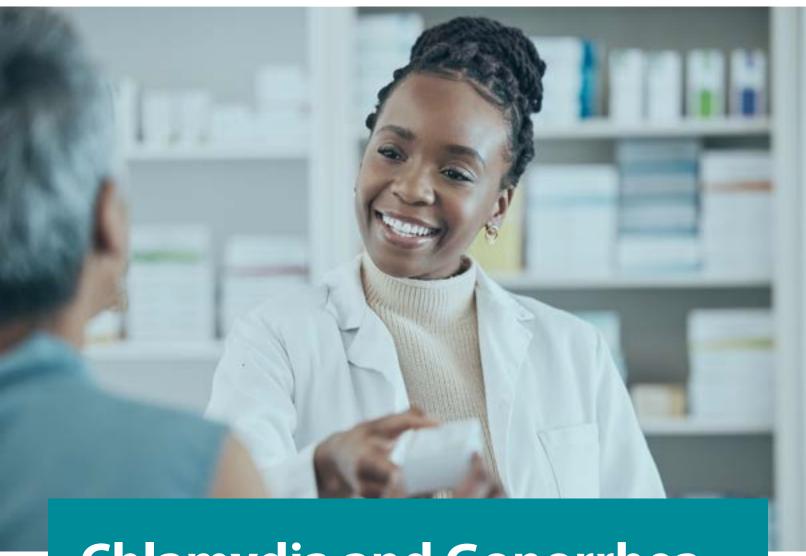
## **January 2024**



# Chlamydia and Gonorrhea Test-to-Treat Toolkit for Community Pharmacies



## **Toolkit Partners**







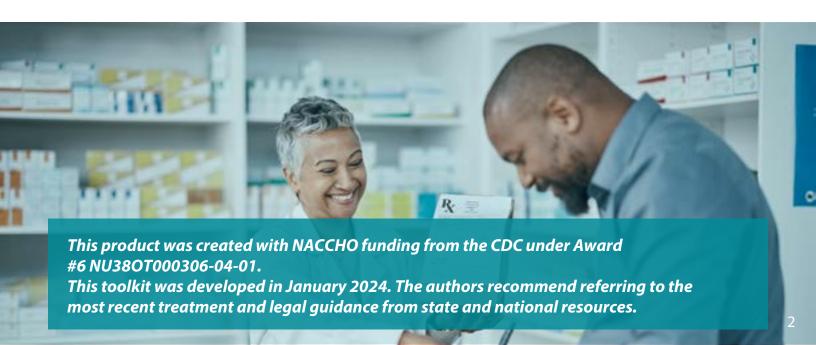
## Background

#### **Dear Colleagues:**

Welcome to this Sexually Transmitted Infection (STI) Test-to-Treat Toolkit for Community Pharmacies. This toolkit was developed as part of a pilot program funded by the National Association of County & City Health Officials (NACCHO) with support from the Centers for Disease Control and Prevention Division of STD Prevention. The objective of the pilot program was to expand access to testing and treatment for gonorrhea and chlamydia by partnering with the Allegheny County Health Department (ACHD) and Hilltop Pharmacy, a local independent pharmacy in Pittsburgh, Pennsylvania. Self-collected testing kits and laboratory services were provided, so patients can order their STI test online via the health department's website and ship it directly to their home or select to pick up at Hilltop Pharmacy for additional privacy. If the patient receives a positive test result, they will be contacted by staff at ACHD's STI clinic and offer treatment at either the clinic or at Hilltop Pharmacy. Hilltop Pharmacy can then provide treatment to patients via standing orders signed by ACHD's physician. The pilot project began on November 1st, 2022.

NACCHO recognizes that "practicing pharmacists are highly trained healthcare professionals, most accessible, and well positioned to consider innovative ways" to deliver STI services. There's a growing recognition of pharmacists and pharmacies for the public health work accomplished during the COVID-19 pandemic. As a result, there will be increased opportunities for community pharmacies to provide enhanced clinical services, like test-to-treat programs. Community pharmacies are in a unique position to provide access to STI services in communities that have limited access to these services.

This toolkit was developed in collaboration between a community pharmacy, a local health department, and The University of Pittsburgh School of Pharmacy. The collaboration and this subsequent toolkit was created when the collaborators recognized the need to share learnings from the pilot project with others. We hope that this toolkit will help you with implementing these services at your pharmacy to address the STI needs of your community.



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## TL;DR: Is your pharmacy ready for Test-to-Treat of Sexually Transmitted Infections?

### **Key items to have:**



### **Key Partnerships:**

Prescribers provide prescriptive authority for both testing and treatment depend-ing on state laws and regulations. CLIA-Certified lab

capable of conducting non-CLIA waived tests or carry Point-of-Care Tests that your pharmacy have CLIA-waiver to conduct. Others to consider are local health department and academic partner.



#### Workflow:

Draft up a workflow to ensure that all partners are on the same page with the program.



## Prescriptive Authority:

Determine if standing orders, protocols or a collaborative practice agreement is applicable to

your program. Remember to consult your pharmacy and physician scope of practice state laws.



# Pharmacy Training and Resources:

Make sure your pharmacists and

staff are trained and knowledgeable on STIs using the National STD Curriculum and trainings available through the American Pharmacists Association. Download the <u>STI Treatment Guide Mobile App</u> to your phone for quick referencing.



## Communication with the Public:

Consider how you will promote these services to the public.

## Samples in this toolkit that you may find helpful:

### **Testing Standing Order:**

Example testing standing order from Allegheny County pilot

### **Treatment Standing Order:**

Example treatment standing order from Allegheny County pilot

### **Pharmacy Intake Form:**

Example screening form used by the community pharmacy to capture your program. Remember to consult your pharmacy and physician scope of practice state laws

#### **Patient Education:**

Medication education handouts with patientfriendly STI language are a great way to remind patients of key recommendations discussed during the visit

- Make QR code and PDF available for patients who are concerned with privacy
- <u>Tell Your Partner</u> text service help patients anonymously notify their partners

### **Pharmacy Supply List:**

List of medications and supplies needed to administer treatment for gonorrhea and chlamydia that can be adapted for each pharmacy

#### Workflow:

A swimlane workflow diagram that demonstrates the role of each program partner as the patient is utilizing the service

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#### **Overview and Rationale**

Welcome to the Gonorrhea and Chlamydia Test-to-Treat Toolkit for Community Pharmacies. **The purpose of this toolkit is to assist pharmacists with the implementation of a chlamydia and gonorrhea test-to-treat programs in the community pharmacy setting.** Toolkit items can be used or adapted to fit the needs of your practice.

