Expedited Partner Therapy (EPT) for Chlamydia and Gonorrhea: Guide for Health Care Providers in Maryland



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The EPT Guide for Health Care Providers in Maryland was developed by the Maryland Department of Health and Mental Hygiene's Center for STI Prevention in consultation with the following advisors:

Jenell S. Coleman, MD, MPH, FACOG Reproductive Infectious Diseases Assistant Professor of Gynecology & Obstetrics Assistant Professor of Medicine Johns Hopkins University School of Medicine

Scott A. Feeser, MD
Office Medical Director
Johns Hopkins Community Physicians, Wyman Park Internal Medicine
Medical Director for Patient-Centered Medical Home
Johns Hopkins Community Physicians

Luke Johnsen, DO Clinical Associate, Infectious Diseases Johns Hopkins University School of Medicine Medical Director, STD Clinics Baltimore City Health Department

Laurence Polsky, MD Health Officer Calvert County Health Department

Anne M. Rompalo, MD, ScM Professor, Departments of Medicine, Infectious Diseases Johns Hopkins University School of Medicine

Oscar Taube, MD Coordinator, Adolescent Medicine Attending Pediatrician, Greenspring Pediatric Associates The Herman and Walter Samuelson Children's Hospital at Sinai

Maria Trent, MD, MPH Associate Professor of Pediatrics Division of General Pediatrics and Adolescent Medicine Johns Hopkins University School of Medicine

This EPT Guide is intended to be used as an educational aid to help clinicians make informed decisions about patient care. The ultimate decisions regarding clinical management should be made by health care providers in consultation with their patients. This Guide is not intended to be regulatory.

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BACKGROUND

Expedited Partner Therapy (EPT) is the clinical practice of treating the sex partners of patients diagnosed with sexually transmitted infections (STIs) without an intervening medical evaluation. The purpose of EPT is to reduce the likelihood of reinfection of the index patient, prevent sequelae, and halt the further spread of infection. It is important to stress that the practice of EPT is not mandatory, nor is it intended as a first-line or optimal partner management strategy. It is an evidence-based partner treatment option in which antibiotic therapy is dispensed or prescribed to patients for their partners who are unlikely or unable to obtain a timely medical assessment. Providers should use their best clinical judgment to determine which patients and partners are good candidates for this treatment option.

The Centers for Disease Control and Prevention (CDC) recommended EPT in 2006 as a useful partner management option when patients with *Chlamydia trachomatis* or *Neisseria gonorrhoeae* indicate their heterosexual partners are unlikely to seek medical evaluation and treatment [1]. Professional organizations such as the American Academy of Pediatrics (AAP), American Academy of Family Physicians (AAFP), American Bar Association (ABA), American College of Obstetricians and Gynecologists (ACOG), Society for Adolescent Health and Medicine (SAHM), and the American Medical Association (AMA) have endorsed EPT. Maryland organizations supporting the use of EPT include: the Board of Physicians; Board of Pharmacy; Board of Nursing; MedChi, the Maryland State Medical Society; and the Maryland chapters of ACOG and AAP.

In 2007, a Pilot EPT Program in Baltimore City was authorized through statute permitting clinicians in the health department's two sexually transmitted disease clinics to dispense prepackaged EPT medications to patients with chlamydia or gonorrhea for treating their partners. On June 1, 2015, EPT became legally permissible statewide, and Maryland joined nearly 40 other states in authorizing the practice of EPT. The Maryland EPT law allows physicians, physician assistants, advanced practice registered nurses and certain registered nurses employed by local health departments to prescribe or dispense, within their current scopes of practice, antibiotic therapy for the sex partners of patients diagnosed with chlamydia or gonorrhea. This law provides an important means to help combat a serious public health problem in Maryland – consistently high rates of both chlamydia and gonorrhea.

The EPT statute, Health General Article §18–214.1, can be found on the Maryland Department of Health and Mental Hygiene's (DHMH) EPT web page at: http://tinyurl.com/EPTMaryland. Regulations addressing the implementation of EPT, developed with input from clinicians and health officials from around the state, went into effect March 29, 2016. The regulations, COMAR 10.06.07, can be found on the DHMH EPT web page and in Appendix A in this document.

This EPT guide includes a brief discussion of the importance of partner management, the shortcomings of traditional partner notification and management strategies, and the rationale for EPT as an effective option in circumstances in which sex partners are unlikely or unable to obtain a prompt medical evaluation. The clinical guidance provides information on: the most appropriate patients and partners for EPT; recommended EPT treatment regimens; prescribing and dispensing requirements; counseling and education required by health care providers and pharmacists for patients and partners; requirements for documentation and reporting; and, implementation issues for consideration.

SUMMARY OF CLINICAL GUIDANCE FOR EPT

- Health care providers permitted to prescribe or dispense EPT: Within their current scopes of practice - physicians; physician assistants; advanced practice registered nurses; certain registered nurses employed by local health departments.
- **Eligible partners**: Certain sex partners of patients diagnosed with chlamydia or gonorrhea, who are unable or unlikely to obtain a prompt clinical evaluation.
- Optimal partner management strategy: Attempt to bring partners in for a clinical evaluation, including STI testing, counseling, and treatment.
- Recommended EPT drug regimens:
 - Sex partners of patients with <u>chlamydia</u>, but not gonorrhea:
 Azithromycin (Zithromax*) 1 gram orally once
 - Sex partners of patients with <u>gonorrhea</u>, regardless of the chlamydia diagnosis:

Dual treatment:

Cefixime (Suprax*) 400 mg orally once **PLUS** Azithromycin (Zithromax*) 1 gram orally once

