

**Expedited Partner Therapy (EPT) Guidelines for
Health Care Providers in New York State for *Chlamydia trachomatis***

Summary Guidelines

- **Patient's diagnosis:** Clinical or laboratory diagnosis of *Chlamydia trachomatis* (Ct).
- **First-choice partner management strategy:** Ideally, all partners should have a clinical evaluation, STI testing, counseling, and treatment.
- **Eligibility criteria for EPT.** EPT shall:
 1. Be provided only for partners of a patient diagnosed with Ct infection.
 2. Not be provided for any partners when the patient with Ct infection seen by the health care practitioner is concurrently infected with gonorrhea or syphilis.
- **Ideal (most appropriate) patient candidates:**
 1. Laboratory-confirmed diagnosis of Ct in the index patient
 2. Heterosexuals
 - EPT is not recommended for men who have sex with men (MSM) due to lack of study of EPT effectiveness in MSM partnerships and risk of STI/HIV co-infection among partners.
 3. Partners who are unable or unlikely to seek timely clinical services

Note: EPT is not appropriate for use in cases of child abuse, sexual assault, sexual abuse, or in cases where the patient's safety is in doubt.

- **Recommended drug regimen:** Azithromycin* 1 gram orally in a single dose.
- **Number of doses:** Limited to the number of known sex partners in previous 60 days (or most recent sex partner if none in the previous 60 days).
- **Informational materials:** Must be provided to patient to be given to partner(s) with medication/prescription and must include clear instructions, warnings, and referrals.
- **Patient counseling:** Sexual abstinence until seven days after treatment and until seven days after partners have been treated.
- **Patient re-testing:** Complete STI/HIV screening recommended three months after treatment.
- **Liability:** Health care providers or pharmacists who dispense EPT in accordance with the law shall not be subject to liability or be deemed to have engaged in unprofessional conduct.
- **Adverse events:** Report any EPT-related adverse events to your local public health authority.

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

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Background of EPT

Expedited Partner Therapy (EPT) is a strategy for treating the sex partner(s) of persons diagnosed with *Chlamydia trachomatis* (Ct), a bacterial sexually transmitted disease (STI). EPT allows health care providers to provide patients with medication or a prescription for Ct treatment to deliver to his or her sex partner(s) without a prior medical evaluation or clinical assessment of those partners. This strategy should not replace but augment current strategies such as provider referral (i.e., provider notifies partners of the possibility of exposure to an STI) and patient referral (i.e., patient informs partners of exposure to an STI and need for follow-up with appropriate services), when those services are available.

Under the New York State (NYS) law and regulations permitting EPT (Section 2312 of Public Health Law and 10 NYCRR §23.5), health care providers (i.e., physicians, midwives, nurse practitioners and physician assistants) or pharmacists who dispense EPT in accordance with this law shall not be subject to liability or be deemed to have engaged in unprofessional conduct.

Public Health Impact

Sexually transmitted chlamydial infections are a significant public health problem. More than 116,000 cases of *Chlamydia* were reported in New York State in 2017, making it the most common reportable communicable infection.ⁱ Women infected with *Chlamydia* are at increased risk for pelvic inflammatory disease (PID) and its complications, including chronic pelvic pain, ectopic pregnancy, and infertility.ⁱⁱ

Patients with this infection are also at increased risk of acquiring sexually transmitted HIV.ⁱⁱⁱ Repeat chlamydial infections occur in up to 13% of patients within 20 weeks post-treatment.^{iv} To prevent repeat infections, reduce complications in individuals, and reduce further transmission of infection in the community, sex partners of infected patients must be provided timely and appropriate antibiotic treatment.

Benefits of EPT

EPT is a useful strategy for treating the sex partners of heterosexual men and women with Ct infection. Randomized controlled trials have found that EPT decreases rates of Ct reinfection among index patients and increases the proportion of sex partner(s) reported to be treated for Ct.

It is important to note that EPT for gonorrheal infection is *not permissible* in New York State due to concerns about emerging antibiotic resistance (ex. Cephalosporins).