Preliminary 2021 sexually transmitted infection (STI) surveillance data from the Centers for Disease Control and Prevention showed 2.5 million reported cases of chlamydia, gonorrhea, and syphilis nationally<sup>1</sup>. However, STI test-to-treat services are not widely accessible in all communities in the United States (US). Implementation of test-to-treat programs for chlamydia and gonorrhea in community pharmacies provides pharmacists with an opportunity to collaborate with other providers to meet a public health need.



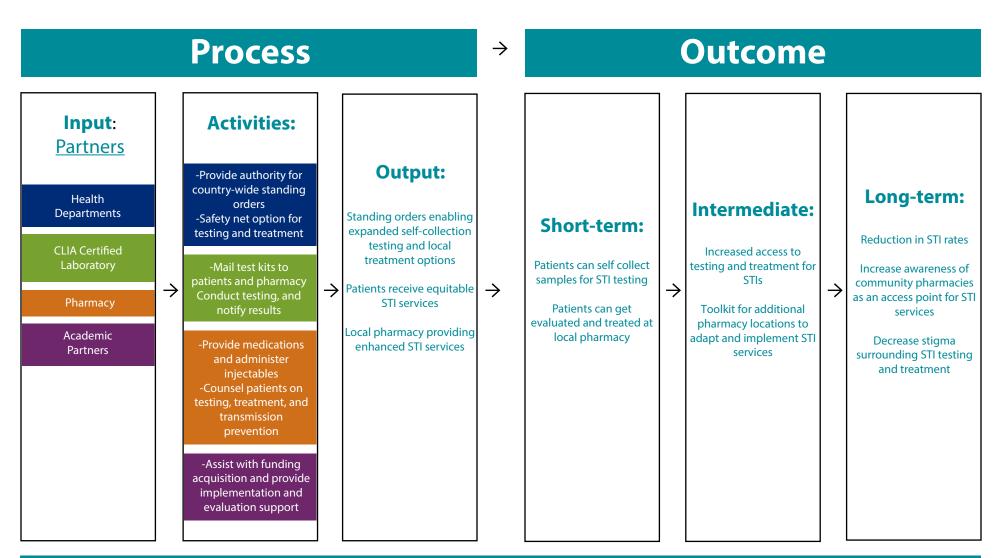
#### Why a test-to-treat model for pharmacies? What are the benefits?

Test-to-treat models for sexually transmitted infections increase access to STI services where testing options are limited. A recent nationwide analysis illustrated that nearly 90% of the US population lives within 5 miles of a community pharmacy<sup>2</sup>. This places community pharmacists among the most accessible healthcare personnel. As such, community pharmacies are well-positioned to combat the issue of rising STI rates by offering services to screen and treat common STIs, including chlamydia and gonorrhea. Additionally, pharmacies may offer discreet locations for accessing STI testing and treatment because these locations do not carry the same stigma as STI clinics.



### **Key Partnerships: Roles and Responsibilities**

Figure 1. Logic model for Partnership surrounding STI Self-Testing and Treatment in Community Pharmacies in Allegheny County pilot:



#### **Assumptions/Contextual Factors:**

CLIA-waived Point-of-Care STI tests are not currently available.

STIs are stigmatizing illnesses; therefore, patients may want more accessible and discreet testing and treatment options.

Statewide pharmacy law can constrain pharmacists' ability to provide similar services.

#### **Role of Community Pharmacies**

Community pharmacies can serve as a discreet location for patients to pick up self-collected testing kits and receive treatment because they are not associated with the same stigma that often surrounds STI clinics. Treatment at pharmacies can occur when the clinical responsibilities of a pharmacist are expanded with the use of standing orders. Standing orders can include written protocols that authorize designated members of a healthcare team to complete certain clinical tasks as delegated by a physician or other authorizing prescriber. Within the context of an STI test-to-treat pro-gram, a standing order gives authorization to pharmacists to initiate testing and provide treatment for patients with a positive result under the authority of an eligible prescriber.

#### **Roles and Responsibilities**

- Provide access point for self-collection testing kits
- Provide treatment to patients with positive results
- Provide patient education
- Counsel patients on how to tell partner(s) about their results
- Refer and connect patients to other healthcare providers when needed
- Give recommendations on expedited partner therapy (EPT)
  - For more information regarding EPT, see <u>CDC Legal Status of EPT</u>

#### **Role of Prescribers**

Partnership between a prescriber and a community pharmacy is necessary to implement a test-to-treat program for STIs within a community pharmacy. Prescriptive authority can be delegated by the prescriber to the pharmacy through a collaborative practice agreement (CPA) and/or through standing orders, depending on state laws and regulations. This prescriptive authority is necessary for both the testing and treatment components of the project. Partnerships between prescribers and community pharmacies have the most success when strong collaborative working relationships exist and test-to-treat programs are co-developed.

For more information regarding CPAs and standing orders, see Prescriptive Authority: Standing Orders, Protocols, and Collaborative Practice Agreements (Page 13).

#### **Roles and Responsibilities**

- Collaborate with pharmacy teams to write and sign-off on the standing order protocol or CPA
- Co-develop patient workflow with partners
- Triage clinically complex patient cases



#### **Role for Local or State Health Department(s)**

Members of the health department staff may include physicians, other providers who have prescriptive authority, as well as public health clinical and non-clinical staff who triage patient care needs. Including these staff from your local health department in your program can increase the impact of the program.

#### **Non-prescriber roles**

- Advertise/market the test-to-treat service to the community
- Provide input on health topics (e.g. STI testing guidelines, patient-friendly language)
- · Interface with the other community partners, labs, or testing providers
- Notify patients who have tested positive to provide counseling, education, and treatment recommendations

#### **Role of CLIA-Certified Laboratories**

CLIA-certified laboratories may provide a wide range of tests for different biomarkers and conditions. For a STI test-to-treat program, CLIA-certified laboratory is needed because of limited availability of CLIA-waived rapid diagnosis tests for STIs, however, they may be more widely available in the future. Self-collected test kits for chlamydia and gonorrhea are beneficial because patients may self-collect specimens outside of an STI clinic, increasing their accessibility to testing. Direct partnerships between CLIA-certified laboratories and pharmacies allow for quick treatment, if indicated.

CLIA-waived point-of-care testing that provides rapid results may be available after the development of this toolkit. If a pharmacy wants to provide rapid testing on-site, they will need to explore their own state laws around obtaining a CLIA waiver for testing and reporting at the pharmacy.