- Time-frame and number of partners: All sex partners in the 60 days prior to the patient's diagnosis should be considered at risk for infection and should be treated. If the last sexual encounter was > 60 days prior to diagnosis, the most recent sex partner should be considered eligible. No limit to number of sex partners.
- Prescribing & dispensing: Prescriptions issued and medications dispensed must include the designation Expedited Partner Therapy, or EPT. If sex partners' names are unknown, the written designation EPT will be sufficient for the pharmacist to fill the prescription. Separate prescriptions must be issued for each sex partner.
- Informational materials and counseling: Patients must be given written
 information for each partner that includes advice to seek a medical
 evaluation, educational information about their infection, medication
 instructions, allergic and adverse reaction warnings, and advice to abstain
 or have protected sex as required during treatment.
- **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: To report adverse events, call 410-767-6690, or email <u>dhmh.STIclinicalconsult@maryland.gov</u>. No instances of adverse reactions have been reported in states where EPT is practiced.

^{*} Use of trade names is for identification only and does not imply endorsement.

RATIONALE FOR EPT

Public Health Importance of Chlamdyia and Gonorrhea in Maryland

Sexually transmitted infections are a significant public health concern in Maryland. In 2015, there were 27,450 cases of chlamydia (a rate of 457 cases per 100,000) and 6,858 cases of gonorrhea (a rate of 114 cases per 100,000) reported to the state or local health departments, making them the two most common reportable infections in the state, as they are nationally [2]. In Maryland, 27% of chlamydia cases and 21% of gonorrhea cases in 2015 were among 15-19 year olds [2].

Genital infections, which are often asymptomatic, can lead to serious sequelae, especially in females including pelvic inflammatory disease (PID), chronic pelvic pain, ectopic pregnancy, and preventable infertility [3]. Patients with these infections are also at increased risk of acquiring sexually transmitted HIV [4]. Repeat chlamydia and gonorrhea infections, which increase the risk of complications, occur in 10% -15% of females and males within six months after treatment [5].

Challenges of Standard Partner Notification and Management Strategies

Currently, there are considerable challenges to effective partner notification and management for chlamydia and gonorrhea. Effective clinical management of patients with treatable STIs requires treatment of the patients' current sex partners to prevent reinfection and curtail further transmission. The standard approach to partner treatment has included clinical evaluation in a health care setting, with partner notification accomplished by the index patient, by the provider or an agent of the provider, or a combination of these methods. Provider-assisted referral is not available to most patients with gonorrhea or chlamydial infection because of resource limitations. The usual alternative is to advise patients to refer their partners for treatment.

Studies indicate that standard partner referral approaches for chlamydia and gonorrhea are suboptimal, resulting in many partners remaining untreated. Studies among women with chlamydia who were asked to refer their partners for care demonstrated that only 25% to 40% of named male partners actually sought and received care and treatment [6]. Reasons cited for partners not receiving treatment included: 1) partner was never told of STI exposure by the index patient; 2) partner was told of exposure, but did not seek care; and 3) partner was told and sought care, but was not properly treated by the health care provider.

Public health efforts to notify, test, and treat sex partners have proven successful and are considered a cornerstone of syphilis and HIV control [7]. However, because of the high burden of STIs in Maryland, and limited public health resources for partner notification and management activities, it is difficult for local health departments to provide investigation and partner notification for cases of chlamydia and gonorrhea.

Evidence for the Effectiveness of EPT

The evidence of the efficacy of EPT is based on three clinical trials in the United States involving heterosexual males and females with chlamydia or gonorrhea [8]. The three trials each reported a higher proportion of partners treated when patients were offered EPT as compared to standard partner management - two studies reported statistically significant reductions in reinfection rates, and one reported a lower risk of persistent or recurrent infection that was not

statistically significant. A fourth trial in the United Kingdom did not demonstrate a difference in the risk of reinfection or in the numbers of partners treated when comparing EPT to patient-delivered partner notification and referral [8].

U.S. trials and a meta-analysis of EPT revealed that the magnitude of reduction in reinfection of index case-patients compared with patient referral differed according to the STI and the sex of the index case-patient. However, across trials, reductions in chlamydia prevalence at follow-up were approximately 20%; reductions in gonorrhea at follow-up were approximately 50%.

To date, no large-scale studies of safety and efficacy of EPT have been conducted among men who have sex with men (MSM).

Researchers in Baltimore conducted a retrospective cohort study to measure and compare retreatment rates between patients receiving two different treatment regimens for uncomplicated gonorrhea. The investigators found that patients receiving EPT were 45% less likely to be retreated compared with patients treated before EPT became available in 2007 [9].

CLINICAL GUIDANCE FOR USING EPT FOR CHLAMYDIA AND GONORRHEA

Health Care Providers Authorized to Prescribe or Dispense EPT

In accordance with current scopes of practice, EPT may be prescribed or dispensed by:

- · Licensed physicians;
- Authorized licensed physician assistants;
- Advanced practice registered nurses;
- Registered nurses employed by Local Health Departments who comply with the drug formulary and complete specified training developed by the Nurse Dispensing Committee and Board of Nursing.

Selecting Appropriate Patients for EPT

Diagnostic Criteria

Patients with either a clinical or laboratory-confirmed diagnosis of chlamydia or gonorrhea may be eligible for EPT. Providing EPT without laboratory confirmation of chlamydia or gonorrhea should be considered when the provider has a high clinical suspicion for chlamydia or gonorrhea and there is concern about loss of follow-up.

Age of Patient

Patients of any age with a diagnosis of chlamydia or gonorrhea infection may be given EPT for their partners.

