

## VAGINAL INFECTIONS

A majority of women will experience a vaginal infection during their reproductive years. Family PACT benefits available for vaginitis management are centered mainly on the diagnosis of women with acute vulvovaginal symptoms and treatment of acute episodes of vaginitis. While this Clinical Practice Alert covers a variety of clinical information regarding vaginal infections, some tests and drugs mentioned are not Family PACT benefits. *Services for sexually transmitted infections (STIs) are covered only when the STI is identified or diagnosed during a family planning visit or as follow-up to a family planning visit.*

### KEY POINTS

- A careful history, vulvovaginal exam, and office lab testing all are necessary to evaluate vaginal complaints. Information on sexual practices, gender of sex partners, menses, douching, and other medications should be elicited.<sup>1</sup>
- The saline suspension may yield motile trichomonads, or clue cells, which are characteristic of bacterial vaginosis (BV). White blood count without evidence of trichomonads or yeast is suggestive of cervicitis. The potassium hydroxide (KOH) specimen is used to identify the pseudohyphae of *Candida*.
- Because the sensitivity of microscopy is about 50%, the absence of trichomonads or pseudohyphae does not rule out these infections. In settings where pH paper, KOH, and microscopy are not available, alternative point-of-care tests can be used.

## QUESTIONS AND ANSWERS

### How do women acquire vaginal trichomoniasis (VT)?

VT virtually is always sexually transmitted and the primary risk factor for infection is having had a history of unprotected intercourse with multiple sexual partners. Since a woman can carry vaginal trichomonads for many years, it is not possible to determine if a newly diagnosed infection was caused by a current sexual partner or a previous one.

### Who should be screened or tested for VT?

The 2010 Centers for Disease Control and Prevention (CDC) Sexually Transmitted Diseases (STD) Treatment Guidelines<sup>1</sup> recommend testing for *T. vaginalis* in women seeking evaluation of a vaginal discharge. They add that screening for *T. vaginalis* "can be considered" in those at high risk for VT (i.e., new or multiple partners, a history of STIs, exchange of sex for payment, and use of injection drugs).

### How is VT diagnosed?

Diagnosis is based upon identification of motile trichomonads by saline suspension microscopy. The organism is very sensitive to light, heat, and the concentration of the suspension fluid, so it is important to evaluate the sample within a few minutes. The diagnosis also can be made with a point-of-care test (such as the OSOM Trich Rapid<sup>®</sup>) and a nucleic acid amplification test performed in the laboratory. **NOTE: Neither of these tests are Family PACT benefits.**

### What is the preferred drug regimen to treat VT?

The 2010 CDC STD Treatment Guidelines recommend either metronidazole 2 grams or tinidazole 2 grams taken as a single dose as first line treatment. An alternative regimen is metronidazole 500 mg orally twice a day for 7 days.

### When should tinidazole be used?

The purported benefits of tinidazole include fewer side effects (nausea, vomiting, dizziness) and marginally higher cure rate when compared to oral metronidazole. Since tinidazole is significantly more expensive than metronidazole, its use should be limited to metronidazole failure or intolerance of oral metronidazole due to side effects.

### How should a sexual partner be managed when a woman is diagnosed with VT?

All sexual partners should be treated with metronidazole 2 grams taken as a single oral dose. Patients should be instructed to abstain from sex until they and their sex partners are cured.

### What should I do if a woman has a treatment failure for VT?

Most cases are due to re-infection by an untreated partner or by a new partner who is infected. Because a few strains of *T. vaginalis* are resistant to metronidazole, the CDC STD Treatment Guidelines<sup>1</sup> list a number of alternative regimens.

### What should be done when trichomonads are identified on cervical cytology?

Pap smears are 97-99% specific for the protozoa. If your practice has a high prevalence of trichomonas ( $\geq 5\%$ ), clients with trichomonads on Pap smear should be treated for VT. If the prevalence is low, offer the client a confirmatory exam or test.

### Is bacterial vaginosis (BV) sexually transmitted?

- BV is associated with having multiple male or female partners, a new sex partner, douching, and lack of condom use.
- BV appears to be "sexually associated" in heterosexuals. It is rare in virginal women. There is an increased risk of BV with multiple male partners. A BV carrier state has not been identified in men and treatment of males does not affect recurrence rates in women. Condom use decreases the risk of acquiring BV.
- In women having sex with women, BV can be sexually transmitted. Infected vaginal fluid shared between women can transmit the pathogenic bacteria of BV and studies of concurrence in lesbian couples suggest horizontal transmission.

## VAGINAL INFECTIONS (CONTINUED)

### How is BV diagnosed?

BV is diagnosed on the basis of 3 or more of the following findings:

- A thin white discharge that smoothly coats the vaginal walls and has the appearance and consistency of homogenized milk.
- A fishy odor before or after the addition of 10% KOH to a sample of the discharge ("whiff" test).
- A vaginal pH greater than 4.5, as determined by pH testing of a sample of the discharge taken from the vaginal wall.
- Clue cells constitute 20% or more of all vaginal epithelial cells seen on microscopy of a discharge sample.