#### **Role of Academic Partners**

Consider partnering with faculty from a local university's school/college of pharmacy or school/college of public health who can help connect you to partners to make your test-to-treat programs a success. Universities can assist pharmacy teams and health departments with acquiring grant funding, and provide research, program evaluation, education, training, or implementation support. University teams can help gather evidence needed to demonstrate impact or build capacity for programs to grow and continue.

#### **Roles and Responsibilities**

- · Assist with grant funding acquisition
- · Provide program evaluation
- Connect to additional partners
- Provide additional support through student pharmacists
- Training and educational support for pharmacy teams
- Creation of patient education, tools, and resources

## Prescriptive Authority: Standing Orders, Protocols, and Collaborative Practice Agreements

Laws and regulations vary widely from state-to-state regarding standing orders, protocols, and collaborative practice agreements (CPA) for expansion of pharmacists' scope of practice. For example, some state laws may prevent pharmacists from initiating treatment under a CPA, therefore a standing order and protocol may need to be explored instead. Additionally, some states require that pharmacists only enter into CPAs with physicians (and not mid-level prescribers). The authors recommend consulting your state laws and regulations and the links below for further information.

#### More information on CPAs and standing orders can be found at:

Associations (NASPA) and with support from CDC's Division of STD Preventing and Treating STIs Report <sup>3</sup> Centers for Medicare & Medicaid Services Guidance Document <sup>4</sup> National Association of State Pharmacy Associations <sup>5</sup> National Associations <sup>5</sup> National Associations State Pharmacy Associations <sup>5</sup> NASPA – Pharmacist Prescribing: "Test and Treat" <sup>6</sup> NASPA – Pharmacist Prescribing: "Test and Treat" <sup>6</sup> CDC Collaborative Practice Agreements and Pharmacists' Patient Care Services <sup>7</sup> Associations (NASPA) and with support from CDC's Division of STD Prevention created this resource for local health departments and pharmacists to provide information from all states on what activities can be provided within the pharmacists' scope of work regarding STIs/HIV  CMS memorandum in support of pharmacists utilizing collaborative practice agreements, standing orders, or other protocols to address priority public health issues  Overview of definitions of collaborative practice agreement alo with a toolkit to develop one  Categorizes states based on which pharmacists have prescripting authority, which need a collaborative practice agreement, and includes a link to Point-of-Care Test and Treat National Certification Program  CDC Collaborative Practice Agreements and Pharmacists' Patient Care Services <sup>7</sup> Associations (NASPA) and with support from CDC's Division of STD Prevention created this resource for local health departments and pharmacists to provide information from all states on what activities can be provided within the pharmacists' scope of work regarding pharmacists or what activities can be provided within the pharmacists or what activities can be provided within the pharmacists or what activities can be provided within the pharmacists or what activities can be provided within the pharmacists or what activities can be provided within the pharmacists or what activities can be provided within the pharmacists or what activities can be provided within the pharmacists or what activities can be provided within the pharm		ind Standing Orders can be round att
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<u>CDC Creating Community-Clinical Linkages Between Community Pharmacists and Physicians: A Practitioner's Guide</u> CDC guidance for <b>providers</b> on effectively creating a collaborative practice agreement with a physician in the community	<u>ical Linkages Between Com-</u> <u>munity Pharmacists and Physi-</u>	collaborative practice agreement with a physician in the

## **Pharmacy Team Training and Resources**

Per the STI and HIV National Strategic Plans (2021-2025), pharmacists are included providers who are integral in supporting ongoing scale-up of HIV and STI screening and linkage to care. NACCHO collaborated with the National Network of STD Clinical Prevention Training Centers to develop a series of six 30-minute educational modules to orient pharmacists to sexual health topics broadly, and specifically.

STI and HIV prevention CE is available through NCPA, and you can access them here  $\frac{11}{2}$ 

Module 1 Intro and Sexual Health Discussions with Patients	This module discusses the role of the pharmacist in sexual health and STI management as well as communication strategies to obtain an accurate sexual history.
Module 2 Creating an Environment of Equitable Care	This module discusses the concept of gender diversity, the needs of LGBTQ+ patients, medical mistrust and equity gaps, and unique aspects of STI care for minors.
Module 3 STI Diagnosis and Testing	This module discusses diagnosis/testing for chlamydia, gonorrhea, and syphilis and how to collaborate with local health jurisdictions/health departments in patient care.
Module 4 HIV Testing for Non- Traditional Settings	This module discusses testing for HIV in the pharmacy setting, health department reporting requirements, and the pharmacist's role in supporting and connecting patients to HIV care.
Module 5 STI Treatment	This module discusses treatment for gonorrhea, chlamydia, and syphilis, follow-up for patients diagnosed with these STIs, and the pharmacist's role in caring for both the patient and their partner(s).
Module 6 HIV PEP, PrEP, and Prevention	This module discusses HIV prevention strategies including, (post-exposure and pre-exposure prophylaxis (PEP and PrEP), HIV treatment, and key STI/HIV counseling messages for use in the pharmacy setting.



Any members of the pharmacy team who provide any STI services or counseling are recommended to review the most updated educational materials regarding STI testing and treatment. The National STD Curriculum is a free educational website developed by the University of Washington STD Prevention Training Center through funding from the Centers for Disease Control and Prevention (CDC). The training modules include information related to epidemiology, pathogenesis, clinical manifestations, management, and prevention of each sexually transmitted infection (STI). The curriculum serves to provide pharmacy team members with a basis of clinical knowledge needed to implement an STI test-to-treat service into your pharmacy's workflow. Module 1 focuses on chlamydia, and Module 2 focuses on gonorrhea. You must register for a free account to access the modules. Each module takes approximately 45 minutes to complete and provides a certificate upon completion.

These modules are accessible at 12: <a href="https://www.std.uw.edu">https://www.std.uw.edu</a>

Additional Training Resources	Description
Center for Disease Control and Prevention <sup>13</sup>	The CDC provides a wide variety of statistics, fact sheets, and infographics about sexually transmitted infections. In addition, there is information available for healthcare providers regarding treatment for STIs and monitoring.
STI Treatment Guide Mobile App <sup>14</sup>	This is a mobile app, available through Google Play or the Apple App Store. It is also available for web browsers. This application is a quicker way to access additional information that patients may need regarding these disease states.
CDC's Guide to Taking a Sexual History <sup>15</sup>	This guide from the CDC provides a framework for discussing sexual health history with patients. Included in this guide are sample discussion points and appropriate, patient-friendly language.
Full STI Treatment Guidelines <sup>16</sup>	Full clinical guidelines and treatment recommendations from the CDC, last updated in 2021.
CDC Legal Status of EPT <sup>1Z</sup>	CDC resource that outlines the legality of expedited partner thera-py by jurisdiction.