EPT and Adolescents

Adolescents bear a disproportionate burden of chlamydia and gonorrhea. Although these infections are easily treated with antibiotics, many adolescents are reinfected within 3–6 months, usually because their partners remain untreated. In-person testing, treatment and risk-reduction counseling for partners remain the optimal and preferred partner management strategy, especially in settings where free and/or low-cost care with directly observed therapy can be provided. The Society for Adolescent Health and Medicine and the American Academy of Pediatrics endorse using EPT as an option for treating heterosexual male and female partners when inperson evaluation of partners is impractical or unsuccessful [18] [19].

Nonjudgmental, age-appropriate counseling is particularly essential for adolescents when assessing the potential for EPT use for their partners. Providers should assess their adolescent patient's comfort level or ability to talk with their partners about EPT. The patient education fact sheets at the end of this EPT Guide include suggestions for how patients might initiate discussions of EPT with their partners.

Gender or Sexual Orientation

EPT may be used regardless of the patient's gender, but should not be **routinely** offered to male index patients who have sex with other men (MSM) because of a high risk for coexisting infections, especially undiagnosed HIV infection, in their partners. See discussion about EPT and MSM in the section below, Selecting Appropriate Partners for EPT.



Co-infection: Patients co-infected with other STIs that are not covered by EPT medication should not be offered EPT for their partners. Every attempt should be made to bring those partners in for a comprehensive STI exam. Your Local Health Department may be able to assist you in this.



Risk of partner violence: EPT is not appropriate for index patients with a history of, or at risk of, sexual assault, intimate partner violence, or other situations in which the patients' safety is in question.

Selecting Appropriate Partners for EPT

The most appropriate partners for EPT are those who are unable or unlikely to obtain 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.

Health care providers should try to elicit information about the partner's symptom status, particularly symptoms indicative of a complicated infection, pregnancy status, and risk for severe medication allergies. EPT should not preclude provider attempts to get partners in for care. Even if EPT is provided, partners should still be encouraged to seek a medical evaluation as soon as possible to be screened for other STIs, including HIV.

Number of Partners

There is no limit to how many partners may be treated using EPT. Patients can be provided with the number of doses or prescriptions necessary to treat each at-risk partner who can be located by the index patient. A combination of partner strategies also may be used - a patient with several partners may refer one partner to a health care provider, but take EPT for other partners. Furthermore, EPT may be prescribed for some partners, and dispensed for others.

Time-Frame

All sex partners in the 60 days prior to the patient's 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 sex partner should be treated.

Pregnant Women

The American College of Obstetricians and Gynecologists supports the use of EPT in pregnant women to prevent chlamydia and gonorrhea reinfection when partners are unable or unwilling to seek medical care [10]. Partners receiving EPT who are or may be pregnant should be encouraged to seek a medical evaluation as soon as possible to be screened for other STIs, including HIV, and for referrals to prenatal care, as needed. The local health department may be of assistance for this special situation.

EPT Medications during Pregnancy: Azithromycin and cefixime are considered safe in pregnancy (Category B).

Test-of-Cure at Three Weeks: Health care providers should emphasize that pregnant partners need a test-of-cure for chlamydia or gonorrhea three weeks after treatment to assure eradication of infection and prevent severe maternal and neonatal sequelae.

Men Who Have Sex with Men

EPT should not be offered **routinely** to male partners who have sex with other men; it should be used only selectively and with caution.

EPT and Men Who Have Sex with Men

No large-scale studies assessing the efficacy of EPT use in MSM have been conducted to date. Concerns about using EPT in MSM include the risk of undertreating complicated infections and pharyngeal gonorrhea and undertreating other STIs. Missing concurrent syphilis and/or HIV among MSM is a particular concern in Maryland due to high rates of both infections [11] [12].



Known Drug Allergies: For partners with known severe allergies to antibiotics, EPT should <u>not</u> be used.

Recommended Treatment Regimens

Antibiotic treatment regimens for EPT use must follow the CDC's most current Sexually Transmitted Diseases Treatment Guidelines. These are typically updated every four years, but may be revised at any time based on national surveillance of disease trends. The EPT therapies listed below are from the 2015 Guidelines [8], and can be found at: www.cdc.gov/std/treatment.

Infection Diagnosed in Index Patient	Recommended EPT Treatment Regimen
Chlamydia only	Azithromycin (Zithromax*) 1 gram orally once
Gonorrhea (regardless of chlamydia diagnosis)	Dual Treatment: Cefixime (Suprax*) 400 mg orally once PLUS Azithromycin (Zithromax*) 1 gram orally once

^{*}Use of trade names is for identification only and does not imply endorsement.

Issues for Consideration

Single Dose Treatments

These are recommended for either prescribed or dispensed EPT treatment for chlamydia or gonorrhea to achieve the greatest likelihood of treatment compliance among partners.

Antimicrobial-resistant Gonorrhea

N. gonorrhoeae isolates with decreased susceptibility to cefixime or azithromycin, as well as a limited number with decreased susceptibility to ceftriaxone, have been documented globally and in the United States [8] [13]. 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* [8].

Currently the first-line therapy for in-office gonorrhea treatment is ceftriaxone 250 mg IM plus azithromycin 1 g orally [8] [14]. However, the CDC recommends if a partner of a patient with gonorrhea cannot be linked to evaluation and treatment in a timely fashion, EPT with cefixime and azithromycin should still be considered, as not treating partners is significantly more harmful than is the use of EPT for gonorrhea [15].

Azithromycin two grams orally should not be used for EPT for gonorrhea due to evidence that widespread use would increase *N. gonorrhoeae* antimicrobial resistance [8]. Additionally, the two-gram dose of azithromycin can cause gastrointestinal distress.

