 4 days after the last dose

Policy Guidelines

Patients who have filled at least a 1-day supply of fluconazole in the last 30 days are exempt from these Prior Authorization (PA) requirements.

Pre–PA Allowance

None

Prior–Approval Limits

Indication	Quantity	Duration
Vulvovaginal candidiasis (VVC)	4 tablets	7 days
Recurrent vulvovaginal candidiasis (RVVC)	12 tablets per 90 days	6 months

Prior–Approval *Renewal* Limits

Each prior authorization (PA) request for Vulvovaginal candidiasis (VVC) is considered initiation of therapy due to the acute nature of the infection

Indication	Quantity	Duration
Recurrent vulvovaginal candidiasis (RVVC)	12 tablets per 90 days	6 months (**ONE** renewal only)

Rationale

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.

Policy History

Date	Action
December 2021	Addition to PA
March 2022	Annual review
December 2022	Annual review and reference update. Changed policy number to 5.01.072. Per PI update, added indication of recurrent vulvovaginal candidiasis and added contraception requirement
March 2023	Annual review
June 2023	Annual review
March 2024	Annual review
June 2024	Annual review
March 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.