#### **Communication with the Public**

One goal of implementing STI test-to-treat programs at community pharmacies is to increase patient access to these services in a non-stigmatized environment. To improve patient access, the public must first be aware of the services offered at the pharmacy. Communication with the public through various media sources may be beneficial for community awareness and engagement. Methods of communication and advertisement should be tailored for the target population. Below are a list of suggestions for communicating the availability of your STI program with the community.

Considerations for communicating your test-to-treat service with the public:

# 1

#### **Press Release:**

Press releases are one way to advertise your program to the public broadly. We've linked real examples here.

- Press Release Example 1<sup>18</sup>
- Press Release Example 2<sup>19</sup>

#### **Internet/Google Search:**

2

In our pilot program, search engine advertisement was one of the most effective ways to reach the people who already want to access testing. This had higher return on investment for the pilot program than advertising broadly on social media and dating apps to increase awareness.

#### **Social Media:**

3

Utilize popular platforms that are used frequently by your target demographic. Twitter, Instagram, Facebook and TikTok are popular social networking sites for younger populations. Posts and advertisements can reach more people using hashtags such as #STITreatment, #GetTested. Additionally, advertisements can be tailored to target certain demographic or geographic areas using the social network advertising manager.



#### **Dating Apps:**

Tinder and Grindr are popular dating apps used by young adults and may be opportune platforms for advertising your service.

#### **Utilize Patient-Friendly Language:**



The CDC has examples of appropriate language to use when writing and designing advertisements or other documents displayed to the public. It is important to use patient-friendly language that can be easily understood by individuals at any level of health literacy. See the following resources for more detail:

- CDC Health Equity Guiding Principles for Inclusive Communication<sup>20</sup>
- CDC Plain Language Thesaurus for Health Communication<sup>21</sup>
- CDC Clear Communication Index<sup>22</sup>

## Partner with Community Organizations who Serve Priority Populations:

6

Consider partnering with local community organizations, colleges/universities, physician practices, and community centers who serve priority populations (e.g. young adults, LGBTQIA+) to increase public awareness of your service.

#### **Advertise in Highly Trafficked Locations for Young People:**

7

Place physical advertisements like fliers or signs in restaurants or bars to increase awareness in the target demographic (e.g. "get tested" drink coasters at local bars).

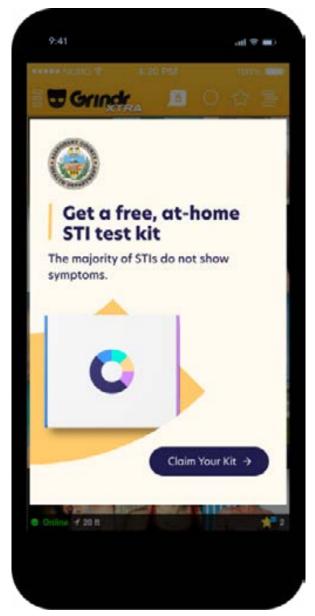
#### **Create Billboards and Bus Signs:**



Consider placing large physical advertisements, such as billboards or bus signs, in areas where STI rates are particularly high or in neighborhoods your pharmacy serves.



#### **Sample Advertisements Used in the Pilot Program**











# **Appendices**

We invite you to explore the appendices provided that offer resources you can use for your upcoming partnerships.

## **Appendix A. Testing Standing Order**

Most testing for chlamydia and gonorrhea currently requires an order from an authorizing prescriber and a CLIA-certified laboratory to carry out the testing. CLIA-waived STI testing may become more available in the future. The testing standing order is a written legal agreement from the prescriber to allow the CLIA-certified laboratory to supply the self-collection test kits to patients. This agreement may also serve to protocolize the testing and results reporting processes. A standing order with the lab allows for a more accessible way for patients to get tested because they don't need to see a provider before getting tested.

The included example testing standing order was implemented in the Allegheny County Health Department (ACHD) pilot program. Testing offered in this pilot program was a direct partnership between the health department and the CLIA-certified laboratory. The testing standing order was signed by a physician at the health department. It outlines criteria for patient eligibility and the types of tests available to be ordered depending on a person's sexual history. The procedure document from ACHD outlines the roles and responsibilities of staff at the health department who verify and document test results, screen for eligibility to obtain treatment at a pharmacy, and provide referral for treatment at the pharmacy. The pharmacy should strive to work collaboratively with the prescriber on the testing standing order if they wish to play a role in the testing phase of the test-to-treat program.

Community pharmacies can also consider a direct partnership with a CLIA-certified lab to provide testing services to their patients. In this scenario, the testing company may have an affiliated physician who would be the ordering prescriber on a testing standing order. Pharmacies can potentially have faster access to test results and more autonomy to implement the program into the pharmacy workflow with this type of partnership. Chlamydia and gonorrhea are reportable diseases affecting public health.<sup>23</sup> Ensure the lab you work with has the capabilities to report test results in accordance with national, state, and local standards.



#### **Sample Testing Standing Order**

#### **Criteria for Identifying Eligible Individuals**

#### Individuals that meet the following criteria are eligible to participate in the STI Program:

- Individuals aged 18 years and older, AND,
- Individuals that provide a shipping address located in a zip code within Allegheny County

#### Individuals with ANY of the following will be encouraged to seek in-person evaluation:

- Individuals reporting any of the following symptoms of chlamydia/gonorrhea:
  - Blister, sore, or bump on vagina, penis, or anus
  - New or unusual vaginal discharge
  - Rash
  - Persistent lower abdominal pain
  - Fever
  - Dyspareunia ("Pain during sex")
  - Dysuria ("Pain or burning while peeing")
- Known exposure to an STI
- Individuals reporting known or possible pregnancy ("I am or think I may be pregnant")

#### Individuals that meet the following criteria are eligible to receive a 1-site CT/GC collection kit:

- Who do not meet criteria to receive 3-site testing, AND,
  - Who have not been screened for gonorrhea or chlamydia in the past 3 months

#### Individuals that meet the following criteria are eligible to receive a 3-site CT/GC collection kit:

- Male sex or "not otherwise represented" sex who report anal or oral intercourse AND
  - Who have not been screened for gonorrhea or chlamydia in the past 3 months

By my signature below, I attest that I am a physician duly licensed to practice in the State of Pennsylvania, with the authority to request a qualified clinical laboratory to perform and report the results of the Chlamydia/Gonorrhea Molecular Test (the "CT/GC Test") for individuals requesting home STI testing in Allegheny County and/or other individuals affiliated with the STI Program Sponsor that are separately identified to [Lab Name] (each, an "Eligible Individual"). I have provided the criteria for identifying Eligible Individuals below and hereby attest that Chlamydia/Gonorrhea Testing is appropriate for Eligible Individuals because Eligible Individuals who are infected with Chlamydia/Gonorrhea may pose a direct threat to the health and safety of themselves and others, or because they meet the CDC's criteria for such testing.