Both the CDC and the Maryland Department of Health and Mental Hygiene's Laboratories Administration are performing culture and antibiotic sensitivity testing - actively monitoring antimicrobial resistance to gonorrhea to guide national and local therapy recommendations. The future of using EPT to treat gonorrhea will depend on national and/or local resistance trends.

Pharyngeal Gonorrhea

In general, oral cephalosporins are less effective in eradicating pharyngeal gonorrheal infection [8]. Partners at risk for pharyngeal infection (i.e., history of performing oral sex) should be informed that the oral medications (cefixime 400 mg plus azithromycin 1 g) used for EPT may not cure pharyngeal gonorrhea and that they should be seen by a medical provider, even if they've already taken the medication.

RISK OF ADVERSE REACTIONS TO MEDICATIONS

Adverse reactions to single-dose cefixime and/or azithromycin, beyond mild to moderate side effects, are rare. 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 EPT partner instructions and information are available at the end of this document.

It is important to note that from 2001 through January 2016, California, the first state to legalize EPT, received no calls to their EPT hotline about adverse reactions to EPT medications for gonorrhea or chlamydia, and no reports of lawsuits related to the practice of providing EPT [16].

Although the CDC does not actively monitor EPT therapy, it, as well as several other national research and policy organizations do monitor states' EPT laws, policies and rulings. As of June 1, 2016, none of these organizations monitoring states' EPT policies, were aware of any reports of adverse events resulting from EPT therapy.

Because the Maryland Department of Health and Mental Hygiene's Center for STI Prevention is interested in receiving information on EPT-related adverse events, we ask that providers report any known adverse events to (410) 767-6690 or dhmh.STIclinicalconsult@maryland.gov.

Prescribing and Dispensing

Regulat	tions Pertaining to Prescribing and Dispensing EPT Medications
Prescribing	 Separate prescriptions are needed for each person being treated. Prescriptions must be written separately for the patient and for each of the patient's partners. Extra doses of medication should not be included on an index patient's prescription. Prescriptions must include: The designation "EPT" or "Expedited Partner Therapy" on the face of each prescription issued; The partner's name, if known; If the partner's name is unknown, the health care provider may write the prescription for "EPT" or "Expedited Partner Therapy." Refills - EPT prescriptions may not be refilled.
Dispensing	 Medication must be dispensed separately for each partner and must include: The designation "EPT" or "Expedited Partner Therapy;" Partner's name, if known; If the partner's name is unknown, the written designation "EPT" or "Expedited Partner Therapy" is sufficient for the pharmacist to fill the prescription.

PATIENT COUNSELING AND PARTNER EDUCATION

Health care providers and pharmacists who dispense or prescribe EPT must counsel patients to encourage their partners to seek medical care, and must provide patients with written materials for each partner about:

- Their exposure to chlamydia and/or gonorrhea, and information about the infections;
- The importance of a seeking a medical evaluation even if the medication has been taken, especially for pregnant women and MSM;
- Medication instructions;
- Warnings about adverse or allergic reactions;
- Advice to abstain from sexual activity for 7 days after single dose antibiotics

Informational materials are available for downloading on the DHMH EPT website at: http://tinyurl.com/EPTMaryland. Any written materials may be provided to patients for each of their partners as long as the above-listed information is included.

Patient Follow-Up and Retesting at Three Months

Because a high prevalence of chlamydia and gonorrhea reinfection has been observed in females and males after treatment, the CDC recommends that patients be retested approximately 3 months after treatment, regardless of whether they believe that their sex partners were treated [8].

Documenting EPT in A Medical Chart

Health care providers prescribing or dispensing EPT must document the provision of EPT in the patient's chart. Documentation should include:

- Number of EPT prescriptions or medications provided to the patient for each partner;
- Medication and dosage being provided to the patient for each partner.

Sex partners are not required to have a medical chart in order to be provided EPT.

Documenting partners' names in patients' medical charts is not recommended due to partner confidentiality concerns.

Reporting Requirements

The EPT regulations do not affect the obligation of Maryland health care providers to report to the state or local health department cases of chlamydia and gonorrhea, as well as the treatment provided to those cases.

Additionally, the revised Maryland Confidential Morbidity Report Form (DHMH 1140 form) now includes fields to report whether or not EPT was provided for an index patient's partners. Health care providers must report the number of partners for whom EPT prescriptions provided and/or medication was dispensed. See Maryland Confidential Morbidity Report Form, Appendix B, or go to: http://tiny.cc/frsb8x.

IMPLEMENTATION ISSUES

Liability

The legislation under which EPT was made lawful did not include immunity provisions that would shield health care providers from lawsuits resulting from adverse outcomes related to the practice. However, numerous national and state organizations support the use of EPT: the Centers for Disease Control and Prevention (CDC); the American Academy of Pediatrics (AAP); American Academy of Family Physicians (AAFP), American Bar Association (ABA); American College of Obstetricians and Gynecologists (ACOG), Society for Adolescent Health and Medicine (SAHM); the American Medical Association (AMA); the Maryland Boards of Physicians, Pharmacy and Nursing; Maryland chapters of ACOG and AAP.

Providers with questions or concerns related to liability should consult with their own counsel.

Costs

Barriers to implementation of EPT include the cost of additional medication for uninsured partners and reimbursement for time spent counseling patients about giving EPT to their partners.

Medication costs may be:

- Self-paid (paid by whoever picks up prescription, the patient or partner);
- Paid by the partner's commercial health insurance or Medicaid, if partner is enrolled;
 - o Reimbursement for EPT medication costs varies by insurance plan;
 - Maryland Medicaid covers EPT medications, with low co-pays;
- Covered by some medical practices that choose to dispense medications for partners at no cost in order to remove cost and access barriers and ensure confidentiality, especially for adolescents.

