



# Patient-Delivered Partner Therapy (PDPT) for Chlamydia, Gonorrhea, and Trichomoniasis: Guidance for Medical Providers in California

These guidelines were developed by the California Department of Public Health Sexually Transmitted Diseases (STD) Control Branch in collaboration with the California STD Controllers Association, and the California Prevention Training Center (CAPTC)

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## **Disclaimer for public health clinical guidelines:**

These guidelines are intended to be used as an educational aid to help clinicians make informed decisions about patient care. The ultimate judgment regarding clinical management should be made by the health care provider in consultation with their patient in light of clinical data presented by the patient and the diagnostic and treatment options available. Further, these guidelines are not intended to be regulatory and not intended to be used as the basis for any disciplinary action against the health care provider.

## Introduction

Patient-delivered partner treatment (PDPT) is an alternative strategy for ensuring that the exposed sex partners of patients diagnosed with a sexually transmitted disease (STD) get needed medication. Specifically, medical providers give medication to the patient, who in turn delivers the medication to his or her sex partner(s).

Since 2001, California medical providers have had the option of using PDPT for the sex partners of patients diagnosed with *Chlamydia trachomatis*, and in 2007 this legislation was expanded to include *Neisseria gonorrhoeae* and other sexually transmitted infections.

In combination, SB 648 (Ortiz, Chapter 835, Statutes of 2000) and AB 2280 (Leno, Chapter 771, Statutes of 2006) amended the law (Health and Safety Code Section 120582) to allow physicians to prescribe, and nurse practitioners, physician assistants, and certified nurse-midwives to dispense, antibiotic therapy for the sex partners of individuals infected with *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, or other sexually transmitted infections as determined by the department, even if they have not been able to perform an exam of the patient's partner(s). This law provides an important means to combat a serious public health problem and prevent adverse reproductive health outcomes.

These guidelines, which are focused on PDPT strategies for chlamydia, gonorrhea, and trichomoniasis, provide information on the most appropriate patients, medications, and counseling procedures developed to maximize patient and public health benefit while minimizing risk.

Importantly, PDPT is not intended as the first-line or optimal partner management strategy. However, this strategy can serve as a useful alternative when the partner is unable or unlikely to seek care. Providers should use their best judgment to determine whether partners will or will not come in for treatment, and to decide whether or not to dispense or prescribe additional medication to the index patient.

This document updates the August 2012 "Patient-Delivered Partner Therapy (PDPT) for Chlamydia, Gonorrhea, and Trichomoniasis: Guidance for Medical Providers in California".

## Summary PDPT Clinical Guidelines for Chlamydia, Gonorrhea, and Trichomoniasis

- **Patient's diagnosis:** Clinical or laboratory diagnosis of chlamydia, gonorrhea, or trichomoniasis.
- **First-choice partner management strategy:** Attempt to bring partners in for complete clinical evaluation, STD testing, counseling, and treatment.
- **Most appropriate patients:** Those with partners who are unable or unlikely to seek timely clinical services.
- **Recommended drug regimens:**
  - Sexual partners of patients with chlamydia, but not gonorrhea: Azithromycin (Zithromax\*) 1 gram (250 mg tablets x 4) orally once
  - Sexual partners of patients with gonorrhea regardless of the chlamydia test result: Cefixime (Suprax\*) 400 mg orally once PLUS Azithromycin (Zithromax\*) 1 gram (250 mg tablets x 4) orally once
  - Sexual partners of patients with trichomoniasis: Metronidazole (Flagyl\*) 2 grams (500 mg tablets x 4) orally once
- **Number of doses:** Limited to the number of known sex partners in previous 60 days (or most recent sex partner if none in the previous 60 days).
- **Labeling and informational materials:** Medications should be properly labeled, and clear instructions, warnings, and clinic referrals should be provided.
- **Patient counseling:** Abstinence until seven days after treatment and until seven days after partners have been treated.
- **Patient retesting:** Recommended three months after treatment.
- **Adverse events:** The law does not protect providers from liability, as is the case for any medical treatment. To report adverse events, email [EPT@cdph.ca.gov](mailto:EPT@cdph.ca.gov) or call 510-620-3400.

\* Use of trade names is for identification only and does not imply endorsement.

## **Background and Rationale**

### **PUBLIC HEALTH IMPORTANCE OF CHLAMYDIA, GONORRHEA, AND TRICHOMONIASIS**

Sexually transmitted chlamydia and gonorrhea infections are significant public health problems. More than 174,000 cases of chlamydia and 44,000 cases of gonorrhea were reported in California in 2014, making them the two most common reportable infections [1]. Genital infections, which are often asymptomatic, can lead to pelvic inflammatory disease (PID), chronic pelvic pain, ectopic pregnancy, and preventable infertility in women [2]. Patients with these infections are also at increased risk of acquiring sexually transmitted HIV [3]. Repeat chlamydia and gonorrhea infections, which increase the risk of complications, occur in 10-15 percent of women and men within six months after treatment [4].

Trichomoniasis is the most common curable sexually transmitted infection. In the United States, the estimated prevalence of trichomoniasis in women is 3 percent with a disproportionate rate of infections (over 10 percent) in non-Hispanic black women [5]. Because trichomoniasis is not a reportable disease and research on prevalence is limited, the epidemiology of the infection in California is not well known and formal screening and control programs are limited. Trichomoniasis infections, which are typically asymptomatic, are associated with adverse pregnancy outcomes including premature rupture of membranes, preterm labor, and low birth weight. Trichomoniasis also increases the risk of acquiring sexually transmitted HIV [3]. Trichomoniasis in male partners of infected women is common (37- 70 percent) [6, 7], as is repeat infection, with 5-16 percent of women reinfected within three months after treatment [8, 9].

To prevent repeat infections, reduce complications in individuals, and reduce further transmission of infection in the community, sex partners of infected patients must be provided timely and appropriate antibiotic treatment.