By signing below, I confirm that the STI Program Sponsor has agreed to procure the CT/GC Test from a qualified clinical laboratory, and that this Test Authorization and Request serves as my blanket physician order requesting a qualified clinical laboratory to perform the CT/GC Test for each Eligible Individual. I hereby request such CT/GC Testing be performed at a frequency and in a population specified by the STI Program Sponsor. In all cases, I hereby instruct [Lab Name] to deliver each CT/GC result to me and directly to the Eligible Individual.

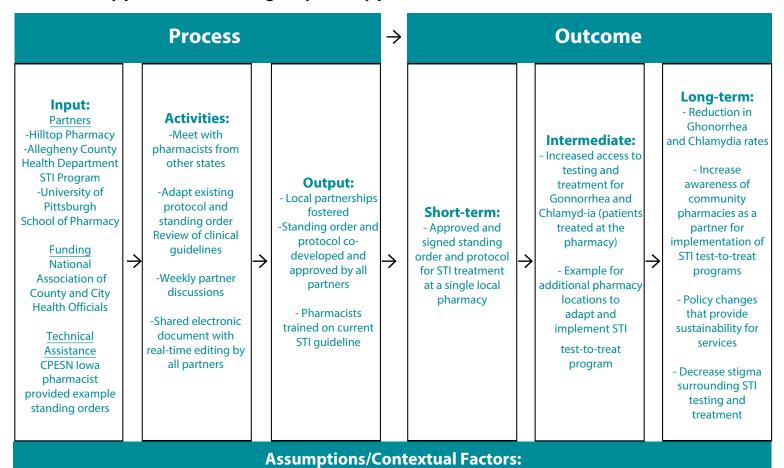
This Physician Authorization and Request expires upon my instruction or at the end of the STI Program Sponsor's CT/GC testing program, whichever occurs first.

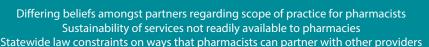
Signature:				
Print Name:	Authorizing Physicial, MD/DO	Title:	Physician on Record	
State of Licensure:	PA	Date:	March 31, 2023	

## **Appendix B. Treatment Standing Order**

To initiate treatment for patients who tested positive, some states may require a mechanism to delegate prescribing authority to pharmacists. Depending on state rules and regulations, this mechanism could be a standing order and protocol or a collaborative practice agreement between a pharmacist and a prescriber (see page 10). A standing order created in collaboration with your selected prescribing entity will include details on guideline-recommended treatments for gonorrhea and chlamydia.

Logic model for the collaborative development of standing order for STI treatment in community pharmacies in Allegheny County pilot:







## Sample Allegheny County Standing Order Directed to Partner Pharmacy for the Treatment of Chlamydia and Gonorrhea

#### I. Authority

Pursuant to Title 49, Pa Code § 18.402. Delegation: A medical doctor may under certain conditions delegate to a health care practitioner or technician the performance of a medical service. Under this standing order, a pharmacist may order and administer treatment pursuant to a protocol developed collaboratively by the Allegheny County Health Department ("ACHD") to individuals aged 18 years and older, and only in accordance with this protocol. For the purpose of this protocol, "pharmacist" shall include a licensed pharmacist or registered pharmacist-intern who has completed the training requirements identified in Section III (Qualification). Non-clinical, technical functions may be delegated to a pharmacy technician who has documented training in the function being delegated and who is under the supervision of a pharmacist.

#### II. Purpose

As of the date of this Standing Order and until otherwise revised, this protocol, a modification of the Sexually Transmitted Diseases: CDC Treatment Guidelines, will serve as Standing Orders for use by pharmacists employed by Hilltop Pharmacy to treat patients with antibiotic therapies for chlamydia and gonorrhea upon receipt of a positive test through the Allegheny County Health Department's Sexually Transmitted Infections (STI) home testing program. This Standing Order includes implementation of expedited partner therapy (EPT) for those patients. EPT uses antibiotic therapies for chlamydia and gonorrhea to treat patients' sex partner(s) who are unable or unlikely to be evaluated or treated by a health professional. EPT does not replace standard, traditional partner management.

#### III. Qualification

Prior to dispensing and/or administering antibiotic therapy under this protocol, all pharmacists who will be involved shall document successful completion of the National STD Curriculum Chlamydia and Gonorrhea Self Study modules. Documentation of completion shall be shared with ACHD.

Pharmacists are required to demonstrate ongoing competency with respect to the administration of injectables by maintaining up-to-date basic life support/CPR training and an injectable administration license.

#### IV. Patient Evaluation

- **A. Medical and social history.** Prior to dispensing and/or administering antibiotic therapy under this protocol, the pharmacist shall collect and evaluate the following medical and social history:
  - i. Past medical history;
  - ii. Current clinical comorbidities or disease states, including current mental status;

- iii. Current blood pressure, pulse, temperature, and weight;
- iv. Relevant social history;
- v. For females of child-bearing potential, pregnancy or breastfeeding status
- vi. Current medication use;
- vii. Allergies and hypersensitivities (pharmacist shall assess reported allergies for validity by reviewing the patient's pharmacy record, if applicable, and documenting the reported reaction);
- viii. Positive test for chlamydia or gonorrhea;
- ix. Consent for treatment
- B. Exclusion criteria. Upon evaluation of the medical and social history in paragraph A, the pharmacist shall not dispense antibiotic therapy to a patient who meets ANY of the criteria listed below and shall refer the patient to the ACHD STD/HIV program, their primary care provider, or other urgent/emergency treatment facility as clinically appropriate:
  - i. Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than two (2) weeks, HIV/AIDS);
  - ii. History of rheumatic fever, rheumatic heart disease, scarlet fever, or GAS-induced glomerulonephritis;
  - iii. Clinical instability based on the pharmacist's clinical judgment or ANY of the following conditions:
    - a. Acute altered mental status;
    - b. Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;</li>
    - c. Pulse > 125 beats/minute;
    - d. Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit;
    - e. Symptoms of pelvic inflammatory disease, for any female persons or persons with uterus, fallopian tubes, or ovaries (e.g. lower bilateral abdominal pain, abnormal uterine bleeding, urinary frequency, vaginal discharge, pain during intercourse, etc.

