

Clinical Policy Title:	Brexafemme®
Policy Number:	RxA.716
Drug(s) Applied:	ibrexafungerp
Original Policy Date:	12/07/2021
Last Review Date:	12/07/2021
Line of Business Policy Applies to:	All lines of business

## Background

ibrexafungerp (Brexafemme®) is a triterpenoid antifungal. It is indicated for the treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis (VVC).

## Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
ibrexafungerp (Brexafemme®)	vulvovaginal candidiasis (VVC)	300 mg (two tablets of 150 mg) orally twice a day for one day, for a total treatment dosage of 600 mg.	600 mg/day

## Dosage Forms

- Tablets: 150 mg

## Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

### I. Initial Approval Criteria

#### A. Vulvovaginal candidiasis (must meet all):

- Diagnosis of vulvovaginal candidiasis;
- Prescribed by or in consultation with a gynaecologist;
- Age ≥ 12 years;
- Member must be post-menarchal;
- Pregnancy status has been verified and the patient is not pregnant;
- Not more than 2 previous episodes of acute VVC within the past 12 months;
- Failure of both fluconazole and at least one (1) topical antifungal for VVC (e.g., miconazole, tioconazole, clotrimazole, etc), unless contraindicated or clinically significant adverse effects are experienced;
- Dose does not exceed 600 mg per day.

#### Approval Duration

**Commercial:** 7 day (1 course of treatment)

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

**Medicaid:** 7 day (1 course of treatment)

**II. Continued Therapy Approval**

**A. Vulvovaginal candidiasis (must meet all):**

1. Re-authorization is not permitted. Members must meet the initial approval criteria and at least 14 days should have elapsed since the previous claim for Brexafemme®.

**Approval Duration**

**Commercial:** Not applicable

**Medicaid:** Not applicable

**III. Appendices**

**APPENDIX A: Abbreviation/Acronym Key**

VVC: vulvovaginal candidiasis

FDA: Food and Drug Administration

**APPENDIX B: Therapeutic Alternatives**

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Oral fluconazole	<ul style="list-style-type: none"> <li>• Uncomplicated: 150 mg orally as a single dose (FDA dosage);</li> <li>• Complicated: Initial therapy 100 mg, 150 mg, or 200 mg oral dose of fluconazole every third day for a total of 3 doses [days 1, 4, and 7]) is recommended, to attempt mycologic remission. Maintenance regimen: Oral fluconazole (100 mg, 150 mg, or 200 mg dose) weekly for 6 months is the indicated maintenance regimen.</li> </ul>	<ul style="list-style-type: none"> <li>• Uncomplicated: 150 mg</li> <li>• Complicated: Initial therapy: 600 mg Maintenance: 800 mg/week</li> </ul>

Therapeutic alternatives are listed as “generic name (Brand name®)” when the drug is available by both generic and brand, “Brand name®” when the drug is available by brand only, and “generic name” when the drug is available by generic only.

**APPENDIX C: Contraindications/Boxed Warnings**

- Contraindication(s):
  - Pregnancy;
  - Hypersensitivity to ibrexafungerp.
- Boxed Warning(s):
  - None reported

**APPENDIX D: General Information**

None

**References**

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4. Brexafemme® Micromedex Solutions. Truven Health Analytics Inc. Ann Arbor, MI. Available at: <http://www.micromedexsolutions.com>. Accessed September 01, 2021.
5. Fluconazole Micromedex Solutions. Truven Health Analytics Inc. Ann Arbor, MI. Available at: <http://www.micromedexsolutions.com>. Accessed September 01, 2021.
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7. Vulvovaginal candidiasis - sti treatment guidelines. Available at: <https://www.cdc.gov/std/treatment-guidelines/candidiasis.html>. Accessed September 01, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	09/01/2021	12/07/2021