### **BARRIERS TO EFFECTIVE PARTNER MANAGEMENT**

Currently, there are considerable challenges to effective partner management. Public health efforts to notify and treat sex partners have proven successful and are considered a cornerstone of syphilis control [10]. However, because of the high burden of infection and limited public health resources for partner notification activities, it is difficult for local health departments to provide investigation and partner notification for cases of chlamydia and gonorrhea [11]. In general, public health department resources are not used for partner notification of patients with trichomoniasis since it is not a reportable infection. Thus, the most common strategy for partner management for the majority of chlamydia, gonorrhea, and trichomoniasis cases is patient referral, whereby providers counsel patients about the need for partner treatment and advise them that the responsibility for notifying partners rests with the patient.

Although providers have the option to collect the partners' contact information and notify them, there are no reimbursement mechanisms, and few clinics have the resources for this activity. The effectiveness of patient referral is limited by the patient's ability to notify his or her partner(s), as well as by the partner's willingness and ability to seek

treatment. In particular, some partners may be uninsured and have limited access to medical care. Further, infected partners who are asymptomatic may be less likely to seek needed medical treatment.

## CALIFORNIA LEGISLATION ALLOWING PDPT

In 2001, SB 648 (Ortiz, Chapter 835 Statutes of 2000) amended California law to allow PDPT for chlamydia, and in January 2007, AB 2280 (Leno, Chapter 771 Statutes of 2006) further amended the law to allow PDPT for gonorrhea and other sexually transmitted infections. The current law allows physicians to prescribe, and nurse practitioners, physician assistants, and certified nurse-midwives to dispense, furnish or otherwise provide antibiotic therapy for the male and female sex partners of individuals infected with *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, or other sexually transmitted infections as determined by the department, even if they have not been able to perform an exam of the patient's partner(s).

This legislation (Section 120582 of the Health and Safety Code) provides an exception to the Medical Practice Act, which states that the prescribing, dispensing, or furnishing of dangerous drugs, as defined, without a good-faith prior examination and medical indication, constitutes unprofessional conduct. The new law provides that a licensee acting in accordance with provisions of the law with regard to a prescription for antibiotic therapy has not committed unprofessional conduct under this provision.

## HEALTHCARE PROVIDER RESPONSIBILITIES FOR ENSURING PARTNER TREATMENT

Because of the risk of repeat infection from untreated partners, patients diagnosed with chlamydia, gonorrhea, or trichomoniasis infection cannot be considered adequately treated until all their partners have been treated. All sexual contacts within the previous 60 days from the onset of symptoms or diagnostic test results need to be treated.

For reportable STDs in California, physicians are required by law to: 1) endeavor to discover the source of infection, as well as any sexual or other intimate contacts that the patient made while in the communicable stage of the disease (California Code of Regulations, Title 17, Section 2636); 2) make an effort, through the cooperation of the patient, to bring these persons in for examination and, if necessary, treatment (California Code of Regulations, Title 17, Section 2636); and 3) report cases to the local health officer (California Code of Regulations, Title 17, Section 2500).

The optimal partner management strategy involves providing comprehensive STD care to ensure treatment, confirm the exposure and/or diagnosis, examine the patient, test for other STDs and HIV, provide needed vaccinations, and offer risk-reduction counseling and community referrals.

## EVIDENCE FOR THE EFFECTIVENESS OF PDPT

Several research studies, including randomized clinical trials, have demonstrated that expedited partner treatment (EPT) is safe and as effective as other partner management strategies in facilitating partner notification and reducing recurrent

infection among index cases [12]. EPT is the general term for the practice of treating sex partners of patients diagnosed with an STD without an intervening medical evaluation. PDPT is the most common type of EPT; other types involve alternative delivery mechanisms, such as pharmacies. Data supporting EPT for heterosexual partners of patients with chlamydia or gonorrhea is particularly compelling [13-15]. A meta-analysis that included five clinical trials showed an overall reduced risk (summary risk ratio 0.73, 95 percent confidence interval (CI) 0.57 to 0.93) of recurrent infection in patients with chlamydia or gonorrhea who received EPT, compared with those who received standard partner treatment methods [16]. A report published by the Centers for Disease Control and Prevention (CDC) in 2006 and updated in 2012 provided a review of the research literature, a discussion of programmatic issues related to EPT, and guidance for public health programs and clinicians [17].

Of two randomized trials that evaluated the effectiveness of PDPT for trichomoniasis in women, one trial found no difference in reinfection rates in the PDPT group compared with booklet-enhanced partner referral and partner referral groups [18]. The other trial found significantly lower reinfection rates at 1 month for PDPT compared to public health department partner tracing or partner referral combined with partner tracing [8]. In both trials, PDPT for trichomoniasis was found to be well-accepted, safe, and less expensive than partner referral.

## IMPLEMENTATION AND USE OF PDPT

According to a statewide survey conducted in 2002, nearly half of California physicians and nurse practitioners reported that they routinely use PDPT to treat partners of patients with chlamydia [19]. A 2007 survey of California family planning providers also found that routine use of PDPT was common: 73 percent for chlamydia, 39 percent for gonorrhea, and 56 percent for trichomoniasis [20].

A large study of California family planning clinics from 2005-2006 found that 19 percent of women with chlamydia were given PDPT, and of these, the reported partner treatment rate was as high (80 percent) as for those women who agreed to bring their partners with them to the clinic [21]. An evaluation in San Francisco, California demonstrated successful implementation, with 23 percent of STD patients receiving PDPT [22]; however, an assessment of repeat infection found similar rates regardless of the partner management strategy [23].

As of January 2016, the STD Control Branch had not received any reports of adverse events related to PDPT, despite the availability of a toll-free reporting line from 2001 to 2007 and starting in 2007, an email ([ept@cdph.ca.gov](mailto:ept@cdph.ca.gov)) and telephone (510-620-3400) reporting system.

Reimbursement for PDPT varies by insurance plan.