Eligibility Criteria for EPT

EPT can be provided for the following persons:

- Partners of patients diagnosed (either through laboratory confirmation or clinical diagnosis) with Ct infection.
 - Health care provider may ask about 60 day interval to identify sex partners or may give EPT for most recent sex partner(s) if none in the 60 day interval.
 - Partners who are pregnant - If the patient's sex partner is pregnant or may be pregnant, azithromycin is the recommended EPT treatment. The partner should take the medicine and then seek medical care as soon as possible.
 - Partners of patients who are unable or unlikely to seek timely clinical services may be ideal candidates for treatment via EPT.

EPT cannot be provided for the following persons:

- As stated in Section 23.5 of Title 10, Official Compilation of Codes, Rules, and Regulations of the State of New York, partner(s) of Ct infected patients who are co-infected with either gonorrhea or syphilis at time of Ct diagnosis are not eligible to receive EPT.

Special populations:

- Male patients known to have sex with other men (MSM)
 - EPT is not recommended for MSM due to the lack of data to demonstrate the effectiveness of EPT in the MSM population and the risk of missing STI/HIV co-infections.
- Adolescents
 - Provider referral, which is defined as partner notification carried out by health department staff, is the preferred approach to managing the sex partners of adolescent patients, where feasible. If provider referral is not available, and providers choose to use EPT for adolescent patients, EPT should be offered as medication, not prescription.
- Victims of sexual assault/abuse
 - In instances of suspect or confirmed child abuse, sexual abuse/assault, or in cases where the patient's safety may be at risk, EPT should not be offered.

Recommended treatment for EPT

The recommended EPT treatment for Ct infection is 1g of azithromycin taken as a single oral dose.

If the patient's sex partner is allergic to azithromycin, the partner should seek medical care as soon as possible so a health care provider can provide a suitable alternative Ct treatment.

Providing medication for EPT

The medication for EPT may be dispensed or prescribed. The preferred method is dispensing in a pre-packaged “partner pack” that includes medication, informational materials, and clinic referral.

If a health care provider provides EPT using medication:

Prescription medication should be dispensed and labeled in accordance with Federal & NYS rules and regulations (NYS Education Law Title VIII, Article 137: Section 6810).

If a health care provider provides EPT using a prescription, it must contain the following information:

- The designation “EPT” must be written in the body of the prescription form above the name of the medication and dosage for all prescriptions issued.
- If the sex partner’s name, address, and date of birth are **not** available, the written designation “EPT” shall be sufficient for the pharmacist to fill the prescription.
- If the name, address, and date of birth of the sex partner is available, this information should be written in the designated area of the prescription form.
- Prescription medication should be dispensed and labeled in accordance with Federal & NYS rules and regulations (NYS Education Law Title VIII, Article 137: Section 6810).

In addition to providing EPT, the provider:

- **Should** advise index patients to return for medical care three months after treatment for follow-up and re-testing for Ct.
- **Should** counsel the patient to notify sex partner(s) that they may have been exposed to Ct and should seek evaluation and treatment.
- **Must** ensure that patients receive informational materials for themselves and their sex partner(s).
- **Must** counsel patient to inform his or her sex partners that it is important to read the partner information prior to the partner or partners taking the medication.

Health Education Materials

NYS law requires that health education materials must be distributed when providing EPT (medication and prescription).

Health education materials must include the following information:

- Disclose the risk of potential adverse drug reactions, including allergic reactions, and the possibility of dangerous interactions between EPT and other medications that the partner may be taking.
- Recommend that partners who have allergies to antibiotics or who have serious health problems should **not** take the medication and should seek care

as soon as possible so a health care provider can provide the best Ct treatment for them.

- Inform the partner that if symptoms of a more serious infection are present (such as abdominal, pelvic, or testicular pain, fever, nausea, or vomiting) he or she should seek medical care as soon as possible.
- Recommend that sex partners who are or could be pregnant should consult a health care provider as soon as possible for follow-up care.
- Instruct the patient and partner to abstain from sexual activity for at least seven days after treatment of both the patient and partner in order to decrease the risk of recurrent infection.
- Inform the patient and the partner on how to prevent repeated Ct infection.
- Inform the partner that he or she may be affected by other STIs that may be left untreated by the delivered medicine.
- Encourage the partner to consult a health care provider for a complete STI evaluation as a preferred alternative to EPT regardless of whether he or she takes the medicine.
- Inform a partner who is at high risk of co-morbidity with HIV infection that he or she should consult a health care provider for a complete evaluation including testing for HIV and STIs.

