



CALIFORNIA
STD/HIV PREVENTION
TRAINING CENTER



Patient-Delivered Partner Therapy (PDPT) for *Chlamydia trachomatis* and *Neisseria Gonorrhoeae*: Interim* 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, the California STD/HIV Prevention Training Center, and the California Chlamydia Action Coalition

* These Interim Guidelines, published June 2011, are based on the 2007 PDPT Guidance and have been revised to include updated gonorrhea treatment recommendations for dual therapy and precautions related to the treatment of pharyngeal gonorrhea infection.

Patient-Delivered Partner Therapy (PDPT) for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*: Interim Guidance for Medical Providers in California

Introduction

As of January 1, 2007, California medical providers have the option for ensuring effective partner treatment for the sex partners of patients diagnosed with *Neisseria gonorrhoeae*. The 2007 legislation expands upon the 2001 legislation allowing patient-delivered partner therapy (PDPT) for *Chlamydia trachomatis*.

In combination, SB 648 (Ortiz, Chapter 835, Statutes of 2000) and AB 2280 (Leno, Chapter 771, Statutes of 2006) amended current law and 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* and *Neisseria gonorrhoeae*, even if they have not been able to perform an exam of the patient's partner(s).

This document is intended to provide interim guidance for clinical practice in the implementation of this California legislation (Health and Safety Code Section 120582). It updates the March 2007 document, "Patient-Delivered Partner Therapy (PDPT) for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*: Guidance for Medical Providers in California," which in turn updated the June 2001 PDPT guidance for chlamydia PDPT.

The following guidelines are focused on PDPT strategies and provide information on the most appropriate patients, medications, and counseling procedures developed to maximize patient and public health benefit while minimizing risk.

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. The California Department of Public Health disclaims all liability for the accuracy or completeness of these guidelines and disclaims all warranties express or implied. 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.

Summary Clinical Guidelines

- **Patient's diagnosis:** Clinical or laboratory diagnosis of *Chlamydia trachomatis* or *Neisseria gonorrhoeae*.
- **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 diagnosed with chlamydia, but not gonorrhea:
Azithromycin (Zithromax^{*}) 1 gram (250 mg tablets x 4) orally once
 - Sexual partners of patients diagnosed 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
- **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).
- **Informational materials** with clear instructions, warnings, and clinic referrals should accompany PDPT medication.
- **Patient counseling:** Abstinence until seven days after treatment and until seven days after partners have been treated.
- **Patient re-testing** for gonorrhea and chlamydia is 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 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 AND GONORRHEA

Sexually transmitted chlamydia and gonorrhea infections are significant public health problems. More than 150,000 cases of chlamydia and 26,000 cases of gonorrhea were reported in California in 2010, making them the two most common reportable infections [1]. Genital infections 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 gonorrhea infections, which increase the risk of complications, occur in up to 11 percent of women and men within six months after treatment [4, 5]. Repeat chlamydia infections occur in up to 13 percent of patients in this same time period [6]. 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 [7]. 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 gonorrhea and chlamydia [8]. Thus, the standard of care for partner management for gonorrhea and chlamydia cases has become 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 choice in notifying the partner, as well as by the partner's choice in seeking 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 FOR CHLAMYDIA AND GONORRHEA

Expedited partner treatment (EPT) for chlamydia and gonorrhea is an alternative strategy for ensuring that sex partners get needed medication. 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, in which the patient delivers the medication to his or her sex partner(s). Other types of EPT involve alternative delivery mechanisms, such as pharmacies.

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. 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* or *Neisseria gonorrhoeae*, 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. This new law provides an important means to combat a serious public health problem and prevent adverse reproductive health outcomes.

This option allowing providers to use PDPT is not intended as the first and optimal choice of treatment for partners of individuals diagnosed with gonorrhea and chlamydia. 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.

HEALTHCARE PROVIDER RESPONSIBILITIES FOR ENSURING PARTNER TREATMENT

Patients diagnosed with chlamydia or gonorrhea 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.

In California, physicians are still 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).

EVIDENCE FOR THE EFFECTIVENESS OF EPT FOR CHLAMYDIA AND GONORRHEA

Several research studies, including randomized clinical trials, have demonstrated that EPT is as effective as other partner management strategies in facilitating partner notification and reducing recurrent infection among index cases. 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 [9]. Several trials in the U.S. have demonstrated

that EPT is safe and effective for treating heterosexual partners of patients with chlamydia or gonorrhea [10, 11, 12].

A report published by the Centers for Disease Control and Prevention (CDC) in 2006 provided a thorough review of the research literature, a discussion of programmatic issues related to EPT, and guidance for public health programs and clinicians [13].

IMPLEMENTATION AND USE OF PDPT

In a national physician survey conducted in 2000, researchers at CDC found that the practice of PDPT for chlamydia and gonorrhea was not uncommon [14, 15]. According to a 2002 California survey, nearly half of California physicians and nurse practitioners reported that they routinely use PDPT to treat partners of patients with chlamydia [16]. A local evaluation, in San Francisco, California demonstrated successful implementation, with 23 percent of STD patients receiving PDPT [17].