## LIABILITY ISSUES

The current legislation allowing PDPT for sexually transmitted infections does not protect healthcare providers from lawsuits resulting from adverse outcomes related to

the practice. This liability is no different from the liability of any other action taken by a healthcare provider, including prescribing or dispensing medicine for any medical condition, in which the provider remains liable. The best way to reduce medicolegal liability risk is to practice evidence-based medicine as promulgated by national and state guidelines.

It is reassuring that, as of January 2016, the STD Control Branch had not received any reports of lawsuits related to the practice of providing PDPT. When the prescribing physician is a public official or employee, he or she is immune from tort liability in California when acting within the scope of their authority (Government Code Section 820 and 820.2). However, immunity does not apply to acts of negligence (e.g., prescribing a dangerous or non-therapeutic regimen).

### POTENTIAL PITFALLS IN USING PDPT

There are several concerns about PDPT. First, the medication could cause a serious adverse reaction, including allergy. Second, PDPT may compromise the quality of care provided to partners, particularly if it is used as a first-line approach for partners who would otherwise seek clinical services. Appropriate care for contacts to STD includes testing for other STDs and HIV, physical examination to rule out a complicated infection, and risk-reduction counseling. Ideally, partners who receive PDPT will still access these clinical services.

Despite these concerns, PDPT is likely to benefit partners who would not otherwise receive treatment. Further, these risks may be mitigated through patient education and written materials for partners that provide warnings and encourage visiting a healthcare provider.

Additional concerns about PDPT include misuse of the medication, waste if the medication is not delivered or not taken, and contribution to antibiotic resistance at the population level. Currently, there is no evidence that PDPT is misused or leads to increasing antimicrobial resistance.

# Guidelines for Using PDPT for Chlamydia, Gonorrhea, and Trichomoniasis

## SELECTING APPROPRIATE PATIENTS FOR PDPT

Appropriate patients are those with a clinical or laboratory diagnosis of sexually transmitted chlamydia, gonorrhea, or trichomoniasis infection. Laboratory confirmation of the diagnosis may be based on the findings of culture, microscopy, or a Food and Drug Administration (FDA)-cleared molecular test for *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, or *Trichomoniasis vaginalis*. Providing PDPT without laboratory confirmation should be considered when the provider has a high clinical suspicion for chlamydia, gonorrhea, or trichomoniasis infection and there is concern about loss of follow-up.

Clinicians should attempt to bring partners in for comprehensive health care, including evaluation, testing, and treatment. Clinical services provide the opportunity to ensure treatment; confirm the exposure and/or diagnosis; examine the patient; test for other STDs and HIV; offer reproductive health services, including emergency contraception, family planning, and pregnancy testing; provide needed vaccinations; and offer risk-reduction counseling and community referrals. These services are recommended for partners of patients infected with a sexually transmitted infection [25]. Furthermore, many clinical settings are able to provide first-line therapy for gonorrhea: an injection of ceftriaxone 250 mg IM plus azithromycin 1 g orally.

Patients most appropriate for PDPT are those with partners who are unable or unlikely to seek prompt clinical services. Factors to consider include whether the partner is uninsured, lacks a primary care provider, faces significant barriers to accessing clinical services, or will be unwilling to seek care. Providers should also assess the acceptability of PDPT to both the patient and the partners receiving it. PDPT does not preclude clinic attempts to get partners in for care. Even if PDPT is provided, the partner should still be encouraged to seek follow-up care as soon as possible.

All sex partners in the 60 days prior to diagnosis should be considered at risk for infection and should be treated. If the last sexual encounter was more than 60 days prior to diagnosis, the most recent sexual partner should be treated. Although no specific critical exposure period has been delineated for contacts to trichomoniasis, clinical trials used the 60-day timeframe.

There is no limit to how many partners may be treated using PDPT. Thus, patients can be provided with the number of doses necessary to treat each at-risk partner who can be located by the index patient. A combination of partner strategies also may be used; for example, a patient with several partners may refer one partner to the clinic but take PDPT for other partners.

Providers should assess the partner's symptom status, particularly symptoms indicative of a complicated infection; pregnancy status; and risk for severe medication allergies. If

the partner is pregnant, every effort should be made to contact her for referral to pregnancy services and/or prenatal care. The local health department may be of assistance for these special situations. For partners with known severe allergies to antibiotics, PDPT should not be used.

Partners being treated for gonorrhea exposure should be informed that the oral medications (cefixime 400 mg plus azithromycin 1 g) used for PDPT are not as effective for treating pharyngeal gonorrhea infection, compared with an injection. First-line therapy for gonorrhea is ceftriaxone 250 mg IM plus azithromycin 1 g orally. If partners are at risk for pharyngeal infection (i.e., history of performing oral sex on a man), they should be informed that the PDPT medication may not cure pharyngeal gonorrhea in all patients and that they should be seen by a medical provider.

PDPT can be used regardless of the patient’s gender or sexual orientation. However, the use of PDPT to treat certain partners (e.g., females or men who have sex with men [MSM]) may increase the risk of under-treating a complicated infection or missing a concurrent STD/HIV infection in the partner. In particular, due to the emergence of gonococcal isolates with decreased susceptibility to cephalosporins, particularly among MSM in California, PDPT for MSM with gonorrhea should not be a first-line strategy.

PDPT is not appropriate for patients co-infected with treatable STDs that are not covered by PDPT medication; cases of suspected child abuse, sexual assault, or intimate partner abuse; or situations in which the patients’ safety is in question.

## RECOMMENDED TREATMENT REGIMENS

The recommended antibiotic therapies for PDPT are listed in the table below.

| <b>Infection Diagnosed in Index Patient</b>               | <b>Recommended Medication for PDPT</b>   |
|---|--|
| <b>Chlamydia only</b>                                     | Azithromycin (Zithromax*) tablets 1 gram (250 mg tablets x 4) orally once  |
| <b>Gonorrhea</b><br>(regardless of chlamydia test result) | Cefixime (Suprax*) 400 mg orally once<br>PLUS<br>Azithromycin (Zithromax*) 1 gram (250 mg tablets x 4) orally once |
| <b>Trichomoniasis</b>                                     | Metronidazole (Flagyl*) 2 grams (500 mg tablets x 4) orally once   |

\*Use of trade names is for identification only and does not imply endorsement.

