

# **Expedited Partner Therapy** for Chlamydia, Gonorrhea and Trichomoniasis

Guide for Health Care Providers and Pharmacists in Maryland

This document updates the June 2016 "Expedited Partner Therapy (EPT) for Chlamydia and Gonorrhea: Guide for Health Care Providers in Maryland". The guide was developed by the Maryland Department of Health's Center for STI Prevention in consultation with the original advisors listed below. The updated guide contains the most recently available data on chlamydia and gonorrhea in Maryland, EPT partner treatment regimens based on the most recent Centers for Disease Control and Prevention (CDC) recommendations, information about EPT use for trichomoniasis treatment, a new contact phone number for reporting concerns about adverse reactions, and updated hyperlinks to CDC and Maryland Department of Health webpages.

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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**

A note about terminology in this guide: The Maryland Department of Health (MDH) Center for STI Prevention (CSTIP) recognizes that people have diverse gender identities and aims to use gender-inclusive language in its publications and materials. Because the gender terminology used in almost all sources referenced throughout this document, the terms "woman", "female", "man" and "male" are used to refer to individuals who were assigned female or male at birth, regardless of their gender identity.

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.

EPT is an evidence-based partner treatment strategy in which antibiotic therapy is dispensed or prescribed to patients for their partners who are unlikely or unable to obtain a timely medical assessment. The goal of EPT is to reduce the likelihood of reinfection of the index patient, prevent sequelae, and halt the further transmission.

The Centers for Disease Control and Prevention (CDC) recommended EPT in 2006 as a useful partner management option when patients with Chlamydia trachomatis (chlamydia) or Neisseria gonorrhoeae (gonorrhea) indicate their heterosexual partners are unlikely or unable to seek medical evaluation and treatment. Evidence supporting EPT for chlamydia and gonorrhea is based on three clinical trials; existing data also indicate that EPT may have a role in partner management of *Trichomonas vaginalis* (trichomoniasis¹). No data support the use of EPT in the routine management of patients with syphilis. As of November 2023, EPT was legally permissible in 46 states in the United States, potentially allowable in 4 states and prohibited in no states.²

In Maryland, EPT for partner treatment of clinically diagnosed or laboratory-confirmed chlamydia and gonorrhea became legally permissible in 2015. The use of EPT expanded in 2017 when EPT for partner treatment of trichomoniasis was authorized. The Maryland EPT law authorizes physicians, physician assistants, advanced practice registered nurses, certain registered nurses employed by local health departments, and pharmacists to prescribe or dispense EPT, within their current scopes of practice. This law provides an important means to help combat a serious public health problem in Maryland – consistently high rates of chlamydia and gonorrhea.

The EPT statute, Health General Article §18–214.1, can be found on the Maryland Department of Health (MDH) EPT web page at: http://health.maryland.gov/EPTMaryland. The EPT implementation regulations, Code of Maryland Regulations (COMAR 10.06.07) were developed with input from clinicians and public health officials from around the state. The link to the regulations also can be found on the MDH EPT web page: <a href="http://health.maryland.gov/EPTMaryland">http://health.maryland.gov/EPTMaryland</a>.

<sup>&</sup>lt;sup>1</sup> CDC. Sexually Transmitted Infections Treatment Guidelines, 2021. https://www.cdc.gov/std/treatment-guidelines/clinical-EPT.htm.

<sup>&</sup>lt;sup>2</sup> CDC. <u>Legal Status of Expedited Partner Therapy (EPT)</u>. https://www.cdc.gov/std/ept/legal/default.htm.

Professional organizations such as the Centers for Disease Control and Prevention (CDC), 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 endorsing the use of EPT include the Board of Physicians; Board of Pharmacy; Board of Nursing; MedChi, the Maryland State Medical Society; the Maryland Pharmacists Association; the Maryland affiliates of ACOG, AAP and the American College of Nurse Midwives, as well as the Mid-Atlantic Association of Community Health Centers.

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.

All clinical guidance in this document is based on the most recent data, evidence base, and treatment recommendations from the Centers for Disease Control and Prevention. This information can be found in the Sexually Transmitted Infections Treatment Guidelines, 2021.<sup>3</sup> As the CDC treatment recommendations may be revised at any time based on antimicrobial resistance data, please check the online recommendations: https://www.cdc.gov/std/treatment-guidelines/intro.htm.