Pharmacists should not bill the partner's prescription under the index patient's name.

Billing for EPT

There is no specific CPT code that covers the counseling or care coordination associated with the provision of EPT. Since patients who receive EPT for their partners are diagnosed with chlamydia and/or gonorrhea, problem-focused Evaluation and Management (E/M) codes 99201-99205 (new patient) or 99211-99215 (established patient) are applicable, based on the "key components" - history, examination and medical decision-making.

If you spend more than fifty percent of the visit time counseling or coordinating care, you can use time as the key factor in determining the level of E/M service instead of using the key components. Be sure to document the time spent on counseling/care coordination.

When considering the cost of EPT versus standard partner management for chlamydia or gonorrhea (i.e., testing and treatment for repeat infection in index patients and the cost of sequelae), EPT is more cost-effective and improves partner treatment [16].

MARYLAND EPT RESOURCES

Maryland's EPT website will be continuously updated with new information and resources.

- EPT patient and partner information materials are available online at http://tinyurl.com/EPTMaryland. Materials are being translated into various languages and will be posted on this website when available.
- Adverse reaction reporting via email: dhmh.STlclinicalconsult@maryland.gov, or call 410-767-6690.
- Maryland's EPT statute and regulations are available at: http://tinyurl.com/EPTMaryland.
- For information on local health department STI testing and treatment activities, please
 call your local health department's STD or Communicable Disease program. Links to
 Maryland's local health departments can be found here:
 http://phpa.dhmh.maryland.gov/OIDPCS/CSTIP/CSTIPDocuments/LHDs_County_Map.pdf.
- The STD/HIV Prevention Training Center at Johns Hopkins offers courses in the diagnosis and clinical management of STIs, as well as partner management and counseling. You can visit their website at www.stdpreventiontraining.com, or call 410-396-0176 for more information.

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APPENDIX A

Maryland EPT Regulations

Expedited Partner Therapy Regulations Effective Date March 28, 2016

Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE Subtitle 06 DISEASES

10.06.07 Sexually Transmitted Infections — Expedited Partner Therapy for Chlamydia and Gonorrhea

Authority: Health General Article, §§2-104(b), 18-102, 18-201, 18-202, and 18-214.1, Annotated Code of Maryland

.01 Purpose and Scope.

- A. The purpose of expedited partner therapy in Maryland is to:
- (1) Provide antibiotic therapy to any partner of a patient diagnosed with chlamydia or gonorrhea without a personal physical assessment of the partner, and without having a previous provider-patient relationship with the partner;
 - (2) Contain and stop the further spread of chlamydia and gonorrhea; and
 - (3) Reduce the likelihood of reinfection in the diagnosed patient.
- B. This chapter applies to the provision of expedited partner therapy, as described in §A of this regulation, in public and private health care settings.

.02 Definitions.

- A. In this chapter, the following terms have the meanings indicated.
- B. Terms Defined.
- (1) "Antibiotic therapy" means the oral antibiotic drug regimens currently recommended by the Centers for Disease Control and Prevention for the treatment of chlamydia and gonorrhea through expedited partner therapy.
 - (2) "Department" means the Department of Health and Mental Hygiene.
- (3) "Expedited partner therapy (EPT)" means the prescribing or dispensing of antibiotic therapy to any partner of a patient diagnosed with chlamydia or gonorrhea by certain health care providers without making a personal physical assessment of the partner, and without having a previous provider-patient relationship with the partner, in order to contain and stop the further spread of the infection and reduce the likelihood of reinfection in the diagnosed patient.
- (4) "Health officer" means the health officer in each of the 23 counties and the Commissioner of Health in Baltimore City, or the duly designated representative of the health officer, or both.
 - (5) "Partner" means an individual with whom one has, or has had, oral, anal or vaginal sexual contact.

.03 Partners Eligible for EPT.

Partners eligible for EPT are:

- A. Any partner within 60 calendar days of the patient's diagnosis; or
- B. The most recent partner of a patient if the patient has not had sex in the 60 days before diagnosis.

.04 Health Care Providers Authorized to Prescribe and Dispense EPT.

Notwithstanding any other provision of law, and only in accordance with their current scope of practice, EPT may be prescribed or dispensed by the following health care providers:

- A. A physician licensed under Health Occupations Article, Title 14, Annotated Code of Maryland;
- B. An authorized physician assistant licensed under Health Occupations Article, Title 15, Annotated Code of Maryland, acting in accordance with Health Occupations Article, §15-302.2, Annotated Code of

Maryland;

- C. An advanced practice registered nurse with prescriptive authority licensed under Health Occupations Article, Title 8, Annotated Code of Maryland, acting in accordance with Health Occupations Article, §8–508, Annotated Code of Maryland; and
 - D. A registered nurse employed by a local health department who complies with:
- (1) The formulary developed and approved under Health-General Article, §3-403(b), Annotated Code of Maryland; and
- (2) The requirements established under Health Occupations Article, §8-512, Annotated Code of Maryland.

.05 Prescribing and Dispensing EPT Medications.

- A. Antibiotic therapy prescribed or dispensed for EPT shall be in accordance with recommendations from the Centers for Disease Control and Prevention.
 - B. Prescribing.
 - (1) A separate prescription shall be issued for each partner;
- (2) The designation "EPT" or "Expedited Partner Therapy" shall be included on the face of the prescription for each prescription issued;
 - (3) If the partner's name is known, the prescription shall be issued in the partner's name;
- (4) If the partner's name is unknown, the written designation "EPT" or "expedited partner therapy" shall be sufficient for the pharmacist to fill the prescription; and
 - (5) An EPT prescription may not be refilled.
 - C. Dispensing. Each EPT medication label shall:
 - (1) Include:
 - (a) The designation "EPT" or "Expedited Partner Therapy"; and
 - (b) The partner's name, if known; and
 - (2) Comply with Health Occupations Article, §12-505, Annotated Code of Maryland.