*N. gonorrhoeae* isolates with decreased susceptibility to cefixime or azithromycin, as well as a limited number with decreased susceptibility to ceftriaxone, have been documented [24]. Dual therapy for all patients with gonorrhea is now recommended, regardless of the chlamydia test result, as a strategy that might slow the development of cephalosporin-resistant *N. gonorrhoeae* [25]. The gonorrhea regimen that provides the most effective treatment with sustained bactericidal levels in the blood is intramuscular

ceftriaxone. Currently the first-line therapy for gonorrhea is ceftriaxone 250 mg IM plus azithromycin 1 g orally.

Because injection is not an option for PDPT, dual treatment with cefixime and azithromycin is recommended for PDPT. In published clinical trials conducted prior to 2007, the 400 mg dose of cefixime alone cured 97.5 percent of uncomplicated urogenital and anorectal gonorrhea infections [25]. Although other oral cephalosporins may be effective against gonorrhea, cefixime is the only oral cephalosporin included as an alternative therapy in the 2015 CDC STD treatment guidelines.

In general, oral cephalosporins are less effective in eradicating pharyngeal gonorrheal infection. Providers who are concerned that the partner is at risk for pharyngeal infection, specifically if the partner has performed oral sex on an infected man, should advise the patient that oral treatment may not cure pharyngeal gonorrhea in all patients and that the partner should still seek care to receive first-line therapy of dual treatment using injectable ceftriaxone.

Azithromycin two grams orally should not be used for PDPT for gonorrhea. Although small studies have shown that this regimen is effective against uncomplicated gonococcal infections, there are concerns that widespread use would increase *N. gonorrhoeae* antimicrobial resistance [25]. Reports of azithromycin resistant isolates from Europe and Hawaii are concerning and are further evidence of emerging resistance. Additionally, the two-gram dose of azithromycin can cause gastrointestinal distress.

The recommended metronidazole regimen for trichomoniasis has a cure rate of 90-95 percent; however, treatment success may be diminished because of low-level drug resistance, which affected 2–5 percent of cases, or high-level drug resistance, which is rare. Additionally, HIV coinfection may reduce treatment efficacy [25]. In general, these factors can be overcome using higher doses and/or longer courses of medication. Patients or partners treated for trichomoniasis with persistent symptoms should receive a clinical evaluation to determine the need for additional treatment.

The medication for PDPT may be dispensed or prescribed. The preferred method is dispensing in a pre-packaged partner pack that includes medication, informational materials, and clinic referral. If dispensing is not possible, prescriptions can be provided; however, these prescriptions should be accompanied by informational materials for the partner. The prescriptions can be written separately for the patient and for each of the patient's partners, or written as a single prescription with the names of the patient and partner(s). Although medication instructions may include "take as directed", patients should receive clear instructions for delivery of tablets.

## RISK OF ADVERSE REACTIONS TO MEDICATIONS

Adverse reactions to single-dose cefixime, azithromycin, and metronidazole, beyond mild to moderate side effects, are rare. This risk of allergy and adverse drug reactions may be best mitigated through educational materials that accompany the medication,

which include explicit warnings and instructions for partners who may be allergic to penicillin, cephalosporins, macrolides, or nitroimidazoles to seek medical advice before taking the medication. Examples of PDPT partner instructions and information are available at the end of this document.

Because the STD Control Branch is interested in monitoring EPT-related adverse events, we ask that providers report any known adverse events via e-mail [EPT@cdph.ca.gov](mailto:EPT@cdph.ca.gov) or telephone (510) 620-3400.

Known adverse reactions to cefixime, azithromycin, and metronidazole are included in the following tables:

| <b>CEFIXIME – Adverse Drug Reactions</b>   |
|--|
| <ul style="list-style-type: none"><li>• Cefixime is generally well tolerated, and most adverse reactions in clinical trials were mild and transient. The most commonly seen adverse reactions were gastrointestinal events. Clinically mild gastrointestinal side (GI) effects occurred in 20 percent, moderate GI events occurred in 9 percent, and severe GI events occurred in 2 percent of patients. Diarrhea was reported in 16 percent, nausea in 7 percent, loose or frequent stools in 6 percent, flatulence in 4 percent, and abdominal pain in 3 percent of patients [26]. No other side effects occurred with a frequency greater than two percent.</li></ul> |
| <ul style="list-style-type: none"><li>• Approximately 1-3 percent of patients have a primary hypersensitivity to cephalosporins; however, rates and cross-reactivity vary, depending on the molecular structure [27]. The risk of anaphylaxis with cephalosporin in the general population is between 1 in one million and 1 in 1000 (0.0001-0.1 percent) [28, 29, 30]. However, patients with IgE-mediated allergy to penicillin are at increased risk for severe allergic reactions to cephalosporins. Evidence of IgE-mediated allergy includes anaphylaxis, hypotension, laryngeal edema, wheezing, angioedema, and/or urticaria.</li></ul>                          |
| <ul style="list-style-type: none"><li>• Cefixime has been assigned to pregnancy category B. Animal studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women; or animal studies have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in any trimester.</li></ul>   |

### **CEFIXIME – Reactions Among Penicillin-Allergic Patients**

- Although up to 10 percent of patients report penicillin allergy, the majority (more than 90 percent) are not found to be allergic and are able to tolerate the drug [31]. Cephalosporins are less allergenic than penicillin. The risk of cephalosporin reaction among patients with penicillin allergy is 5-17 percent for first-generation cephalosporins, 4 percent for second-generation, and only 1-3 percent for third- and fourth-generation cephalosporins [32]. Cefixime and ceftriaxone, recommended for the treatment of gonorrhea, are third-generation cephalosporins.
- In a retrospective cohort study of patients receiving penicillin and a subsequent cephalosporin, the risk of an allergic event was about 10-fold higher among those who had had a prior allergic reaction to penicillin; however, the absolute risk of anaphylaxis was very small: 1 in 100,000 [33]. Further, because the risk was similarly elevated among those subsequently given a sulfonamide antibiotic, cross-reactivity may not be an adequate explanation for the increased risk.
- The American Academy of Pediatrics guidelines state that third-generation cephalosporins can be used to treat penicillin-allergic patients as long as the penicillin reaction is not severe (i.e., not IgE-mediated) [28, 29]. Skin testing for penicillin allergy is recommended for patients if the allergic reaction was consistent with IgE-mediated mechanism or if the history is unclear [34]. Such partners should be brought in for treatment for gonorrhea exposure.