#### V. Patient Education Required

The pharmacist shall counsel and educate the patient on appropriate self-care, including infection control measures and safe sex practices in accordance with CDC guidelines. A pharmacist ordering and dispensing antibiotic therapy under this protocol shall provide the following:

- A. Medication counseling consistent with state and federal requirements for prescription drug products.
- B. Instructions on signs and symptoms that warrant emergency medical care.
- C. Advise patient to reach out to a healthcare provider if after 5 days symptoms do not improve
- D. Advise patient to re-test in 3 months following treatment as re-infection is common.
- E. Test of cure is unnecessary with the following exceptions:
  - i. Pregnant patient with chlamydia should return for test-of-cure 4 weeks after

- ii. Patient with gonorrhea treated with any other agent other than ceftriaxone should return 4 weeks after treatment completion for test-of-cure.
- iii. Patient with pharyngeal gonorrhea should return for test-of-cure 7-14 days after initial treatment.
- F. Abstain from sexual intercourse of 7 days after initiation of appropriate antibiotic therapy.
- G. Abstain from sexual intercourse until are partners have completed treatment and the appropriate no sex timeframe.

#### **VI. Expedited Partner Therapy (EPT)**

EPT is only offered if after providing patient education, patient reports that their sexual partner is unable or unlikely to be evaluated or treated by a health professional.

#### A. Evaluation

- ii. Medical and social history. Prior to dispensing and/or administering antibiotic therapy for partner(s) under this protocol, the pharmacist shall collect and evaluate the following medical and social history:
  - a. Consent for EPT
  - b. Status of HIV and syphilis testing
  - c. Sexual partner status within 60 days of diagnosis including name(s) of partner(s), if known
- *iii. Exclusion criteria.* Upon evaluation of the medical and social history, the pharmacist shall not dispense EPT to a patient who meets ANY of the criteria listed below and shall advise the patient to refer their partner(s) to a health care provider:
  - a. Co-infection with HIV and/or syphilis
  - b. Pregnant
  - c. Partner likely to be evaluated or treated by health professional

#### B. Education

The pharmacist shall counsel and educate the patient on appropriate self-care, including infection control measures and safe sex practices in accordance with CDC guidelines. A pharmacist ordering and dispensing antibiotic therapy under this protocol shall provide the following:

- i. Advise the patient that the gold standard of STI partner treatment is examination and treatment by a clinician
- ii. Counsel the patient about talking to their partner(s) and providing the medication with accurate information including:
  - a. Medication counseling consistent with state and federal requirements for prescription drug products including contraindications (partner is pregnant or has an allergy to the medication)
  - b. Instructions on signs and symptoms that warrant emergency medical care disease information
  - c. Instructions on seeking medical evaluation as soon as possible for HIV infection and any symptoms of STIs

- d. Referral information for STI evaluation including syphilis and HIV testing
- e. Abstain from sexual intercourse of 7 days after initiation of appropriate antibiotic therapy

#### VII. Monitoring and Follow-Up

Except for retesting for gonorrhea or chlamydia as above, no additional follow-up laboratory test(s) shall be required. The pharmacist shall refer the patient to the ACHD Public Health Clinic, a primary care provider or urgent/emergency treatment facility if ANY of the following are reported:

- A. All of the treatment options outlined in the protocol are contraindicated;
- B. Significant deterioration in condition or new evidence of clinical instability;
- C. Lack of improvement in symptoms or onset of symptoms indicative of serious complications;
- D. Medication adverse effects severe enough to warrant discontinuation of therapy.

#### VIII. Protocol, Facility, and Equipment

A pharmacist who orders, dispenses, or administers antibiotic therapies pursuant to this protocol shall maintain a current copy of this protocol and an appropriately private area for patient testing and counseling at each location at which the pharmacist engages in the protocol activities. A pharmacist shall ensure that the following supplies are readily available when engaged in the activities identified in this protocol:

- A. Treatment equipment and associated supplies;
- B. Scale:
- C. Blood pressure cuff (appropriately sized for the patients treated);
- D. Thermometer (oral, tympanic, or temporal);
- E. Supplies needed for antibiotic administration, including an appropriate anaphylaxis response protocol

#### IX. Documentation

The pharmacist shall maintain via patient record or electronic health record the following documentation for each patient who is treated for chlamydia or gonorrhea under this protocol:

- A. Patients' consent for treatment;
- B. The patient's medical and social history collected by the pharmacist;
- C. Result of the test used to determine Chlamydia and Gonorrhea infection;
- D. Required elements for the dispensing of prescription medication, if dispensed, pursuant to 49 Pa. Code § 27.18 (Standards of practice);
- E. The patient's attestation that they received and expressed understanding of the required counseling and education;
- F. The rationale for the antibiotic selected;
- **G. PA-NEDSS Requirements**

- i. Patient's name and date of birth
- ii. Test results
- iii. Medication dispensed or administered
- iv. Follow-up plan
- H. EPT (if dispensed to the patient)
  - i. Patient's medical and social history collected by the pharmacist;
  - ii. Required elements for the dispensing of prescription medication, if dispensed, pursuant to 49 Pa. Code § 27.18 (Standards of practice);
    - a. Label a drug dispensed pursuant to the prescription without the name of the individual for whom the drug is intended if the name of the partner is unknown
  - iii. The patient's attestation that they received and expressed understanding of the required counseling and education for the purpose of sharing the information with their partner
  - iv. The rationale for the antibiotic selected;



#### **Treatment of Chlamydia**

#### FIRST-LINE TREATMENT FOR CHLAMYDIA TRACHOMATIS\*

\*Unless contraindicated or the patient is determined to be likely non-adherent with doxycycline per previous medical record

#### A positive chlamydia infection shall be treated with:

1. Doxycycline monohydrate capsule 100 mg orally BID for 7 days.

#### **CONTRAINDICATIONS TO DOXYCYCLINE:**

- 1. Hypersensitivity to tetracyclines
- 2. Myasthenia gravis
- 3. Concurrent use with isotretinoin
- 4. Pregnancy
- 5. Breastfeeding

#### The dispensing pharmacist shall provide patient with:

1. #14 Doxycycline monohydrate 100mg capsules for oral use.

## The following instruction for use will be provided to the patient:

- 1. Take one 100 mg Doxycycline monohydrate capsule two times a day for seven days.
- 2. Take medicine at the same time each day.
- 3. Medication may be taken with or without food.
- 4. Take with a whole glass of water.
- 5. Do not take bismuth, calcium, iron, magnesium, zinc, multivitamins with minerals, colestipol, cholestyramine, didanosine, or antacids within 2 hours of this drug.