The full (print version) of the guidelines reference is: MMWR Recommendations and Reports, Vol. 70, No. 4, p. 10 or K. Workowski, L. Bachmann, P. Chan, C. Johnston, C. Muzny, I. Park, et al, Sexually Transmitted Infections Treatment Guidelines, 2021, MMWR Recommendations and Reports, Vol. 70, No. 4, https://www.cdc.gov/std/treatment-guidelines/STI-Guidelines-2021.pdf.

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<sup>&</sup>lt;sup>3</sup> CDC. Sexually Transmitted Infections Treatment Guidelines, 2021. https://www.cdc.gov/std/treatment-guidelines/clinical-EPT.htm.

#### SUMMARY OF CLINICAL GUIDANCE FOR EPT IN MARYLAND

- Eligible partners: Sex partners of patients with clinical or laboratory diagnosis chlamydia, gonorrhea or trichomoniasis who are unable or unlikely to obtain a prompt medical evaluation.
  - Adolescents and pregnant persons are eligible for EPT. EPT is not recommended for routine
    use in men who have sex with men (MSM) due to lack of EPT efficacy data in MSM
    partnerships and risk of STI/HIV co-infection among partners.
- Optimal partner management strategy: Attempt to bring partners in for a clinical evaluation, including STI testing, counseling, and treatment.
- 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 treated. If the last sexual encounter was more than 60 days prior to diagnosis, the most recent sex partner should be considered eligible. There is no limit to the number of sex partners who can be treated.
- Prescribing and dispensing: Prescriptions issued, and medications dispensed, must include the designation Expedited Partner Therapy, or EPT. If sex partners' names are unknown or undisclosed, the written designation EPT is sufficient for the pharmacist to fill the prescription. Separate prescriptions must be issued for each sex partner.
- > Recommended EPT treatment:
  - Sex partners of patients with chlamydia:
    - Doxycycline (Vibramycin) 100 mg orally 2 times a day for 7 days
  - Sex partners of patients with gonorrhea (only):
    - Cefixime (Suprax) 800 mg orally in a single dose
  - o Sex partners of patients with chlamydia/gonorrhea coinfection, or chlamydia not ruled out
    - Cefixime (Suprax) 800 mg orally in a single dose PLUS
    - Doxycycline (Vibramycin) 100 mg orally 2 times for day for 7 days
  - Sex partner of patients with trichomoniasis
    - Female partners: Metronidazole (Flagyl) 500 mg orally two times a day for 7 days
    - Male partners: Metronidazole (Flagyl) 2 g orally in a single dose

\*Note: Substitute azithromycin (Zithromax) 1 gram orally in a single dose for doxycycline for partners who may be pregnant or unlikely to adhere to a 7-day regimen

- ➤ Information and counseling: Patients must be given written information about the EPT partner medication or prescription they are receiving and information for each partner. Partner information should include advice to seek a medical evaluation; infection information; medication instructions; adverse reactions warnings; advice to abstain from sex for 7 days after patient/partner treatment completion. Fact sheets are available on the Maryland Department of Health's EPT web page for downloading at: <a href="http://health.maryland.gov/EPTMaryland">http://health.maryland.gov/EPTMaryland</a>. Any materials with comparable information may be used.
- **Patient retesting:** Recommended three months after completion of treatment.
- Adverse events: Report to the Maryland Department of Health: 410-767-6700. There have been no known instances of adverse reactions reported in Maryland, or in any other states where EPT is practiced.

#### **RATIONALE FOR EPT**

#### Public Health Importance of Chlamydia, Gonorrhea and Trichomoniasis

Sexually transmitted infections pose significant public health concerns in Maryland, amidst ongoing increases in reportable STIs - chlamydia, gonorrhea and syphilis - mirroring national trends. Data on chlamydia and gonorrhea in Maryland appear below. Like other STIs, trichomoniasis is associated with reproductive morbidity, an increased risk for HIV acquisition and significant racial and ethnic disparities in the United States. Unlike with chlamydia and gonorrhea, though, there are no routine trichomoniasis surveillance programs or reporting requirements, so the exact prevalence is undetermined. It is estimated to be the most prevalent nonviral STI in the world.<sup>4</sup> Based on available population-based and clinic-based surveillance studies, trichomoniasis is estimated to affect approximately 2.6 million people in the United States.<sup>5</sup>