### **AZITHROMYCIN – Adverse Drug Reactions**

- Azithromycin is generally well tolerated [35]. The most common side effects in patients receiving a single-dose regimen of one gram of azithromycin are related to the gastrointestinal system: diarrhea/loose stools (7 percent), nausea (5 percent), abdominal pain (5 percent), vomiting (2 percent), and dyspepsia (1 percent). Vaginitis occurs in about one percent of women taking azithromycin. No other side effects have been documented with a frequency greater than one percent.
- Anaphylaxis or severe allergy to macrolides generally, or to azithromycin specifically, is very rare.
- Azithromycin has been assigned to pregnancy category B. Animal studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women; or animal studies have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in any trimester.

| <b>METRONIDAZOLE – Adverse Drug Reactions</b>   |
|---|
| <ul style="list-style-type: none"> <li>• Metronidazole is generally well tolerated; however, nausea is a common adverse reaction affecting about 12 percent of patients [36]. Less common gastrointestinal side effects include vomiting, diarrhea, epigastric distress and abdominal cramping.</li> </ul>  |
| <ul style="list-style-type: none"> <li>• Importantly, alcohol should be avoided until 24 hours after the final metronidazole dose because alcoholic beverages consumed during metronidazole treatment can lead to abdominal cramps, nausea, vomiting, headaches and flushing [36].</li> </ul>   |
| <ul style="list-style-type: none"> <li>• More serious adverse events are very rare, but may include central nervous system reactions such as seizures, encephalopathy, aseptic meningitis, and optic and peripheral neuropathy.</li> </ul>  |
| <ul style="list-style-type: none"> <li>• Hypersensitivity reactions to metronidazole include erythematous rash, urticaria, Stevens-Johnson Syndrome, toxic epidermal necrolysis, flushing, nasal congestion, dry mouth, and/or fever.</li> </ul>  |
| <ul style="list-style-type: none"> <li>• Metronidazole should be used with caution in patients with blood dyscrasias or severe hepatic disease. Metronidazole drug interactions can occur with warfarin, phenytoin, phenobarbital, cimetidine, lithium, and disulfiram.</li> </ul>  |
| <ul style="list-style-type: none"> <li>• Metronidazole has been assigned to pregnancy category B. Animal studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women; or animal studies have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in any trimester.</li> </ul> |

**RISK OF UNDER-TREATING COMPLICATED INFECTIONS AND PHARYNGEAL GONORRHEA, AND MISSING CONCURRENT STD/HIV**

Another risk of PDPT is missing concurrent STD and HIV infections. There is particular concern related to using PDPT for MSM because of the risk of missing an undiagnosed HIV infection. In a multi-site study of STD/HIV co-infection among STD patients who presented as contacts to infected patients, 6.3 percent of MSM had newly diagnosed HIV infection [37]. The risk of missing new HIV infections may be less in areas with easy access to HIV screening.

Because oral cephalosporins are less effective in eradicating pharyngeal gonorrhea infection, inadequate treatment of partners with pharyngeal infection is a potential limitation of PDPT. Providers who are concerned that the partner is at risk for pharyngeal infection should advise the patient that oral treatment may not cure pharyngeal gonorrhea and that the partner should seek clinical services where dual therapy with ceftriaxone and azithromycin is available.

Each of these risks can be mitigated through educational materials that clearly instruct all PDPT recipients to seek care for STD and HIV testing, regardless of whether or not they take the medication. Examples of PDPT partner instructions and information are available at the end of this document. Assistance from the local health department also may be available for challenging partner management situations.

## **PDPT AND PREGNANCY**

Although PDPT is not contraindicated when a patient reports that his female partner may be pregnant, providers should assess whether the pregnant partner is receiving pregnancy services or prenatal care. Every effort should be made to contact the pregnant partner and ensure appropriate care; PDPT should be considered a last resort. The local health department may be of assistance for these special situations. The need for a test of cure for chlamydia and gonorrhea in pregnancy three weeks after treatment should be emphasized. All three recommended PDPT regimens are considered safe in pregnancy (assigned to category B). Doxycycline, a potential alternative to azithromycin for treating chlamydia, should not be used in pregnancy.

## **KEY EDUCATION AND COUNSELING**

Ideally, the medications and educational material should be given to the patient to deliver to the partner. If a prescription is used, then the provider should give the patient both the educational material and the prescription and encourage the patient to deliver both the medication and accompanying informational material to the partner. Examples of PDPT partner instructions and information are available at the end of this document. Providers should discuss the following key counseling messages with their patient when prescribing PDPT.

## KEY PATIENT COUNSELING MESSAGES FOR PDPT

- Partners should seek a complete STD evaluation as soon as possible, regardless of whether they take the medication.
- Partners should read the informational material very carefully before taking the medication.
- Partners who have allergies to antibiotics or who have serious health problems should not take the medications and should see a healthcare provider.
- Partners who have symptoms of a more serious infection (e.g., pelvic pain in women, testicular pain in men, and fever in women or men) should not take the PDPT medications and should seek care as soon as possible.
- Partners who are or could be pregnant should seek care for their pregnancy as soon as possible.
- Patients and partners should abstain from sex for at least seven days after treatment and until seven days after all partners have been treated, in order to decrease the risk of recurrent infection.
- Partners should be advised to seek clinical services for retesting three months after treatment.

