

Clinical Policy Title:	ibrexafungerp
Policy Number:	RxA.716
Drug(s) Applied:	Brexafemme®
Original Policy Date:	12/07/2021
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Vulvovaginal candidiasis (must meet all):

1. Diagnosis of vulvovaginal candidiasis (VVC);
2. Member is post-menarchal;
3. Member is not pregnant;
4. History of no more than 2 previous episodes of acute VVC within the past 12 months;
5. Trial and 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.

Approval Duration

All Lines of Business (except Medicare): 7 day (1 course of treatment)

B. Recurrent vulvovaginal candidiasis (must meet all):

1. Diagnosis of recurrent vulvovaginal candidiasis (RVVC);
2. History of RVVC (≥ 3 acute VVC episodes within 12 months);
3. Member is not pregnant;
4. Member is post-menarchal;
5. Trial and failure of oral fluconazole maintenance treatment for at least 6 months unless contraindicated or adverse effects are experienced (such as hypersensitivity or drug-drug interaction);
6. Member has positive KOH (potassium hydroxide) test or gram stain test.

Approval Duration

All Lines of Business (except Medicare): 6 months

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

All Lines of Business (except Medicare): Not applicable

B. Recurrent vulvovaginal candidiasis (must meet all):

1. Re-authorization is not permitted. Brexafemme® is not indicated for continuous use. Members must meet the initial approval criteria.

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.

Approval Duration

All Lines of Business (except Medicare): Not applicable

References

1. Vulvovaginal candidiasis - STI treatment guidelines. Available at: <https://www.cdc.gov/std/treatment-guidelines/candidiasis.htm>. Accessed March 24, 2025.
2. Scynexis, Inc. A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Oral Ibrexafungerp (SCY-078) Compared to Placebo in Subjects with Recurrent Vulvovaginal Candidiasis(RVVC). clinicaltrials.gov; 2022. Available at: <https://clinicaltrials.gov/ct2/show/NCT04029116>. Accessed March 24, 2025.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	09/01/2021	12/07/2021
Policy was reviewed: <ol style="list-style-type: none"> 1. Initial Approval Criteria I.A.2: Updated to add infectious disease physician. 2. References were reviewed and updated. 	09/07/2022	10/19/2022
Policy was reviewed: <ol style="list-style-type: none"> 1. Initial Approval Criteria, I.B: Updated to include approval criteria for indication, Recurrent vulvovaginal candidiasis (RVVC). 2. Continued Therapy Approval, II.B: Updated to include approval criteria for indication, Recurrent vulvovaginal candidiasis (RVVC). 3. References were reviewed and updated. 	12/20/2022	01/17/2023
Policy was reviewed: <ol style="list-style-type: none"> 1. Removed prior age criteria. 2. Removed prior dosing criteria. 3. Updated approval duration. 4. References were reviewed and updated. 	11/22/2023	01/01/2024
Policy was reviewed: <ol style="list-style-type: none"> 1. Removed prescriber criteria. 	03/24/2025	04/10/2025
Policy reviewed.	12/11/2025	12/11/2025

