

# Initial Step Therapy with Quantity Limit; Post Step Therapy Prior Authorization with Quantity Limit Brexafemme

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Brexafemme	ibrexafungerp

## Indications

### FDA-approved Indications

Brexafemme is indicated in adult and post-menarchal pediatric females for:

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

## Initial Step Therapy with Quantity Limit

Include Rx and OTC products unless otherwise stated.

If the patient has filled a prescription for at least a 1-day supply of generic fluconazole within the past 180 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid

under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

If the patient meets the initial step therapy criteria, then the initial limit criteria will apply. If the patient is requesting more than the initial quantity limit the claim will reject with a message indicating that a PA is required.

## Initial Limit Quantity

Limits should accumulate across all drugs and strengths up to highest quantity listed depending on the order the claims are processed.

This drug is for short-term, acute use; therefore, the mail limit will be the same as the retail limit

Drug	Limit
Brexafemme (ibrexafungerp)	4 tablets / 7 days

## Coverage Criteria

### Recurrent Vulvovaginal Candidiasis (RVVC)

Authorization may be granted when the requested drug is being prescribed for reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC) when ALL of the following criteria are met:

- The requested drug is being prescribed for an adult or post-menarchal pediatric patient.
- The patient meets ONE of the following:
  - The patient has experienced an inadequate treatment response to a course of therapy with fluconazole.
  - The patient has experienced an intolerance to fluconazole.
  - The patient has a contraindication that would prohibit a trial of fluconazole.
- The requested drug is NOT being used in a footbath.

### Vulvovaginal Candidiasis (VVC)

Authorization may be granted when the requested drug is being prescribed for the treatment of vulvovaginal candidiasis (VVC) when ALL of the following criteria are met:

- The requested drug is being prescribed for an adult or post-menarchal pediatric patient.
- The patient meets ONE of the following:
  - The patient has experienced an inadequate treatment response to a course of therapy with fluconazole.

Reference number(s)
4778-E

- The patient has experienced an intolerance to fluconazole.
- The patient has a contraindication that would prohibit a trial of fluconazole.
- The requested drug is NOT being used in a footbath.

## Quantity Limits Apply

Vulvovaginal candidiasis (VVC): 4 tablets per 7 days

Recurrent vulvovaginal candidiasis (RVVC): 4 tablets per 25 days or 12 tablets per 75 days

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

## Duration of Approval (DOA)

- 4778-E:
  - Vulvovaginal Candidiasis (VVC) DOA: 7 days
  - Recurrent vulvovaginal Candidiasis (RVVC) DOA: 6 months

## References

1. Brexafemme [package insert]. Jersey City, NJ: SCYNEXIS, Inc.; November 2022.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed November 29, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 11/29/2024).
4. Pappas PG, Kauffman CA, Andes DR, et al. Clinical practice guideline for the management of candidiasis: 2016 update by the infectious diseases society of America. Clin Infect Dis. 2016;62(4):e1-e50.
5. Paladine HL, Desai UA. Vaginitis: diagnosis and treatment. Am Fam Physician. 2018;97(5):321-329.