In Maryland, in 2022, the latest for year for which data are available, there were 31,236 cases of chlamydia (a rate of 507 cases per 100,000) and 11,164 cases of gonorrhea (a rate of 181.1 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. <sup>6,7</sup> In Maryland, 26.7% of chlamydia cases and 18.1% of gonorrhea cases in 2022 were among 15-19 year olds. <sup>8</sup>

STIs are most often asymptomatic. If left untreated, they can lead to serious sequelae, especially in females, including pelvic inflammatory disease (PID), chronic pelvic pain, ectopic pregnancy, and preventable infertility. Repeat chlamydia and gonorrhea infections, which increase the risk of complications, occur in 10% -15% of females and males within six months after treatment. Up to 14% of people with chlamydia and 12% of people with gonorrhea become reinfected within 12 months of treatment, often through untreated partners. Subsequent chlamydial infections can lead to a higher risk for complications compared with first time chlamydial infections. <sup>10</sup>

Like chlamydia and gonorrhea, trichomoniasis infections are typically asymptomatic and are associated with serious adverse pregnancy outcomes including premature rupture of membranes, preterm labor, and low birth weight. Reinfection occurs in about 1 in 5 people within 3 months after receiving treatment.<sup>11</sup>

<sup>&</sup>lt;sup>4</sup> CDC. Sexually Transmitted Infections Treatment Guidelines, 2021. https://www.cdc.gov/std/treatment-guidelines/trichomoniasis.htm.

<sup>&</sup>lt;sup>5</sup> Ibid.

<sup>&</sup>lt;sup>6</sup> CDC. Sexually Transmitted Infections Surveillance, 2022. https://www.cdc.gov/std/statistics/2022/default.htm.

<sup>&</sup>lt;sup>7</sup> Maryland Department of Health. 2022 Maryland STI Annual Report.

https://health.maryland.gov/phpa/OIDPCS/CSTIP/Pages/STI-Data-Statistics.aspx.

<sup>&</sup>lt;sup>8</sup> Ibid.

<sup>&</sup>lt;sup>9</sup> E. Hook and H. Handsfield, "Gonococcal infections in the adult," in Sexually Transmitted Diseases, 3rd Edition, New York, McGraw Hill, 1999, pp. 451-466.

<sup>&</sup>lt;sup>10</sup> Hosenfeld CB, Workowski KA, Berman S, et al. Repeat infection with chlamydia and gonorrhea among females: a systematic review of the literature. Sexually transmitted diseases. Aug 2009;36(8):478-489.

<sup>&</sup>lt;sup>11</sup> CDC. About Trichomoniasis. https://www.cdc.gov/trichomoniasis/about/index.html.

#### **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. 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 number of partners treated when comparing EPT to patient-delivered partner notification and referral.

U.S. trials and a meta-analysis of EPT revealed that the magnitude of reduction in reinfection of index patients compared with patient referral differed according to the STI and the sex of the index patient. However, across trials, reductions in chlamydia prevalence at follow-up were approximately 20%; reductions in gonorrhea were approximately 50%.<sup>12</sup>

Existing data indicate that EPT might have a role in partner management for trichomoniasis; however, no partner management intervention has been demonstrated to be superior in reducing reinfection rates.<sup>13</sup>

In 2007, EPT was legally authorized for partner treatment of chlamydia and gonorrhea for patients seen in Baltimore City Health Department clinics. 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. <sup>14</sup>

## 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. 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

<sup>12</sup> CDC. STI Treatment Guidelines. https://www.cdc.gov/std/treatment-guidelines/clinical-EPT.htm

<sup>&</sup>lt;sup>13</sup> CDC. Sexually Transmitted Infections Treatment Guidelines, 2021. https://www.cdc.gov/std/treatment-guidelines/clinical-EPT.htm

<sup>&</sup>lt;sup>14</sup> C. Schumacher and K. Ghanem, "Retreatment Rates for Uncomplicated Gonorrhea Infection: Comparing Ceftriaxone and Azithromycin Versus Ceftriaxone and Doxycycline.," Sexually Transmitted Diseases, vol. 40, no. 7, pp. 539-545, 2013.

<sup>&</sup>lt;sup>15</sup> P. Kissinger and M. Hogben, "Expedited partner treatment for sexually transmitted infections: an update," Current Infectious Disease Reports, vol. 13, no. 2, pp. 188-195, 2011.