### *Additional key counseling message for patients given PDPT for gonorrhea:*

- Partners who are at risk for gonorrhea infection in the pharynx (history of performing oral sex on a man) should be informed that the PDPT medicines given to them may not cure pharyngeal gonorrhea in all patients. These partners should seek care regardless of whether they take the medication.

## PATIENT FOLLOW-UP AND RETESTING AT THREE MONTHS

Because a high prevalence of chlamydia, gonorrhea, and trichomonas infection has been observed in women and men after treatment [4], the CDC recommends that these patients be retested approximately 3 months after treatment, regardless of whether they believe that their sex partners were treated [25]. Additionally, partners should be encouraged to get tested three months after treatment.

No data support retesting in men diagnosed with trichomoniasis.

## Resources

### CALIFORNIA PDPT RESOURCES:

- [PDPT partner information materials](http://www.std.ca.gov/) (<http://www.std.ca.gov/>) are available online at [www.std.ca.gov](http://www.std.ca.gov/). Materials are available in English and Spanish and include instructions for chlamydia treatment, gonorrhea treatment, and trichomonas treatment.
- Adverse reaction reporting via email: [EPT@cdph.ca.gov](mailto:EPT@cdph.ca.gov); or telephone: (510) 620-3400
- [Information on California legislation](http://leginfo.legislature.ca.gov/) (<http://leginfo.legislature.ca.gov/>) is available. Search California Law, Health and Safety Code, Keyword "120582".
- For information on local STD control efforts, please call your local STD control program, visit the [California Department of Public Health STD website](http://www.std.ca.gov/) ([www.std.ca.gov](http://www.std.ca.gov/)) or call the California Department of Public Health STD Control Branch at (510) 620-3400.
- The California STD/HIV Prevention Training Center offers courses in the clinical management of STDs ([www.stdhivtraining.org](http://www.stdhivtraining.org)), as well as partner management and counseling. Please visit the [California STD/HIV Prevention Training Center website](http://www.stdhivtraining.org) ([www.stdhivtraining.org](http://www.stdhivtraining.org)) or call (510) 625-6000.

### CALIFORNIA STD CLINICAL PRACTICE GUIDELINES

(available on the [CDPH STD Control Branch website](http://www.std.ca.gov/) ([www.std.ca.gov](http://www.std.ca.gov/)))

- California STD Treatment Guidelines for Adults and Adolescents (two-page summary table, updated 2015)
- California STD Screening Recommendations (2015)
- Best Practices for Preventing Repeat Chlamydial and Gonococcal Infections (2015)
- California Guidelines for STD Screening and Treatment in Pregnancy (2015)
- Clinician's Guide to Sexual History Taking (2015)

### CDC STD GUIDELINES

- [Sexually Transmitted Disease Treatment Guidelines](http://www.cdc.gov/std/treatment) ([www.cdc.gov/std/treatment](http://www.cdc.gov/std/treatment))
- [Expedited Partner Therapy in the Management of Sexually Transmitted Diseases](http://www.cdc.gov/std/EPT) ([www.cdc.gov/std/EPT](http://www.cdc.gov/std/EPT))

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## **Examples of PDPT Partner Information Materials**

Directions for Sex Partners of Persons with Chlamydia

Directions for Sex Partners of Persons with Gonorrhea

Directions for Sex Partners of Persons with Trichomoniasis

\* Spanish language materials available upon request.

**URGENT and PRIVATE**  
***IMPORTANT INFORMATION ABOUT YOUR  
HEALTH***

**DIRECTIONS FOR SEX PARTNERS OF  
PERSONS WITH CHLAMYDIA**

PLEASE READ THIS VERY CAREFULLY.

Your sex partner has recently been treated for chlamydia.

Chlamydia is a sexually transmitted disease (STD) that you can get from having any kind of sex (oral, vaginal, or anal) with a person who already has it. You may have been exposed. The good news is that it's easily treated.

You are being given a medicine called azithromycin (sometimes known as "Zithromax") to treat your chlamydia. Your partner may have given you the actual medicine or a prescription that you can take to a pharmacy. These are instructions for how to take azithromycin.

The best way to take care of this infection is to see your own doctor or clinic provider right away. If you can't get to a doctor in the next several days, you should take the azithromycin.

Even if you decide to take the medicine, it is very important to see a doctor as soon as you can, to get tested for other STDs. People can have more than one STD at the same time. Azithromycin will not cure other infections. Having STDs can increase your risk of getting HIV, so make sure to also get an HIV test.

#### **SYMPTOMS**

Some people with chlamydia have symptoms, but many do not. Symptoms may include having an unusual discharge from the penis, vagina, or anus. You may also have pain when you urinate (pee) or when having sex. Symptoms may include pain in your testicles (balls), pelvis, or lower part of your belly. Many people with chlamydia do not know they are infected because they feel fine.

#### **BEFORE TAKING THE MEDICINE**

Before you take the medicine, please read the following:

The medicine is very safe. However, **DO NOT TAKE IT** if any of the following are true:

- You are female and have lower belly pain; pain during sex; vomiting; or fever.
- You are male and have pain or swelling in the testicles (balls) or fever.
- You have ever had a bad reaction, rash, breathing problems, or allergic reaction after taking azithromycin or other antibiotics. People who are allergic to some

antibiotics may be allergic to other types. If you do have allergies to antibiotics, you should check with your doctor before taking this medicine.

- You have a serious long-term illness, such as kidney, heart, or liver disease.
- You are currently taking another prescription medication.

If any of these circumstances exist, or if you are not sure, do not take the azithromycin. Instead, you should talk to your doctor as soon as possible. Your doctor will find the best treatment for you.

## WARNINGS

If you do not take medicine to cure chlamydia, you can get very sick. If you are a woman, you might not be able to have children.

If you are pregnant, it is safe to take the azithromycin, but you should still get a full check-up.

