Clinical Policy Title:	ibrexafungerp
Policy Number:	RxA.716
Drug(s) Applied:	Brexafemme®
Original Policy Date:	12/07/2021
Last Review Date:	01/01/2024
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;
2. Prescribed by or in consultation with a gynecologist or an infectious disease physician;
3. Member is post-menarchal;
4. Member is not pregnant;
5. History of no more than 2 previous episodes of acute VVC within the past 12 months;
6. 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. Prescribed by or in consultation with a gynaecologist;
3. History of RVVC (≥ 3 acute VVC episodes within 12 months);
4. Member is not pregnant;
5. Member is post-menarchal;
6. 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);
7. 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.

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 November 22, 2023.
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 November 22, 2023.

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