UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2263-4
Program	Prior Authorization/Medical Necessity
Medication	Brexafemme® (ibrexafungerp)
P&T Approval Date	12/2021, 2/2022, 2/2023, 2/2024
Effective Date	5/1/2024

1. Background:

Brexafemme (ibrexafungerp) is indicated for the treatment of adult and post-menarchal pediatric females for the treatment of vulvovaginal candidiasis (VVC) and for the reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC).

Coverage will be provided for members who meet the following criteria.

2. Coverage Criteria[a]:

A. Authorization

1. **Treatment of vulvovaginal candidiasis**

a. **Brexafemme** will be approved based on **ALL** of the following criteria:

1) Diagnosis of vulvovaginal candidiasis (VVC)

-AND-

2) **One** of the following:

a) Confirmed azole resistance demonstrated by culture and susceptibility testing

-OR-

b. **Both** of the following:

i. Other causes (including but not limited to bacterial vaginosis or trichomoniasis) have been ruled out

-AND-

ii. Failure of a 7-day course of oral fluconazole therapy defined as 100-mg, 150-mg, or 200-mg taken orally every third day for a total of 3 doses [days 1, 4, and 7] for the current episode of VVC

-AND-

3) Prescribed by or in consultation with **one** of the following:

a) Infectious disease physician
b) Obstetrician/Gynecologist

Authorization will be issued for 3 months.

2. **Recurrent vulvovaginal candidiasis**

a. **Brexafemme** will be approved based on **ALL** of the following criteria:

1) Diagnosis of recurrent vulvovaginal candidiasis (RVVC)

-AND-

2) **One** of the following:

a) Confirmed azole resistance demonstrated by culture and susceptibility testing

-OR-

b) Both of the following:

i. Other causes (including but not limited to bacterial vaginosis or trichomoniasis) have been ruled out

-AND-

ii. Failure of a maintenance course of oral fluconazole defined as 100-mg, 150-mg, or 200-mg taken weekly for 6 months[b]

-AND-

3) Prescribed by or in consultation with **one** of the following:

a) Infectious disease physician
b) Obstetrician/Gynecologist

Authorization will be issued for 6 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

[b] For Connecticut, Kentucky and Mississippi business, only a 30 day trial will be required.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-

10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. Brexafemme [package insert]. Jersey City, NJ: Scynexis, Inc; November 2022
2. Sexually Transmitted Infections Treatment Guidelines, 2021. Vulvovaginal Candidiasis (VVC). Centers for Disease Control and Prevention. https://www.cdc.gov/std/treatment-guidelines/candidiasis.htm. Accessed December 2023.

Program	Prior Authorization/Medical Necessity – Brexafemme
Change Control	
12/2021	New program
2/2022	Removed the trial and failure language. Added that other causes of infection have been ruled out.
2/2023	Annual review. Added the new indication for recurrent vulvovaginal candidiasis (RVVC).
2/2024	Annual review. Updated mandated states.