## HOW TO TAKE THE MEDICINE

- You can take these pills with or without food.
- You should have four pills of azithromycin. Each pill contains 250 mg of the medicine. You should take all four pills with water at the same time. You need to take all four pills to be cured.
- Do NOT take antacids (such as Tums, Roloids, or Maalox) for one hour before or two hours after taking the azithromycin pills.
- Do NOT share or give this medication to anyone else.

## SIDE EFFECTS

You may experience some side effects, including:

- Slightly upset stomach;
- Diarrhea;
- Dizziness;
- Vaginal yeast infection.

These are well-known side effects and are not serious.

## ALLERGIC REACTIONS

**Call 911 or go to the nearest emergency room immediately if you have:**

- Difficulty breathing/tightness in the chest;
- Closing of your throat;
- Swelling of your lips or tongue;
- Hives (bumps or welts on your skin that itch intensely).

## NEXT STEPS

Now that you have your azithromycin, do not have sex for the next seven days after you have taken the medicine. It takes seven days for the medicine to cure chlamydia. If

you have sex without a condom, or with a condom that breaks, during those first seven days, you can still pass on the infection to your sex partners. You can also get re-infected yourself.

If you have any other sex partners, tell them you are getting treated for chlamydia, so they can get treated too.

People who are infected with chlamydia once are very likely to get it again. It is a good idea to get tested for chlamydia three months from now to be sure you did not get another infection.

If you have any questions about the medicine, chlamydia, or other STDs, please call:  
*[Each local health jurisdiction (LHJ) will list its phone number here.]*

All calls are confidential.

For a free STD exam, testing, and medicine, you can come to:  
*[Each LHJ will list local clinics here.]*

Congratulations on taking good care of yourself!

For more information on chlamydia and other STDs, please visit the [inSPOT website](http://www.inspot.org) (www.inspot.org) or the [American Sexual Health Association website](http://www.ashasexualhealth.org) (www.ashasexualhealth.org).

## URGENT and PRIVATE

### ***IMPORTANT INFORMATION ABOUT YOUR HEALTH***

## **DIRECTIONS FOR SEX PARTNERS OF PERSONS WITH GONORRHEA**

### PLEASE READ THIS VERY CAREFULLY.

Your sex partner has recently been treated for gonorrhea. Chlamydia also may have been diagnosed and treated.

Gonorrhea and chlamydia are sexually transmitted diseases (STD) that you can get from having any kind of sex (oral, vaginal, or anal) with a person who is infected. You may have been exposed. The good news is that it's easily treated.

You are being given two different types of medicine. One is called cefixime (sometimes known as "Suprax"). The other is called azithromycin (sometimes known as "Zithromax"). You need to take both medicines at the same time to treat your infection. Your partner may have given you both medicines or a prescription that you can take to a pharmacy. These are instructions for how to take cefixime and azithromycin.

The best way to take care of this infection is to see your own doctor or clinic provider right away. The best medication to treat gonorrhea is an injection (shot) of a medication called ceftriaxone plus the azithromycin. If you can't get to a doctor in the next several days, you should take the cefixime and azithromycin.

If you performed oral sex on someone with gonorrhea, these medicines may not work as well to cure an infection in your throat. You should be seen by a doctor or clinic provider.

Even if you decide to take the medicines, it is very important to see a doctor as soon as you can to get tested for other STDs. People can have more than one STD at the same time. Cefixime and azithromycin will not cure other infections. Having STDs can increase your risk of getting HIV, so make sure to also get an HIV test.

### **SYMPTOMS**

Some people with gonorrhea or chlamydia have symptoms, but many do not. Symptoms may include having an unusual discharge from the penis, vagina, or anus. You may also have pain when you urinate (pee). Symptoms sometimes include pain in your testicles (balls), pelvis, or lower part of your belly. Many people do not know they are infected because they feel fine.

### **BEFORE TAKING THE MEDICINE**

Before you take the medicine, please read the following:

The medicines are safe. However, **DO NOT TAKE IT** if any of the following are true:

- You are female and have lower belly pain; pain during sex; vomiting; or fever.

- You are male and have pain or swelling in the testicles (balls) or fever.
- You have one or more painful and swollen joints or a rash all over your body.
- You have ever had a bad reaction, rash, breathing problems, or an allergic reaction to cefixime, azithromycin or other antibiotics. People who are allergic to some antibiotics may be allergic to other types. If you do have allergies to antibiotics, you should check with your doctor before taking this medicine.
- You have a serious long-term illness, such as kidney, heart, or liver disease.
- You are currently taking another prescription medication.

If any of these circumstances exist, or if you are not sure, do not take the cefixime or the azithromycin. Instead, you should talk to your doctor as soon as possible. Your doctor will find the best treatment for you.

## WARNINGS

If you performed oral sex on someone who was infected with gonorrhea, the medicines may not work as well. You should see a doctor to get stronger medicine.

If you do not take these medicines, you can get very sick. If you are a woman, it can make you unable to have children.

If you are pregnant, it is safe to take the cefixime and azithromycin, but you should still get a full check-up.

## HOW TO TAKE THE MEDICINE

- Take the medicines with food. This will decrease the chances of having an upset stomach and will increase the amount your body absorbs.
- You should have one pill of cefixime (400 mg) and four pills of azithromycin (250 mg each). Take all 5 pills with water at the same time. You need to take all 5 pills to be cured.
- Do NOT take antacids (such as Tums, Roloids, or Maalox) for one hour before or two hours after taking the medicine.
- Do not share or give these medicines to anyone else.

## SIDE EFFECTS

You may experience some side effects, including:

- Slightly upset stomach
- Diarrhea
- Dizziness
- Nausea
- Gas
- Vaginal yeast infection.

These are well-known side effects and are not serious.

## ALLERGIC REACTIONS

**Call 911 or go to the nearest emergency room immediately if you have:**

- Difficulty breathing/tightness in the chest
- Closing of your throat
- Swelling of your lips or tongue\
- Hives (bumps or welts on your skin that itch intensely).