- 1. Side effects of the medication include but are not limited to:
  - Photosensitivity
  - Diarrhea
  - Nasopharyngitis
  - Stevens-Johnson syndrome
  - Toxic epidermal necrolysis
  - Clostridium difficile infection
  - Hepatotoxicity
  - Hypersensitivity reaction
  - Pseudotumor cerebri
  - Upset stomach
  - Vomiting
  - Decreased appetite

#### **Treatment of Chlamydia (continued)**

#### SECOND-LINE TREATMENT FOR CHLAMYDIA TRACHOMATIS\*

\*Patient with contraindication or likely to be non-adherent to doxycycline

#### A positive chlamydia infection shall be treated with:

1. Azithromycin 1 gram (1000 mg) orally as a single dose.

#### **CONTRAINDICATIONS TO AZITHROMYCIN:**

- 1. Cholestatic jaundice with prior azithromycin use.
- 2. Hepatic dysfunction with prior azithromycin use.
- 3. Hypersensitivity reaction to azithromycin or to any product component, erythromycin, or any macrolide or ketolide antibiotic.

#### The dispensing pharmacist shall provide patient with:

1. #2 azithromycin 500 mg tablets for oral use.

#### The following instruction for use will be provided to the patient:

- 1. Take two 500 mg azithromycin orally one time.
- 2. Medication may be taken with or without food.
- 3. Take with a whole glass of water.
- 4. Do not take with antacids that have magnesium or aluminum at the same time as this drug.

- 1. Side effects of the medication include but are not limited to:
  - Abdominal pain
  - Diarrhea
  - Flatulence
  - Nausea
  - Vomiting
  - Increased liver enzymes
  - Headache
  - Abnormal vision
  - Prolonged QTc
  - Stevens-Johnson syndrom
  - Toxic epidermal necrolysis
  - Hypersensitivity reaction



#### **Treatment of Gonorrhea**

#### FIRST-LINE TREATMENT FOR GONORRHEA \*

\*Unless contraindicated or patient refuses injectable medication or is unable to return for treatment and needs medication delivered

#### A positive gonorrhea infection shall be treated with:

- 1. Ceftriaxone at a dose of:
  - a. 500 mg IM single dose if < 150 kg (less than 330 lbs)
  - b. 1 gm IM single dose if  $\geq$  150 kg (greater than or equal to 330 lbs)

#### **CONTRAINDICATIONS TO CEFTRIAXONE:**

- 1. Hypersensitivity to cephalosporins
- 2. If the patient has a penicillin allergy, ask the patient about the symptoms of the allergy and document them in the medical record.
  - a. Patients reporting penicillin allergy who do not recall if they tolerated a penicillin derivative (e.g. amoxicillin, Augmentin, Keflex, Vantin) may receive ceftriaxone ONLY if they did not have a severe reaction to penicillin. (e.g. hives, bronchospasm).

#### The dispensing pharmacist shall provide patient with:

1. Ceftriaxone Intramuscular injection once at the proper dose listed above.

#### Instructions for use

- 1. A concentration of 250 mg/ml or 350 mg/ml is recommended and may be diluted with 1:1 water or 1% lidocaine for IM administration only.
  - a. Inject diluent into the vial, shake the vial thoroughly to form a solution. Withdraw entire contents of vial into syringe to equal total labeled dose.
- 2. Give via deep IM injection into large muscle mass (e.g. intragluteal). Aspiration helps to avoid unintentional injection into a blood vessel.

- 1. Side effects of the medication include but are not limited to:
  - Skin tightness at injection site
  - · Warm sensations at injection site
  - Flushing
  - Diaphoresis
  - Skin rash
  - Pruritus
  - Diarrhea
  - Renal impairment
  - Stevens-Johnson syndrome
  - Toxic epidermal necrolysis

#### **Treatment of Gonorrhea (continued)**

#### SECOND-LINE TREATMENT FOR GONORRHEA \*

\*Patient with contraindication to ceftriaxone

#### A positive gonorrhea infection shall be treated with:

1. Azithromycin 2 gram orally single dose AND gentamicin 240 mg IM single dose given as two divided doses.

#### The dispensing pharmacist shall provide patient with:

Four azithromycin 500 mg tablets orally AND gentamicin 240 mg IM given as two divided doses. (Give two 3ml doses at a concentration of 40 mg/ml)

#### Instructions for use:

#### **Azithromycin**

- 1. Take four (4) 500 mg Azithromycin orally one (1) time.
- 2. Medication may be taken with or without food.
- 3. Take with a whole glass of water.
- 4. Do not take with antacids that have magnesium or aluminum at the same time as this drug

#### Gentamicin

1. Administer as an IM injection in any site EXCEPT the deltoid.

- 1. Side effects of azithromycin are described above in the treatment of Chlamydia
- 2. Side effects of gentamicin include but are not limited to:
  - Worsening kidney function
  - Dizziness
  - Hearing loss
  - Numbness/tingling
  - Muscle twitching
  - Convulsion
  - Myasthenia gravis -like syndrome
  - Lethargy
  - Confusion
  - Visual disturbances
  - · Decrease appetite
  - Rash
  - Itching
  - Alopecia
  - Joint pain

#### **Treatment of Gonorrhea (continued)**

#### **CONTRAINDICATIONS TO AZITHROMYCIN/GENTAMICIN:**

- 1. Cholestatic Jaundice with prior azithromycin use.
- 2. Hepatic dysfunction with prior azithromycin use.
- 3. Hypersensitivity reaction to azithromycin or to any product component, erythromycin, or any macrolide or ketolide antibiotic.
- 4. Hypersensitivity to aminoglycosides
- 5. Pregnancy

#### THIRD LINE TREATMENT FOR GONORRHEA \*

\*Patient refuses injectable medication or is unable to return for treatment and needs medication delivered

#### A positive gonorrhea infection shall be treated with:

1. Cefixime 800 mg PO single dose

#### The dispensing pharmacist shall provide patient with:

1. Two cefixime 400 mg tablets

#### Instructions for use

- 1. Take two cefixime 400 mg tablets once.
- 2. Medication may be taken with or without food.
- 3. Take with a whole glass of water.
- 4. Do not take bismuth, calcium, iron, magnesium, zinc, multivitamins with minerals, colestipol, cholestyramine, didanosine, or antacids within 2 hours of this drug.

