Overview

This policy supports medical necessity review for Brexafemme® (ibrexafungerp) oral tablets.

Medical Necessity Criteria

Ibrexafungerp (Brexafemme) is considered medically necessary when the following are met:

1. **Vulvovaginal candidiasis (VVC).** Individual meets the following criteria:
   A. The individual has a diagnosis of vulvovaginal candidiasis (VVC)

Coverage for Ibrexafungerp (Brexafemme) varies across plans and may require the use of preferred products in addition to the medical necessity criteria listed above. Refer to the customer’s benefit plan document for coverage details.

When coverage requires the use of preferred products, there is documentation of **ONE** of the following:
A. The individual has had inadequate efficacy to the number of covered alternatives according to the table below

OR

B. The individual has a contraindication according to FDA label, significant intolerance, or is not a candidate* for the covered alternatives according to the table below

*Note: Not a candidate due to being subject to a warning per the prescribing information (labeling), having a disease characteristic, individual clinical factor[s], other attributes/conditions, or is unable to administer and requires this dosage formulation

Employer Group Non-Covered Products and Preferred Covered Alternatives by Drug List:

<table>
<thead>
<tr>
<th>Non-Covered Product</th>
<th>Standard / Performance</th>
<th>Value / Advantage</th>
<th>Cigna Total Savings</th>
<th>Legacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brexafemme (ibrexafungerp)</td>
<td>oral fluconazole</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Note: Receipt of sample product does not satisfy any criteria requirements for coverage.

Reauthorization Criteria

Not applicable for continuation beyond initial approval duration.

Authorization Duration

Not applicable.

Conditions Not Covered

Ibrexafungerp (Brexafemme) is considered experimental, investigational or unproven for ANY other use.

Background

OVERVIEW

Brexafemme, an oral antifungal, is indicated for the treatment of vulvovaginal candidiasis in adult and post-menarchal pediatric females. Brexafemme was given a Qualified Infectious Disease Product and Fast Track designations by the FDA.

Guidelines/Recommendations

There are several over the counter (OTC) and prescription therapies available for vulvovaginal candidiasis. OTC intravaginal agents include clotrimazole, miconazole, and tioconazole products. Prescription intravaginal agents include terconazole and butoconazole. Treatment with topical intravaginal azoles results in relief of symptoms and negative cultures in 80% to 90% of patients who complete therapy. There are no data to show superiority of one topical intravaginal product over another. Topical intravaginal treatment may cause local AEs, such as burning and irritation.

With the approval of Brexafemme, there are now two oral options for the treatment of vulvovaginal candidiasis. Oral fluconazole is generally given as a single dose and it is available as a generic product. The efficacy of oral fluconazole and topical intravaginal antifungals are similar. The majority of Candida species, except C. krusei...
and *C. glabrata*, respond to oral fluconazole. Oral fluconazole is an effective treatment option for complicated *C. albicans* and although resistance to *C. albicans* is rare, it has been documented. Neither Brexafemme nor oral fluconazole address the need for an oral product during pregnancy as both products may cause fetal harm. Effective contraception is recommended for females of reproductive potential during treatment and for several days after treatment for both Brexafemme and oral fluconazole. Both products are well-tolerated. AEs associated with oral fluconazole use, such as gastrointestinal intolerance, headache, and liver function test elevations, are usually mild and self-limited. Allergic reactions to oral fluconazole are rare.

Brexafemme is not addressed in the guidelines. According to the American College of Obstetricians and Gynecologists (ACOG) guidelines, the choice of therapy for uncomplicated vulvovaginal candidiasis should be individualized based on patient preference, cost, convenience, adherence, ease of use, and history of response or adverse reactions to previous treatments. The Centers for Disease Control and Prevention (CDC) Sexually Transmitted Disease Treatment Guidelines (2015) and the Clinical Practice Guidelines for the Management of Candidiasis by the Infectious Diseases Society of America (2016) are similar. Guidelines recommend short-courses of topical intravaginal antifungal products to treat uncomplicated vulvovaginal candidiasis. For recurrent vulvovaginal candidiasis, some specialists recommend a longer duration of initial therapy (e.g., 7 to 14 days of topical intravaginal therapy or a 100 mg, 150 mg, or 200 mg oral dose of fluconazole every 3 days for a total of 3 days [Days 1, 4, and 7]) to attempt mycologic remission before starting a maintenance antifungal regimen. Oral fluconazole (given as a 100 mg, 150 mg, or 200 mg dose) weekly for 6 months is the first-line maintenance regimen. For severe vulvovaginal candidiasis, which is associated with lower clinical response rates if treated with short courses of topical intravaginal or oral therapy, either 7 to 14 days of topical intravaginal azole or 150 mg of fluconazole in two sequential oral doses (second dose 72 hours after initial dose) is recommended.

References


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