A point of care test (OSOM BV Blue<sup>®</sup>) is available and has very good sensitivity and specificity for BV. It should be used when microscopy is not available or is inconclusive for the diagnosis of BV. **NOTE: OSOM BV Blue<sup>®</sup> is not a Family PACT benefit.**

### How should bacterial vaginosis be treated?

The antibiotic regimens recommended by the 2010 CDC STD Treatment Guidelines<sup>1</sup> include:

- Metronidazole 500 mg orally twice a day for seven days; or
- Metronidazole gel 0.75% 5g vaginally daily for 5 days; or
- Clindamycin 2% cream 5g vaginally at bedtime for 7 days. **NOTE: that clindamycin cream is oil-based and might weaken latex condoms and diaphragms for 5 days after use (refer to clindamycin product labeling for additional information).**

Treatment selection to consider is a trade-off of convenience, the potential for side effects, and considerations regarding the use consumption of alcoholic drinks.

- Oral metronidazole is easy to use, but it can have more side effects and the client cannot drink alcoholic beverages.
- Topical medications have fewer side effects and the client can consume alcoholic beverages, but it may be less convenient.
- Women should be advised to refrain from intercourse or to use condoms consistently during the treatment regimen.

Follow-up visits are unnecessary if symptoms resolve. Because recurrence of BV is common, women should be advised to return for evaluation if symptoms recur.

### Should women with confirmed BV, but who have no symptoms or complaints, be treated?

Women with symptomatic BV should be treated. Potential benefits of treating women with asymptomatic BV include reduction in the risk for acquiring *C. trachomatis* or *N. gonorrhoeae*, human immunodeficiency virus, and other viral sexually transmitted infections.

### For the purpose of choosing a treatment regimen, how is vulvovaginal candidiasis (VVC) classified by the CDC?

- Uncomplicated VVC: any of sporadic or infrequent VVC, mild-to-moderate VVC, likely to be *C. albicans*, or non-immunocompromised women. In these cases, the duration of treatment is 1-7 days.
- Complicated VVC: recurrent VVC, severe VVC, non-albicans candidiasis, women with uncontrolled diabetes, debilitation, or immunosuppression. In any of these circumstances, the duration treatment is for 7-14 days.

### How should vaginal candidiasis be treated?

Treatment is available with a variety of topical azole creams and suppositories or fluconazole 150 mg orally as a single dose. The topical products are quickly soothing but inconvenient, while oral treatment is convenient but the effect is not immediate.

## APPLICATION OF FAMILY PACT POLICIES

### Which tests does Family PACT cover for the diagnosis of a client with vaginal symptoms?

Benefits include pH determination (current procedural terminology [CPT] code: 83986) and microscopy of saline and KOH suspensions (CPT: Q0111 or 87210).

### What are the International Classification of Diseases, 9th Revision codes reimbursable under Family PACT for diagnosing and treating vaginal infection?

Services related to vaginal infection are covered under Family PACT only when identified during a family planning visit. Code for **both** a primary diagnosis **and** one of the following secondary diagnosis

- 112.1 Candida vulvovaginitis (VVC)
- 616.10 Vaginitis/Vulvitis/Bacterial vaginosis (BV)
- 131.01 Trichomonal vulvovaginitis (VT)
- 131.02 Trichomonas urethritis (confirmed diagnosis in a male)
- 099.40 Presumptive diagnosis of a male with non-specific urethritis (NSU)
- V01.6 Trichomoniasis-exposed partner

### When does the Family PACT formulary permit the prescription or dispensing of tinidazole for VT?

Prescribe tinidazole for VT only if treatment failure or adverse effects (but not allergy) with prior use of metronidazole.

### Does the Family PACT formulary restrict the prescription of any other drug treatment for vaginitis?

Because of its relatively high cost, terconazole cream should be reserved for use in complicated cases of vaginal candidiasis.

### How often will Family PACT cover claims for vaginitis treatments?

Tinidazole can be dispensed once in 15 days from the prior dispensing; all other treatments for VVC and BV are limited to one dispensing in 30 days. While some women will fail therapy in intervals shorter than these, management of complicated cases is beyond the scope of Family PACT.

### Will Family PACT cover suppressive regimens of vaginal metronidazole gel for recurrent BV or of fluconazole for VVC?

No. Management of complicated cases is beyond the scope of Family PACT.

**Providers should refer to the Family PACT Policies, Procedures, and Billing Instructions for the program policies, benefits and billing information.**

## REFERENCES FOR INFORMATION ON VAGINAL INFECTIONS

1. Workowski KA, Berman S; CDC Sexually Transmitted Diseases Treatment Guidelines, 2010. *MMWR Recomm Rep*. 2010 Dec; 17;59(RR-12):1-110.