As of May 2011, the STD Control Branch had not received any reports of adverse events related to PDPT for chlamydia, despite the availability of a toll-free reporting line from 2001 to 2007. Starting in 2007 the mechanism to report adverse events was changed to email (ept@cdph.ca.gov) plus the STD Control Branch main phone line, with no adverse events reported from 2007 to 2011.

For some insurance plans in California, reimbursement for PDPT has not kept up with policy and practice changes. Because this practice provides preventive care for the patient by reducing recurrent infection and subsequent reproductive health complication, the STD Control Branch encourages public and private insurers to support this practice.

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. However, guidelines establish a standard of care, and standard of care is the primary medicolegal standard for appropriate practice. It is reassuring that, as of May 2011, 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 EPT

There are several concerns about EPT. First, the medication could cause a serious adverse reaction, including allergy. Second, EPT 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 EPT will still access these clinical services. Despite these concerns, the benefits of EPT outweigh the risks, since doing nothing for these partners is more harmful. 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 EPT 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 EPT is misused or leads to increasing antimicrobial resistance.

Guidelines for Using PDPT for Chlamydia and Gonorrhea

SELECTING APPROPRIATE PATIENTS FOR PDPT

Appropriate patients are those with a clinical diagnosis of sexually transmitted chlamydia or gonorrhea infection. Laboratory confirmation of the diagnosis may include a gram stain of urethral exudate showing gram negative diplococci indicative of gonorrhea; a positive culture test for chlamydia or gonorrhea; a positive nucleic acid hybridization test for chlamydia or gonorrhea (e.g., GenProbe PACE 2 or Qiagen Hybrid Capture 2); or a positive nucleic acid amplification test (NAAT) for chlamydia or gonorrhea (e.g., GenProbe Aptima Combo 2, Becton Dickinson ProbeTec, Roche polymerase chain reaction (PCR) Amplicor). Because of their high sensitivity, NAATs are the tests of choice for chlamydia screening and testing [18].

Providing PDPT without laboratory confirmation should be considered when the provider has a high clinical suspicion for chlamydia or gonorrhea infection in the index case 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 diagnosis; examine the patient; test for other STDs, HIV, and pregnancy; provide needed vaccinations; and offer risk-reduction counseling and community referrals. These services constitute the standard of care for all partners of patients infected with a sexually transmitted infection. Clinical services also afford partners who have been exposed to gonorrhea the most effective treatment: dual therapy with ceftriaxone 250 mg IM plus either azithromycin 1 g orally once or doxycycline 100 mg twice a day for 7 days.

Thus, patients most appropriate for PDPT are those with partners who are unable or unlikely to seek prompt clinical services. Factors to consider in the patient's report are 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. Partners being treated for gonorrhea exposure should be informed that the oral medications (cefixime 400 mg and azithromycin 1 g) used for PDPT are not as effective for treating pharyngeal gonorrhea infection, compared with an injection. First-line therapy for gonorrhea (ceftriaxone 250 mg IM plus either azithromycin 1 g orally or doxycycline 100 mg orally twice a day for 7 days) is available in many clinical settings. 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.

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.

The legislation permits PDPT 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. Further, PDPT is not appropriate for patients co-infected with STDs that are not covered by PDPT medication; cases of suspected child abuse, sexual assault, or abuse; or a situation in which the patient’s safety is in doubt.

RECOMMENDED TREATMENT REGIMENS

The legislation does not mandate a specific antibiotic. The recommended antibiotic therapy for PDPT is listed in the table below.

Infection Diagnosed in Index Patient	Recommended Medication for PDPT
Chlamydia only	Azithromycin (Zithromax [*]) tablets 1 gram (250 mg tablets x 4) orally once
Gonorrhea (regardless of chlamydia test result)	Cefixime (Suprax [*]) 400 mg orally once PLUS Azithromycin (Zithromax [*]) 1 gram (250 mg tablets x 4) orally once

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CDC monitoring of quinolone-resistant *N. gonorrhoeae* strains have demonstrated wide distribution throughout the United States. As of April 2007, fluoroquinolones were no longer recommended for gonorrhea treatment in the United States [18, 19]. Reports of *N. gonorrhoeae* with decreased susceptibility to cefixime or azithromycin, and a limited number with decreased susceptibility to ceftriaxone have been documented [18]. Dual

therapy for all patients with gonorrhea is being recommended, regardless of the chlamydia test result, as a strategy that might slow the development of antimicrobial-resistant *N. gonorrhoeae* [18]. Few oral cephalosporins have been studied and found to be effective against gonorrhea. Cefixime along with either azithromycin or doxycycline is the only oral cephalosporin that is recommended for gonorrhea treatment in the 2010 CDC STD Treatment Guidelines. However, the gonorrhea regimen that provides the most effective treatment with sustained bactericidal levels in the blood is ceftriaxone IM. Cefixime is recommended for PDPT because IM injection is not an option.

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.