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. 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.

<sup>&</sup>lt;sup>16</sup> M. Golden, M. Hogben, H. Handsfield, J. St. Lawrence, J. Potterat and K. Holmes, "Partner notification for HIV and STD in the United States: low coverage for gonorrhea, chlamydial infection, and HIV," Sexually Transmitted Diseases, vol. 30, no. 6, pp. 490-496, 2003.

## CLINICAL GUIDANCE FOR USING EPT FOR CHLAMYDIA, GONORRHEA AND TRICHOMONIASIS

## Health Care Providers Authorized to Prescribe or Dispense EPT

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

- Physicians
- Authorized physician assistants
- Advanced practice registered nurses with prescriptive authority
- Registered nurses employed by Local Health Departments
- Pharmacists

## Selecting Appropriate Patients for EPT

#### Diagnostic Criteria

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

#### Age of Patient

Patients of any age with a diagnosis of chlamydia, gonorrhea, or trichomoniasis 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 in-person evaluation of partners is impractical or unsuccessful.

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.

#### Pregnant Women

The American College of Obstetricians and Gynecologists supports the use of EPT partner treatment for pregnant women to prevent chlamydia and gonorrhea reinfection when partners are unable or unwilling to seek medical care. <sup>17</sup>

#### Gender or Sexual Orientation

In general, EPT may be used regardless of the patient's gender or sexual orientation.

Data are limited regarding use of EPT for gonococcal or chlamydial infections, and regarding the efficacy of EPT in reducing persistent or recurrent gonorrhea among the MSM populations compared with the heterosexual population. Published studies, including recent data regarding extragenital testing, indicated that male partners of MSM diagnosed with gonorrhea or chlamydia might have other bacterial STIs, such as syphilis, or HIV.<sup>18</sup> EPT should not be routinely offered to male patients who have sex with other men (MSM) because of a high risk for coexisting infections, especially undiagnosed syphilis and/or HIV infection, in their partners. Shared clinical decision-making regarding EPT for MSM is recommended.

In Maryland, due to the increased rates of syphilis and HIV, particularly among men who have sex with men, EPT should not be routinely offered to MSM index patients or partners and should be used selectively and with caution to avoid missing potential concurrent infections.

#### 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.

<sup>&</sup>lt;sup>17</sup> American College of Obstetricians and Gynecologists, "Expedited partner therapy in the management of gonorrhea and chlamydial infection. Committee Opinion No. 632," Obstetrics and Gynecology, vol. 125, no. 6, pp. 1526-1528, 2015.

<sup>&</sup>lt;sup>18</sup> CDC. Sexually Transmitted Infections Treatment Guidelines, 2021. p.10. https://www.cdc.gov/std/treatment-guidelines/STI-Guidelines-2021.pdf

#### **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.

#### Timeframe

All sex partners in the 6o 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 6o days prior to diagnosis, the most recent sex partner should be treated.

#### **Pregnant Partners**

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.

<u>Drug Safety</u>: Azithromycin and cefixime are considered safe in pregnancy (Category B). However, doxycycline should not be provided to women who are pregnant or think that they may be pregnant. Azithromycin should be used as an alternative treatment for chlamydia among pregnant women. *Doxycyline* should not be prescribed for partners who may be pregnant, as it is contraindicated during the second and third trimesters of pregnancy. Although *metronidazole* crosses the placenta, data indicate that it poses a low risk to the developing fetus. No evidence of teratogenicity or mutagenic effects among infants has been found in multiple cross-sectional and cohort studies among pregnant women examining single-dose (2 g) and multidose metronidazole regimens.<sup>19</sup>

<u>Test-of-Cure</u>: Pregnant partners need a test-of-cure for chlamydia or gonorrhea three to four weeks after treatment to assure eradication of infection and prevent severe maternal and neonatal sequelae.<sup>20</sup>

#### Known Drug Allergies



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

<sup>&</sup>lt;sup>19</sup> Workowski K, Bachmann LH, Chan PA, et al. Sexually Transmitted Diseases Treatment Guidelines, 2021. MMWR Recommendations and Reports 2021; 70(No. 4): 1-192. <sup>20</sup> Ibid.