## NEXT STEPS

Now that you have your medicines, do not have sex for the next seven days after you have taken the medicine. It takes seven days for the medicine to cure gonorrhea. If you have sex without a condom, or with a condom that breaks, during those first seven days, you can still pass on the infection to your sex partners. You can also get re-infected yourself.

If you have any other sex partners, tell them you are getting treated for gonorrhea, so they can get treated too.

If you think you have symptoms of a gonorrhea or chlamydia infection and they do not go away within seven days after taking this medicine, please go to a doctor for more testing and treatment.

People who are infected with gonorrhea or chlamydia once are very likely to get it again. It is a good idea to get tested for gonorrhea and chlamydia three months from now to be sure you did not get another infection.

If you have any questions about the medicine, gonorrhea, chlamydia, or other STDs, please call:

*[Each local health jurisdiction (LHJ) will list its phone number here.]*

All calls are confidential.

For a free STD exam, testing, and medicine, you can come to:

*[Each LHJ will list local clinics here.]*

Congratulations on taking good care of yourself!

For more information on gonorrhea and other STDs, please visit the [inSPOT website](http://www.inspot.org) (www.inspot.org) or the [American Sexual Health Association website](http://www.ashasexualhealth.org) (www.ashasexualhealth.org).

## URGENT and PRIVATE

### ***IMPORTANT INFORMATION ABOUT YOUR HEALTH***

## **DIRECTIONS FOR SEX PARTNERS OF PERSONS WITH TRICHOMONIASIS**

### PLEASE READ THIS VERY CAREFULLY.

Your sex partner has recently been treated for trichomoniasis.

Trichomoniasis is a sexually transmitted disease (STD) that you can get from having vaginal sex with a person who already has it. You may have been exposed. The good news is that it's easily treated.

You are being given a medicine called metronidazole (also known as "Flagyl") to treat your trichomoniasis. Your partner may have given you the actual medicine or a prescription that you can take to a pharmacy. These are instructions for how to take metronidazole.

The best way to take care of this infection is to see your own doctor or clinic provider right away. If you can't get to a doctor in the next several days, you should take the metronidazole.

Even if you decide to take the medicine, it is very important to see a doctor as soon as you can, to get tested for other STDs. People can have more than one STD at the same time. Metronidazole will not cure other infections. Having STDs can increase your risk of getting HIV, so make sure to also get an HIV test.

### **SYMPTOMS**

Most of the time men with trichomoniasis don't have any symptoms but some men may have pain when they urinate (pee) or discharge from their penis. Women may have yellow, green or gray vaginal discharge with a fishy smell. Women may also have itching or burning in the vagina and pain or burning with urination. Many people with trichomoniasis do not know they are infected because they feel fine.

### **BEFORE TAKING THE MEDICINE**

Before you take the medicine, please read the following:

The medicine is very safe. However, **DO NOT TAKE IT** if any of the following are true:

- You are female and have lower belly pain; pain during sex; vomiting; or fever.
- You are male and have pain or swelling in the testicles (balls) or fever.
- You have ever had a bad reaction, rash, breathing problems, or allergic reaction after taking metronidazole or other antibiotics. People who are allergic to some antibiotics may be allergic to other types. If you do have allergies to antibiotics, you should check with your doctor before taking this medicine.

- You have a serious long-term illness, such as kidney, heart, or liver disease or a blood or neurological disorder.
- You have blood or liver disease.
- You are currently taking another prescription medication or if you are taking cimetidine, which is available over the counter.

If any of these circumstances exist, or if you are not sure, do not take the metronidazole. Instead, you should talk to your doctor as soon as possible. Your doctor will find the best treatment for you.

## WARNINGS

**DO NOT DRINK ANY ALCOHOL FOR 24 HOURS BEFORE AND AFTER TAKING METRONIDAZOLE. IT CAN CAUSE NAUSEA AND VOMITING. HEADACHE AND FLUSHING.**

If you are pregnant, it is safe to take the metronidazole, but you should still get a full check-up.

## HOW TO TAKE THE MEDICINE

- You should take these pills with food to prevent stomach upset.
- You should have four pills of metronidazole. Each pill contains 500 mg of the medicine. You should take all four pills at the same time. You need to take all four pills to be cured.
- Do NOT share or give this medication to anyone else.

## SIDE EFFECTS

You may experience some side effects, including:

- Upset stomach, nausea, vomiting, diarrhea
- Dizziness, headache
- Dry mouth, change in taste
- Vaginal yeast infection.

These are well-known side effects and are not serious.

## ALLERGIC REACTIONS

**Call 911 or go to the nearest emergency room immediately if you have:**

- Difficulty breathing/tightness in the chest
- Closing of your throat
- Swelling of your lips or tongue
- Hives (bumps or welts on your skin that itch intensely)

## NEXT STEPS

Now that you have your metronidazole, do not have sex for the next seven days after you have taken the medicine. It takes seven days for the medicine to cure trichomoniasis. If you have sex without a condom, or with a condom that breaks, during those first seven days, you can still pass on the infection to your sex partners. You can also get re-infected yourself.

If you have any other sex partners, tell them you are getting treated for trichomoniasis, so they can get treated too.

People who are infected with trichomoniasis once are very likely to get it again. If you are female, it is a good idea to get tested for trichomoniasis three months from now to be sure you did not get another infection. Unfortunately, screening tests are not widely available for males. However, if you have symptoms, you should see a doctor.

If you have any questions about the medicine, trichomoniasis, or other STDs, please call:

*[Each local health jurisdiction (LHJ) will list its phone number here.]*

All calls are confidential.

For a free STD exam, testing, and medicine, you can come to:

*[Each LHJ will list local clinics here.]*

Congratulations on taking good care of yourself!

For more information on trichomoniasis and other STDs, please visit the [inSPOT website](http://www.inspot.org) (www.inspot.org) or the [American Sexual Health Association website](http://www.ashasexualhealth.org) (www.ashasexualhealth.org).