NYS Department of Health and New York City (NYC) Department of Health and Mental Hygiene have developed EPT health education materials with the above elements for patients and partners and they are available online in English and Spanish at:

New York City: www.nyc.gov/health/ept.

New York State:

<https://www.health.ny.gov/diseases/communicable/std/ept/index.htm>.

Other materials that fulfill these requirements may be used. Please note that some states/jurisdictions permit EPT for gonorrhea and, consequently, their educational materials are not appropriate for use in NYS.

Reporting Adverse Events

Severe adverse reactions such as anaphylaxis are rare with azithromycin. Milder side effects including nausea and vomiting, which may impact the success of treatment, occurs in approximately 5 percent and 2 percent of patients, respectively.^v

Please report all known EPT related adverse events in New York City to 311 or the provider access line at 1-866-NYC-DOH1 (1-866-692-3641) and in New York State (outside New York City) to 1-518-474-3598.

Reporting Requirements

In New York State, physicians are still required by law to:

- Report cases to the local health officer (NYS Public Health Law, Article 21, Title 1, Section 2101; NYS Codes, Rules and Regulations, Chapter 1, Part 2, Section 2.10), and
- Cooperate with state and local health official's efforts to determine the source and control the spread of sexually transmitted disease (NYS Public Health Law, Article 23, Title 1, Section 2300; NYS Codes, Rules and Regulations, Chapter 1, Part 2, Section 2.6).

In New York City, report all cases of Ct diagnosis to the NYC DOHMH by submitting the NYC Department of Health & Mental Hygiene Universal Reporting Form (Form PD-16, 9/09). The current URF is available online at

<https://www1.nyc.gov/assets/doh/downloads/pdf/hcp/urf-0803.pdf>

Please complete the form online or mail the completed form to:

NYC Dept. of Health & Mental Hygiene
125 Worth Street
Room 315, CN-6; New York, NY 10013

In New York State (outside New York City), report all cases of Ct diagnosis to the local health department in which the case resides by submitting the completed confidential case report form (Form DOH-389). Confidential case report forms may be obtained by calling (518) 474-0548.

- Providers are required to document the use of EPT and the number of sex partners for whom EPT was provided on the relevant case reporting form.

Contact Us

Providers in New York City, please contact the NYC DOHMH BSTDC at ept@health.nyc.gov.

Providers in New York State outside of New York City, please contact the NYSDOH Bureau of Sexual Health and Epidemiology at ept@health.state.ny.us.

Other Resources

Expedited Partner Therapy EPT webpage. Centers for Disease Control and Prevention. Division of STD Prevention. National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention. <https://www.cdc.gov/std/ept/default.htm>

Centers for Disease Control and Prevention. Expedited partner therapy in the management of sexually transmitted diseases. Atlanta, GA: US Department of Health and Human Services, 2006.

<https://www.cdc.gov/std/treatment/EPTFinalReport2006.pdf>

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ⁱ New York State Department of Health 2017 Communicable Disease Annual Reports. [in print].

ⁱⁱ Stamm WE. *Chlamydia trachomatis* infections of the adult. in: Holmes KK, Sparling PF, Hardh P-A, et. al., eds. *Sexually Transmitted Diseases*, 3rd Edition. New York: McGraw-Hill, 1999:407-422.

ⁱⁱⁱ Wasserheit JN. Epidemiological synergy. Interrelationships between human immunodeficiency virus infection and other sexually transmitted diseases. *Sex Transm Dis* 1992; 19:61-77.

^{iv} Whittington WL, Kent C, Kissinger P, et al. Determinants of persistent and recurrent *Chlamydia trachomatis* infection in young women: results of a multicenter cohort study. *Sex Transm Dis* 2001; 28:117-123

^v Rubinstein E. Comparative safety of the different macrolides. *Int J Antimicrob Agents*. 2001;18:S71-6.