## Recommended EPT Treatment Regimens

The MDH-recommended EPT treatment regimens are based on the CDC's Sexually Transmitted Infections Treatment Guidelines, 2021.

Infection Diagnosed in Index Patient	Recommended EPT Treatment Regimen
Chlamydia Only	❖ Doxycycline (Vibramycin*) 100 mg orally 2 times a day for 7 days NOTE: Substitute azithromycin (Zithromax) 1 gram orally in a single dose for partners who may be pregnant or unlikely to adhere to a 7-day regimen
Gonorrhea Only	Cefixime (Suprax) 800 mg orally in a single dose
Gonorrhea/Chlamydia Coinfection Or Chlamydia Not Ruled Out	<ul> <li>Cefixime (Suprax) 800 mg orally in a single dose</li> <li>PLUS</li> <li>Doxycycline (Vibramycin) 100 mg orally 2 times for day for 7 days</li> <li>NOTE: Substitute azithromycin (Zithromax) 1 gram orally in a single dose for doxycycline for partners who may be pregnant or unlikely to adhere to a 7-day regimen</li> </ul>
Trichomoniasis	<ul> <li>Female partners: Metronidazole (Flagyl) 500 mg orally two times a day for 7 days</li> <li>Male partners: Metronidazole (Flagyl) 2 g orally in a single dose</li> <li>Tinidazole (Tindamax) 2 gm orally in a single dose (Alternative regimen for all non-pregnant partners)</li> </ul>

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

#### **ISSUES FOR CONSIDERATION**

#### Antimicrobial-resistant Gonorrhea

Because of global antimicrobial resistance, prompt diagnosis and accurate, timely treatment of gonorrhea is critical. Currently, the only CDC-recommended treatment of uncomplicated urogenital, anorectal, and pharyngeal gonorrhea is monotherapy with a single intramuscular dose of ceftriaxone 500 mg. However, because of EPT's effectiveness in reducing gonorrhea reinfection rates, CDC has recommended its use since 2006 for the heterosexual partners of patients diagnosed with gonorrhea if it was unlikely the partners would seek timely evaluation and treatment.<sup>21</sup>

If EPT via injection is not possible, CDC continues to recommend EPT for heterosexual men and women with gonorrhea whose partners are unlikely to access timely evaluation and injectable gonorrhea treatment. CDC recommends 800mg cefixime orally in a single dose. If chlamydia has not been ruled out in the index patient, the partner may be treated with a single dose of oral cefixime 800 mg plus oral doxycycline 100 mg 2 times/day for 7 days. If adherence with multiday dosing is a considerable concern, azithromycin 1 g can be considered but has lower treatment efficacy among persons with rectal chlamydia.<sup>22</sup>

Note: Both the CDC and the Maryland Department of Health Laboratories Administration are performing culture and antibiotic sensitivity testing - actively monitoring antimicrobial resistance to gonorrhea to guide national and local therapy recommendations.

#### Risk of adverse reactions to EPT medications

Adverse reactions are rare; the most commonly known reaction is mild gastrointestinal intolerance. EPT has been used across the county since it was authorized in California in 2001. California established a dedicated hotline to monitor adverse reactions. After nearly 10 years with no reports, the hotline was discontinued. The medications are highly effective antibiotics.

Researchers conducting multi-site randomized trials and community-level studies of EPT for chlamydia and gonorrhea received no reports of anaphylaxis or other major adverse drug reactions.<sup>23, 24</sup>

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 counseling information are available on the MDH EPT website. Report any adverse events to the Maryland Department of Health at (410) 767-6670.

<sup>&</sup>lt;sup>21</sup> Workowski K, Bachmann LH, Chan PA, et al. Sexually Transmitted Diseases Treatment Guidelines, 2021. MMWR Recommendations and Reports 2021; 70(No. 4): 1-192. <a href="https://www.cdc.gov/std/ept/gc-guidance.htm">https://www.cdc.gov/std/ept/gc-guidance.htm</a>

<sup>&</sup>lt;sup>22</sup> Workowski K, Bachmann LH, Chan PA, et al. Sexually Transmitted Diseases Treatment Guidelines, 2021. MMWR Recommendations and Reports 2021; 70(No. 4): 1-192. <a href="https://www.cdc.gov/std/ept/gc-guidance.htm">https://www.cdc.gov/std/ept/gc-guidance.htm</a>

<sup>23</sup> Schillinger JA, Kissinger P, Calvet H, et al. Patient-delivered partner treatment with azithromycin to prevent repeated Chlamydia trachomatis infection among women: a randomized, controlled trial. Sexually transmitted diseases. Jan 2003;30(1):49-56.
24 Golden MR, Kerani RP, Stenger M, et al. Uptake and population-level impact of expedited partner therapy (EPT) on Chlamydia trachomatis and Neisseria gonorrhoeae: the Washington State community-level randomized trial of EPT. PLoS medicine. Jan 2015;12(1):e1001777.

