



Prior Authorization Approval Criteria

Diflucan VC (fluconazole)

Generic name:	Fluconazole
Brand name:	Diflucan VC
Medication class:	Antifungal
FDA-approved uses:	Vaginal yeast infections due to <i>Candida</i>
Usual dose range:	150 mg one-time dose
Duration of therapy:	One dose is usually sufficient.

Criteria for use of more than 1 pill per treatment (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Patient must have complicated vulvovaginal candidiasis (VVC)*.
- Documented culture to confirm clinical diagnosis and to identify *Candida albicans* or unusual species, including non-*albicans* species (conventional antimycotic therapies are not as effective against these species as against *C. albicans*).
- Failure/intolerance[†] to over the counter or prescription topical preparations[‡] used for a duration of at least 7 to 14 days.

* *Complicated VVC:*

- *Recurrent vulvovaginal candidiasis (4 or more episodes of symptomatic VVC each year) or,*
- *Severe vulvovaginal candidiasis or,*
- *Women with uncontrolled diabetes, debilitation, or immunosuppression*

[†] *Symptoms that persist or recur within 2 months of onset of initial symptoms.*

[‡] *If only Nystatin has been tried, azoles must be attempted, as they are more effective than Nystatin.*

Contraindication: Hypersensitivity to fluconazole.

Not approved if:

- Does not meet the above-stated criteria.
- Patient is pregnant.
- Patient has any contraindications to the use of fluconazole.

Special notes:

- If approved for treatment of more than one tablet, patient will only be approved for 2 150 mg fluconazole tablets, with the second dose to be taken 3 days following the first.
- If approved for a maintenance regimen, patient will only be approved for one 150 mg fluconazole tablet to be taken once a week for no longer than 6 months at a time.

Issues with Diflucan VC:

- OTC products are as effective as Diflucan VC
- Diflucan VC effectiveness decreases as the number of episodes of vaginal candidiasis increases per patient; patients with greater than 4 episodes/12 months are less likely to respond to therapy
- Side-effect profile is increased over the topical preparation
 - GI effects (26%)
 - Liver toxicity
 - Headache
 - Nausea/diarrhea
- Many women still use a topical preparation for the outer vaginal area in addition to Diflucan VC
- Studies evaluating clinical cure or improvement:
 - At 14 days: fluconazole (92% effective) vs. clotrimazole (97% effective)
 - At 35 days: fluconazole (50% effective) vs. clotrimazole (56% effective)
- Wide-spread use of oral fluconazole may lead to increased resistance
- Drug interactions with fluconazole (inhibits Cyp450 3A4):
 - Increases serum concentrations of phenytoin, zidovudine, cyclosporin, cisapride, and warfarin

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 11/15/04