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5.01.072

Section:	Prescription Drugs	**Effective Date:**	January 1, 2023
Subsection:	Anti-Infective Agents	**Original Policy Date:**	December 24, 2021
Subject:	Brexafemme	**Page:**	1 of 4

Last Review Date: December 2, 2022

Brexafemme

Description

Brexafemme (ibrexafungerp)

Background
Brexafemme (ibrexafungerp) is a triterpenoid antifungal drug indicated for the treatment of vulvovaginal candidiasis (VVC). 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 indication: Brexafemme is a triterpenoid antifungal indicated for the treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis (VVC) (1).

In animal studies, Brexafemme was associated with a risk of fetal toxicity and is contraindicated in pregnant females. 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** for patients 18 years of age and older or for post-menarchal pediatric patients for vulvovaginal candidiasis and if the conditions indicated below are met.

Brexafemme may be considered **investigational** in pre-menarchal pediatric patients and 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

Diagnosis

Patient must have the following:

1. Vulvovaginal candidiasis

AND ALL of the following:

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

Prior–Approval *Renewal* Requirements

None

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

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

Quantity 4 tablets

Duration 7 days

Prior–Approval *Renewal* Limits

None

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

Rationale

Summary

Brexafemme (ibrexafungerp) is an antifungal medication indicated for the treatment of vulvovaginal candidiasis (VVC). 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.; June 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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 2, 2022 and is effective on January 1, 2023.