## PRESCRIBING AND DISPENSING

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

#### 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 persons and MSM;
- Medication instructions;
- Warnings about adverse or allergic reactions;
- Advice to abstain from sexual activity for 7 days after completion of treatment, and seven days after partners have completed treatment.

Informational materials for patients, partners, health care providers and pharmacists are available for downloading on the MDH EPT website at: <a href="http://health.maryland.gov/EPTMaryland">http://health.maryland.gov/EPTMaryland</a>. Any written materials may be provided to patients for each of their partners as long as the above-listed information is included.

#### **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 Maryland Confidential Morbidity Report Form (DHMH 1140 form) 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 EPT prescriptions were provided and/or medication was dispensed. See Maryland Confidential Morbidity Report Form: <a href="https://health.maryland.gov/phpa/Documents/DHMH-1140 MorbidityReport.pdf">https://health.maryland.gov/phpa/Documents/DHMH-1140 MorbidityReport.pdf</a>.

### Implementation Issues

#### Liability

The legislation under which EPT was made lawful did not include immunity provisions that would shield health care providers or pharmacists from lawsuits resulting from adverse outcomes related to the practice. No adverse events and/or life-threatening allergic reactions to these medications when dispensed as EPT have been reported to date in Maryland, and none are known to have been reported in any other states. Moreover, the practice of EPT is considered a best practice, and numerous national and state organizations support the use of EPT: Centers for Disease Control and Prevention (CDC); 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); Maryland Department of Health; Maryland Board of Physicians; Maryland Board of Pharmacy; Maryland Board of Nursing; Maryland Pharmacists Association; MedChi, Maryland Medical Society; Maryland affiliate, American College of Obstetricians and Gynecologists; Maryland affiliate, American Academy of Pediatrics; Maryland affiliate, American College of Nurse Midwives; Mid-Atlantic Association of Community Health Centers and more.

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;
  - 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.

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].

#### **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, treated and counseled about EPT appropriateness for chlamydia, gonorrhea or trichomoniasis partner treatment, problem-focused Evaluation and Management (E/M) codes 99201-99205 (new patient) or 99211-99215 (established patient) are applicable, based on the complexity of medical decision-making.

Instead of using the medical decision-making complexity, the level of the E/M service may be based on the total time spent delivering care and reviewing documentation the day of the visit. Be sure to document that total time to support time-based billing.

#### MARYLAND EPT RESOURCES

- ➤ EPT patient and partner information materials for chlamydia, gonorrhea and trichomoniasis are available online at <a href="http://health.maryland.gov/EPTMaryland">http://health.maryland.gov/EPTMaryland</a>. Also available is a fact sheet about EPT for health care providers and pharmacists.
- To report concerns about adverse reactions, call the Maryland Department of Health at 410-767-6670.
- Maryland's EPT statute: Md. HEALTH-GENERAL Code Ann. § 18-214.1.
- Maryland's EPT implementation regulations: <a href="http://health.maryland.gov/EPTMaryland.">http://health.maryland.gov/EPTMaryland.</a>
- For information on STI testing and treatment services, links to Maryland's 24 local health departments can be found here: <a href="http://health.maryland.gov/sexualhealth.">http://health.maryland.gov/sexualhealth.</a>
- ➤ The STD/HIV Prevention Training Center at Johns Hopkins (PTC) offers technical support on prevention strategies such as EPT, Express STI Testing and more. To contact the PTC, and to see the courses they offer in the diagnosis and clinical management of STIs, visit their website: www.stdpreventiontraining.com



Maryland Department of Health Prevention and Health Promotion Administration Infectious Disease Prevention and Health Services Bureau Center for STI Prevention

More information: <u>health.maryland.gov/EPTMaryland</u>

June 2016; updated June 2024