.06 Counseling and Educational Information Requirements.

- A. A health care provider prescribing or dispensing EPT to a patient shall:
 - (1) Counsel the patient to encourage each partner to seek a personal physical assessment; and
- (2) Provide the patient with educational information for each partner, in accordance with §C of this regulation.
- B. A pharmacist dispensing EPT shall provide educational information for each partner, in accordance with §C of this regulation.
- C. The educational information, that is available or comparable to that available on the Department's website, shall include:
 - (1) Advice for the partner to seek a medical evaluation;
 - (2) Information about chlamydia and gonorrhea;
 - (3) Medication instructions;
 - (4) Warnings about adverse drug or allergic reactions; and
 - (5) Advice to abstain from sexual activity as required during treatment.

.07 Documenting EPT in a Medical Chart.

- A. A health care provider prescribing or dispensing EPT shall document the provision of EPT in the patient's chart.
- B. Documentation shall include the:
 - (1) Number of EPT prescriptions or medications provided to the patient for each partner; and
 - (2) Medication and dosage being provided to the patient for each partner.

.08 Reporting of Chlamydia and Gonorrhea by a Health Care Provider or Institution.

- A. This chapter may not affect the obligation of a health care provider or institution to report to a health officer cases of chlamydia and gonorrhea and the treatment provided to those cases in accordance with COMAR 10.06.01.04.
- B. When reporting a case of chlamydia or gonorrhea for which EPT was prescribed or dispensed, a health care provider or institution shall report the number of partners for whom:
 - (1) Prescriptions were provided; and
 - (2) Medications were dispensed.

APPENDIX B Maryland Confidential Morbidity Report Form

MARYLAND CONFIDENTIAL MORBIDITY REPORT (DHMH 1140) (For use by physicians and other health care providers, but not laboratories. Laboratories should use forms DHMH 1281 & DHMH 4492.) SEND TO YOUR LOCAL HEALTH DEPARTMENT

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APPENDIX C Examples of Patient and Partner Fact Sheets



PATIENT INFORMATION:

Chlamydia Treatment for Your Partners



Why am I getting extra medicine or a prescription?

- You have been diagnosed with chlamydia (kluh-MI-dee-uh). It is a sexually transmitted infection (STI). That means it is transmitted or spread through oral, vaginal, or anal sex with an infected person.
- You have been given a prescription for azithromycin (uh-zith-ro-MY-sin), or the medicine itself, to treat (cure) your chlamydia. You also were given the same prescription or medicine to give to your sex partners. Bringing medicine to your partners this way is called Expedited Partner Therapy, or EPT. Once your partners are treated, they won't develop serious health problems, infect you again, or pass chlamydia on to others.

What do I need to know about chlamydia?

- Most people with chlamydia don't have any symptoms (signs of infection). You can be infected and not know it.
- Or, you may have discharge (drip) from the penis, vagina and/or anus, pain, or a burning feeling when you urinate (pee).
- If you don't get treated, you may develop serious, even life-long health problems.
- If you don't get treated and you are female, you may not be able to get pregnant.
- Pregnant women with chlamydia can pass the infection to their babies during pregnancy causing very serious health problems.



What should I do next?



Get treated.



Tell all your recent sex partners. Explain that you have been diagnosed with chlamydia and got medicine to treat it. They need medicine, too.



Give them the medicine or prescription and the printed information from your health care provider.



Encourage your partners to visit a health care provider. They should get tested for other STIs, even if they take the EPT medicine.



Visit a health care provider in 3 months to get tested again for chlamydia.

How do I tell my partners I was treated for chlamydia?

Telling your partners that you have an STI can be hard, but it is the right thing to do. The best way to tell your partners is by being open and honest.

"This medicine (or prescription) is to cure an STI called chlamydia. I took the medicines, and you should, too, since you also might have the infection. You should read the information that came with the medicine and go to a health care provider to get checked for other STIs."

Your partners may feel surprised, upset, angry, or scared. These feelings are normal. By offering them the EPT medicines, you are showing that you care enough to help.

What if my partner blames me?

People worry about their partners being angry, but you may not be the one who infected them. Explain that chlamydia usually doesn't have symptoms. A person can have it for a long time and not know it. The most important thing is to tell your partners about the infection. Take steps so that you and your sex partners get healthy, and avoid future STIs.



Reasons why EPT might not be a good choice for your partner

Ask your health care provider about ways to get your partners treated other than EPT if:

- You think a partner could become violent.
- You also have been diagnosed with an STI other than chlamydia.
- Your partner is a man who has sex with other men. He may have other infections, like syphilis and/or HIV. He should visit a health care provider as soon as possible to get tested for other STIs.

Avoid STIs in the Future

The only way to completely avoid STIs, including HIV, is not to have sex. If you do have sex, do it safely. Use a latex condom every time and for every kind of sex - anal and vaginal, and a condom or dental dam for oral sex.

You can lower your chances of getting STIs, including HIV, by limiting the number of people you have sex with. The more sex partners you have, the higher your risk of getting an STI.

Other Questions You May Have.

My sex partners have no symptoms. Should they still take the medicine?



Yes. People with chlamydia may not have any symptoms. Taking the medicine will cure it.

What if my sex partner is pregnant or thinks she may be pregnant?

If your sex partner is pregnant or thinks she may be pregnant, it is okay for her to take this medicine. The medicine used to treat chlamydia will not hurt the baby. But she should see a health care provider as soon as possible to be tested for other STIs, which she can pass on to her baby during pregnancy.