Azithromycin two grams orally should not be used for PDPT. 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 [18]. Recent reports from San Diego County of gonococcal isolates with reduced susceptibility to azithromycin are concerning and are further evidence of emerging resistance. In addition, the two-gram dose of azithromycin causes significant gastrointestinal distress and may be expensive.

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. The law does not specify how many partners may be treated through this strategy. Thus, patients should be provided with the number of doses necessary to treat each at-risk partner who can be contacted 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.

The medication for PDPT may be dispensed or prescribed. The preferable method is dispensing in a pre-packaged partner pack that includes medication, informational materials, and clinic referral. If dispensing is not possible, prescriptions also can be provided; however, these prescriptions should include 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). Medication instructions may include "take as directed", and patients should receive clear instructions for delivery of tablets.

RISK OF ADVERSE REACTIONS TO MEDICATIONS

Adverse reactions to single-dose cefixime and azithromycin, 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, or macrolides to seek medical advice before taking the medication. Examples of partner therapy instructions and information are available in English and Spanish online at www.std.ca.gov.

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; or telephone: (510) 620-3400.

Known adverse reactions to cefixime and azithromycin are as follows:

➤ **Cefixime**

Cefixime is generally well tolerated, and most reactions in clinical trials were mild and transient. The most commonly seen adverse reactions were gastrointestinal events. Clinically mild gastrointestinal side effects occurred in 20 percent, moderate events occurred in 9 percent, and severe 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 [21]. No other side effects occurred with a frequency greater than two percent.

Approximately one percent to three percent of patients have a primary hypersensitivity to cephalosporins; however, rates and cross-reactivity vary, depending on the molecular structure [22]. The risk of anaphylaxis with cephalosporin in the general population is 0.0001 percent to 0.1 percent [23-25]. 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.

Approximately 10 percent of patients report penicillin allergy; however, more than 90 percent of them are found not to be allergic and are able to tolerate the drug [26]. Cephalosporins are less allergenic than penicillin. The risk of cephalosporin reaction among patients with penicillin allergy is 5 percent to 17 percent for first-generation cephalosporins, 4 percent for second-generation, and only 1 percent to 3 percent for third- and fourth-generation cephalosporins [27]. 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 ten-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 [28]. 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, which establish a medicolegal standard of care, 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) [23, 24]. 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 [29]. Such partners should be brought in for treatment for gonorrhea exposure.

➤ **Azithromycin**

Azithromycin is generally well tolerated [30]. 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 (seven percent), nausea (five percent), abdominal pain (five percent), vomiting (two percent), and dyspepsia (one 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, and to azithromycin specifically, is very rare.

RISK OF UNDER-TREATING COMPLICATED INFECTIONS 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 infection, 6.3 percent of MSM had newly diagnosed HIV infection [31]. The risk of missing new HIV infections may be less in areas with ready 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 in all patients and that the partner should seek care.

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. In particular, those with specific symptoms such as pelvic pain or testicular pain should seek medical care; pregnant women should seek regular prenatal care and receive a test-of-cure (TOC); and MSM should seek HIV testing. Examples of partner therapy instructions and information are available in English and Spanish online at www.std.ca.gov. Assistance from the local health department also may be available for these challenging partner 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 TOC for chlamydia and gonorrhea in pregnancy in three weeks should be emphasized. Both recommended PDPT regimens are safe in pregnancy. Doxycycline, a potential substitute for azithromycin, 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 partner therapy instructions and information are available in English and Spanish online at www.std.ca.gov.

Providers should discuss the following key counseling messages with their patient when prescribing 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 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 re-testing three months after treatment.

Additional key counseling message to be discussed with patients when prescribing 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 RE-TESTING AT THREE MONTHS

To ensure the effectiveness of PDPT, providers should schedule both male and female patients to return for re-testing for gonorrhea and chlamydia three months after treatment.

Resources

CALIFORNIA EPT RESOURCES:

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

CALIFORNIA STD CLINICAL PRACTICE GUIDELINES (all available online at: www.std.ca.gov)

- California STD Treatment Guidelines Table for Adults and Adolescents (two-page summary, updated 2011)
- California Gonorrhea Screening Guidelines for Women in Family Planning and Primary Care Settings (2006)

CDC STD PRACTICE GUIDELINES

- Sexually Transmitted Disease Treatment Guidelines, 2010. Available online at www.cdc.gov/std/treatment.
- Expedited Partner Therapy in the Management of Sexually Transmitted Diseases. 2006. Available online: 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

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 pain in your testicles (balls), pelvis, or lower part of your belly. You may also have pain when you urinate (pee) or when having sex. 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** 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, including medicine for diabetes.

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 250mg 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

Very serious allergic reactions include:

- 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).

If you experience any of these, call 911 or go to the nearest emergency room immediately.

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 www.inspot.org or www.ashastd.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. 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). 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** 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, including medicine for diabetes.

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

Very serious allergic reactions include:

- 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).

If you experience any of these, call 911 or go to the nearest emergency room immediately.

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:

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Congratulations on taking good care of yourself!

For more information on gonorrhea and other STDs, please visit www.inspot.org or www.ashastd.org.