Effective Date **1/15/2024**
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Coverage Policy Number **IP0301**

Ibrexafungerp

Table of Contents

Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for formulary exceptions for ibrexafungerp oral tablets (**Brexafemme®**).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage criteria are listed for products **in below table:**

Non-Covered Product	Criteria
Brexafemme (ibrexafungerp tablets)	**Brexafemme is considered medically necessary when there is documentation of ONE of the following:**

Non-Covered Product	Criteria
	1. **Treatment of Vulvovaginal Candidiasis.** Individual meets **ONE** of the following criteria: A. Documentation of failure, contraindication, or intolerance to fluconazole B. Is being treated for a Candida species that is not susceptible to fluconazole 2. **To Reduce the Incidence of Recurrent Vulvovaginal Candidiasis.** Individual meets **ONE** of the following criteria: A. Documentation of failure, contraindication, or intolerance to fluconazole B. Is being treated (or has been treated) for a Candida species that is not susceptible to fluconazole

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of ibrexafungerp (Brexafemme) is considered medically necessary when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 6 months
Reauthorization approval duration: up to 6 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Background

OVERVIEW
Brexafemme is a triterpenoid antifungal indicated in adult and post-menarchal pediatric females for:

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

The topical vaginal antifungals, oral fluconazole, and Brexafemme are indicated for the treatment of vulvovaginal candidiasis.[1-4] Brexafemme is also indicated to reduce the incidence of recurrent vulvovaginal candidiasis in adults and post-menarchal pediatric females.[1] Many of the vaginal antifungals are available as over-the-counter (OTC) products.[3,4]

Dosing
For treatment of VVC, the recommended dosage of Brexafemme in adult and post-menarchal pediatric females is 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). For the reduction in the incidence of RVVC, the recommended dosage of Brexafemme in adult and post-menarchal females is 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.

Guidelines
Brexafemme is not addressed in the guidelines. The Centers for Disease Control and Prevention (CDC) Sexually Transmitted Infections Treatment Guidelines (2021) recommend an intravaginal product (e.g., miconazole, tioconazole) or oral fluconazole for the treatment of vulvovaginal candidiasis.[5] Treatment with an azole antifungal typically results in relief of symptoms and negative cultures in 80% to 90% of patients who complete treatment. There are no data to show superiority of one intravaginal product over another.[6] The efficacy of oral fluconazole and intravaginal antifungals is similar.

References

1. Brexafemme® tablets [prescribing information]. Jersey City, NJ: Scynexis; November 2022.
2. Diflucan® tablets and powder for oral suspension [prescribing information]. New York, NY: Pfizer, January 2023.
3. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2023. Available at: http://fco.factsandcomparisons.com/lco/action/home. Accessed on September 5, 2023. Search terms: fluconazole, miconazole, terconazole.
4. Clinical Pharmacology [database online]. Elsevier Inc. © 2023. Available at https://www.clinicalkey.com/pharmacology/. Accessed on September 5, 2023. Search terms: fluconazole, miconazole, terconazole.
5. Workowski KA, Bachmann LH, Chan PA, et al. Sexually transmitted infections treatment guidelines 2021. *MMWR Recomm Rep*. 2021;70(4):1-187.
6. Pappas PG, Kauffman CA, Andes D, et al. Clinical practice guidelines for the management of candidiasis: 2016 update by the Infectious Diseases Society of America. *Clin Infect Dis*. 2006;62(4):e1-50.