What should I do after giving my partners this medicine?

The medicine takes 7 days to work. Do not have sex (vaginal, oral, or anal) for at least 7 days after both you and your partners have been treated. You can get chlamydia again if you have sex before the medicine cures your partners. If you do have sex, use a latex condom or dental dam (for oral sex) so you don't get infected again.

What if a partner won't take the medicine?

If your sex partner won't take the medicine, he or she should see a health care provider as soon as possible to get tested for chlamydia, gonorrhea and other STIs. Tell your partners that not getting treated could result in serious health problems.



Center for STI Prevention www.tinyurl.com/EPTMaryland June 2016



CHLAMYDIA INFORMATION FOR PARTNERS



Why am I getting medicine or a prescription?

- Your sex partner has been diagnosed with chlamydia (kluh-MI-dee-uh). You may have chlamydia, too. It is a sexually transmitted infection (STI). STIs are spread through oral, vaginal, or anal sex with an infected person.
- Chlamydia is easy to treat (cure) by taking a medicine called azithromycin (uh-zith-ro-MYsin). Azithromycin is very safe.
- Your sex partner was treated. You need to be treated, too. That's why a health care provider gave your partner medicine or a prescription for you. Getting treated this way, without seeing a health care provider, is called Expedited Partner Therapy or EPT.

What do I need to know about chlamydia?

- Most people with chlamydia don't have symptoms (signs of infections). You may have chlamydia and not know it. That means you can pass it on to others without knowing it.
- If you do have symptoms, you may have pain or a burning feeling when you urinate (pee). Or you may have a discharge (drip) from the penis, vagina or anus.

Why should I take the medicine?

- If you don't get treated, you may develop serious, even life-long health problems.
- If you don't get treated and you are female, you may not be able to get pregnant.
- Pregnant women with chlamydia can pass the infection to their babies. Chlamydia can cause very serious health problems for babies.
- The good news is once you are treated, you won't infect your partner, or pass the infection on to others.

I'll take the medicine. But should I see a health care provider?

- Seeing a health care provider is best. But, if you cannot see a health care provider in the next few days, take the EPT medicine or fill the prescription your partner has given you.
- ① Even if you take the medicine, see a health care provider as soon as possible.
- That way you can be tested for chlamydia and other STIs, too. You may have more than one STI at the same time. The azithromycin will not cure other STIs.

Reasons not to take the medicine — and see a health care provider instead.

STOP

Azithromycin is a safe medicine. But, do not take it if you:

- Are female and have lower belly pain, pain during sex, vomiting or fever.
- Are male and have pain or swelling in the testicles (balls) or fever.
- Have had a rash, breathing problems or allergic reaction to azithromycin or other medicine.
- Have a serious long-term illness, such as kidney, heart or liver disease.
- Take another prescription medicine, including medicine for diabetes.

If any of these are true for you, see a health care provider <u>as soon as possible</u>. Your health care provider will find the best medicine for you. If you are not sure, see a health care provider as soon as possible.



How to take the medicine

- Take the azithromycin pills all at once and with food, to help prevent upset stomach.
- If you throw up in the hour after taking your medicine, you need to get more medicine. In this case, it's best to see a health care provider as soon as possible.
- After taking your medicine, wait at least 7 days before having sex. If you do have sex, use a condom or dental dam (for oral sex) so you don't get infected again.
- Do not take antacids, such as Tums, Rolaids, or Maalox, for 1 hour before or 2 hours after taking azithromycin.
- Do not share or give your medicine to anyone else.

If you are pregnant

Azithromycin is safe to take during pregnancy. But, even if you take the medicine, you should see a health care provider *right away*. That way you can make sure you get the best care for you and your baby.

If you are a man who has sex with men

In Maryland, men whose sex partners include other men need to be tested for chlamydia and other STIs, too. Since you may have chlamydia, you also may have syphilis and/or HIV and not know it. It is very important that you see a health care provider and get tested for STIs.

Side effects

Most people have no side effects (feel sick) from azithromycin. Some people may get: diarrhea; slightly upset stomach; dizziness; vaginal yeast infection. These side effects are not usually serious.

Allergic reactions

IF YOU HAVE SIGNS OF AN ALLERGIC REACTION, call 911 or go to the Emergency Room immediately.

These include: trouble breathing, throat tightness, swelling of your lips or tongue, or hives (very itchy skin bumps or welts).

The Maryland Department of Health and Mental Hygiene wants to learn about any serious problems you may have had with the medicine. If you think you had an allergic reaction, contact:

adhmh.STIclinicalconsult@maryland.gov

1 410-767-6690

Avoid STIs in the future

The only way to completely avoid STIs, including HIV, is not to have sex. If you do have sex, do it safely. Use a latex condom every time for vaginal and anal sex, and a condom or dental dam for oral sex.

To find low-cost or free STI/HIV testing sites near you, go to: gettested.cdc.gov, call your local health department, or call: 800-232-4636 / TTY: 888-232-6348.



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PATIENT INFORMATION:

Gonorrhea Treatment for Your Partners



Why am I getting extra medicine or a prescription?

- You have been diagnosed with gonorrhea (gon-uh-REE-uh). It is a sexually transmitted infection (STI). That means it is transmitted or spread through oral, vaginal, or anal sex with an infected person.
- You have been given prescriptions for cefixime (su-FIX-eem) and azithromycin (uh-zith-ro-MYsin), or the medicines, to treat (cure) your gonorrhea. You also were given the same prescriptions or medicines to give to your sex partners. Bringing medicines to your partners this way is called Expedited Partner Therapy, or EPT. Once your partners are treated, they won't develop serious health problems, infect you again, or pass gonorrhea on to others.

What do I need to know about gonorrhea?

- Most people with gonorrhea don't have any symptoms (signs of infection). You can be infected and not know it.
- Or, you may have discharge (drip) from the penis, vagina and/or anus, pain, or a burning feeling when you urinate (pee).
- If you don't get treated, you may develop serious, even life-long health problems.
- If you don't get treated and you are female, you may not be able to get pregnant.
- Pregnant women with gonorrhea can pass the infection to their babies during pregnancy.



What should I do next?

V

Get treated.



Tell all your recent sex partners. Explain that you have been diagnosed with gonorrhea and got medicines to treat it. They need medicines, too.



Give them the medicines or prescriptions and the printed information from your health care provider.



Encourage your partners to visit a health care provider. They should get tested for other STIs, even if they take the EPT medicines.



Visit a health care provider in 3 months to get tested again for gonorrhea.

How do I tell my partners I was treated for gonorrhea?

Telling your partners that you have an STI can be hard, but it is the right thing to do. The best way to tell your partners is by being open and honest.

"These medicines (or prescriptions) are to cure an STI called gonorrhea. I took the medicines, and you should, too, since you also might have the infection. You should read the information that came with the medicines and go to a health care provider to get checked for other STIs."

Your partners may feel surprised, upset, angry, or scared. These feelings are normal. By offering them the EPT medicines, you are showing that you care enough to help.

What if my partner blames me?

People worry about their partners being angry, but you may not be the one who infected them. Explain that chlamydia usually doesn't have symptoms. A person can have it for a long time and not know it. The most important thing is to tell your partners about the infection. Take steps so that you and your sex partners get healthy, and avoid future STIs.



Reasons why EPT might not be a good choice for your partner

Ask your health care provider about ways to get your partners treated other than EPT if:

- You think a partner could become violent.
- You also have been diagnosed with an STI other than gonorrhea.
- Your partner is a man who has sex with other men. He may have other infections, like syphilis and/or HIV. He should visit a health care provider as soon as possible to get tested for other STIs.

Avoid STIs in the Future

The only way to completely avoid STIs, including HIV, is not to have sex. If you do have sex, do it safely. Use a latex condom every time and for every kind of sex - anal and vaginal, and a condom or dental dam for oral sex.

You can lower your chances or getting STIs, including HIV, by limiting the number of people you have sex with. The more sex partners you have, the higher your risk of getting an STI.

Other Questions You May Have.

My sex partners have no symptoms. Should they still take the medicines?



Yes. People with gonorrhea may not have any symptoms. Taking the medicines will cure it.

What if my sex partner is pregnant or thinks she may be pregnant?

If your sex partner is pregnant or thinks she may be pregnant, it is okay for her to take these medicines. The medicines used to treat gonorrhea will not hurt the baby. But she should see a health care provider as soon as possible to be tested for other STIs, which she can pass on to her baby during pregnancy.

What should I do after giving my partners these medicines?

The medicine takes 7 days to work. Do not have sex (vaginal, oral, or anal) for at least 7 days after both you and your partners have been treated. You can get gonorrhea again if you have sex before the medicines cure your partners. If you do have sex, use a latex condom or dental dam (for oral sex) so you don't get infected again.

What if a partner won't take the medicine?

If your sex partner won't take the medicine, he or she should see a health car provider as soon as possible to get tested for gonorrhea, chlamydia, and other STIs. Tell your partners that not getting treated could result in serious health problems.



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GONORRHEA INFORMATION FOR PARTNERS



Why am I getting medicine or a prescription?

- Your sex partner has been diagnosed with gonorrhea (gon-uh-REE-uh). You may have gonorrhea, too. It is a sexually transmitted infection (STI). STIs are spread through oral, vaginal, or anal sex with an infected person.
- Gonorrhea is easy to treat (cure) by taking two medicines called azithromycin (uh-zith-ro-MYsin) and cefixime (su-FIX-eem). They are both very safe.
- Your sex partner was treated. You need to be treated, too. That's why a health care provider gave your partner medicines or prescriptions for you. Getting treated this way, without seeing a health care provider, is called Expedited Partner Therapy or EPT.

What do I need to know about gonorrhea?

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- If you do have symptoms, you may have pain or a burning feeling when you urinate (pee). Or you may have a discharge (drip) from the penis, vagina or anus.

Why should I take the medicine?

- If you don't get treated, you may develop serious, even life-long health problems.
- If you don't get treated and you are female, you may not be able to get pregnant.
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- Seeing a health care provider is best. But, if you cannot see a health care provider in the next few days, take the EPT medicines or fill the prescriptions your partner has given you.
- Even if you take the medicines, see a health care provider as soon as possible.
- That way you can be tested for gonorrhea and other STIs too. You may have more than one STI at the same time. The azithromycin and cefixime will not cure most other STIs.

Reasons not to take the medicine — and see a health care provider instead.



Azithromycin and cefixime are safe medicines. But, do not take them if you:

- Are female and have lower belly pain, pain during sex, vomiting or fever.
- ① Are male and have pain or swelling in the testicles (balls) or fever.
- Have had a rash, breathing problems or allergic reaction to azithromycin or other medicine.
- Have a serious long-term illness, such as kidney, heart or liver disease.
- Take another prescription medicine, including medicine for diabetes.

If any of these are true for you, see a health care provider as soon as possible. Your health care provider will find the best medicine for you. If you are not sure, see a health care provider as soon as possible.



How to take the medicine

- Take the azithromycin and cefixime pills all at once and with food, to help prevent upset stomach.
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Parts of this guide were adapted with permission from The California Department of Public Health, STD Control Branch.