#### The patient shall receive the following education:

- 1. Side effects of the medication include but are not limited to:
  - Diarrhea
  - Nausea
  - Abdominal pain
  - Dyspepsia
  - Skin rashes
  - Urticaria
  - Angioedema
  - Stevens-Johnson syndrome
  - Transient elevated liver enzymes
  - Dizziness
  - Seizures

#### **CONTRAINDICATIONS TO CEFIXIME:**

Known allergy to cefixime or other cephalosporins

#### **Expedited partner therapy for Chlamydia**

#### FIRST-LINE EXPEDITED PARTNER TREATMENT FOR CHLAMYDIA TRACHOMATIS\*

\*Unless partner has a known contraindication

#### A partner of a patient with a positive chlamydia infection shall be treated with:

1. Doxycycline monohydrate capsule 100 mg orally BID for 7 days.

#### **CONTRAINDICATIONS TO DOXYCYCLINE:**

- 1. Hypersensitivity to tetracyclines
- 2. Myasthenia gravis
- 3. Concurrent use with isotretinoin
- 4. Pregnancy
- 5. Breastfeeding

#### The dispensing pharmacist shall provide patient with partner pack of:

1. #14 Doxycycline monohydrate 100 mg capsules for oral use.

#### The following instruction for use will be provided to the patient to share with their partner:

- 1. Take one 100 mg Doxycycline monohydrate capsule two times a day for seven days.
- 2. Take medicine at the same time each day.
- 3. Medication may be taken with or without food.
- 4. Take with a whole glass of water.
- 5. Do not take bismuth, calcium, iron, magnesium, zinc, multivitamins with minerals, colestipol, cholestyramine, didanosine, or antacids within 2 hours of this drug.

#### The patient shall receive the following education to share with their partner:

- 1. Side effects of the medication include but are not limited to:
  - Photosensitivity
  - Diarrhea
  - Nasopharyngitis
  - Stevens-Johnson syndrome
  - Toxic epidermal necrolysis
  - Clostridium difficile infection
  - Hepatotoxicity
  - Hypersensitivity reaction
  - Pseudotumor cerebr
  - Upset stomach
  - Vomiting
  - Decreased appetite

#### **Expedited partner therapy for Chlamydia (continued)**

#### SECOND-LINE EXPEDITED PARTNER TREATMENT FOR CHLAMYDIA TRACHOMATIS\*

\*Partner with a known contraindication to doxycycline

#### A partner of a patient with a positive chlamydia infection shall be treated with:

1. Azithromycin 1 gram (1000 mg) orally as a single dose.

#### **CONTRAINDICATIONS TO AZITHROMYCIN:**

- 1. Cholestatic jaundice with prior azithromycin use.
- 2. Hepatic dysfunction with prior azithromycin use.
- 3. Hypersensitivity reaction to azithromycin or to any product component, erythromycin, or any macrolide or ketolide antibiotic.

#### The dispensing pharmacist shall provide patient with partner pack of:

1. #2 zithromycin 500mg tablets for oral use

#### The following instruction for use will be provided to share with their partner:

- 1. Take two 500 mg azithromycin orally one time.
- 2. Medication may be taken with or without food.
- 3. Take with a whole glass of water.
- 4. Do not take with antacids that have magnesium or aluminum at the same time as this drug.

#### The patient shall receive the following education to share with their partner:

- 1. Side effects of the medication include but are not limited to:
  - Abdominal pain
  - Diarrhea
  - Flatulence
  - Nausea
  - Vomiting
  - Increased liver enzymes
  - Headache
  - Abnormal vision
  - Prolonged QTc
  - Stevens-Johnson syndrome
  - Toxic epidermal necrolysis
  - Hypersensitivity reaction



#### **Expedited partner therapy for Gonorrhea**

#### **EXPEDITED PARTNER TREATMENT FOR GONORRHEA\***

\*Unless partner has a known contraindication

#### A partner of a patient with a positive gonorrhea infection shall be treated with:

1. Cefixime 800 mg PO single dose

#### The dispensing pharmacist shall provide patient with partner pack of:

1. Two cefixime 400 mg tablets

#### **Instructions for use**

- 1. Take two cefixime 400 mg tablets once.
- 2. Medication may be taken with or without food.
- 3. Take with a whole glass of water.
- 4. Do not take bismuth, calcium, iron, magnesium, zinc, multivitamins with minerals, colestipol, cholestyramine, didanosine, or antacids within 2 hours of this drug

#### The patient shall receive the following education to share with their partner:

- 1. Side effects of the medication include but are not limited to:
  - Diarrhea
  - Nausea
  - · Abdominal pain
  - Dyspepsia
  - Skin rashes
  - Urticaria
  - Angioedema
  - Stevens-Johnson syndrome
  - Transient elevated liver enzymes
  - Dizziness
  - Seizures

#### **CONTRAINDICATIONS TO CEFIXIME:**

Known allergy to cefixime or other cephalosporins

#### **Standing Order References:**

- 1. National STD Curriculum 2nd E. University of Washington STD Prevention Training Center with funding from the Centers for Disease Control and Prevention. Accessed Sept 2022
- 2. Workowski KA, Bachmann LH, Chan PA, Johnston CM, Muzny CA, Park I, Reno H, Zenilman JM, Bolan GA. Sexually Transmitted Infections Treatment Guidelines, 2021. MMWR Recomm Rep. 2021 Jul 23;70(4):1-187. doi: 10.15585/mmwr.rr7004a1. PMID: 34292926; PMCID: PMC8344968.
- 3. Azithromycin tablets [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; 2019.
- 4. Doxycycline hyclate capsules [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals; 2020
- 5. Cefixime [package insert]. Baltimore, MD: Lupin Pharmaceuticals; 2012
- 6. Ceftriaxone for Injection [package insert]. Lake Forest IL: Hospira, Inc.; 2020.
- 7. Gentamicin Injection [package insert]. Lake Zurich, IL: Fresenius Kabi; 2019.
- 8. Lidocaine hydrochloride Injection, USP [package insert]. Schaumburg, IL: APP Pharmaceuticals; 2010.

## **Appendix C. Pharmacy STI Treatment Intake Form**

The pharmacist carrying out the treatment service needs to document in their pharmacy dispensing system a prescription as well as the clinical decision making needed to determine the most effective and safe treatment option. This STI treatment screening form is designed to be similar to existing vaccination screening forms that many pharmacies are currently using as part of workflow. The pharmacy can fill out this form with the patient and scan it into their dispensing or pharmacy management systems for documentation of the treatment provided.



#### **Pharmacy STI Treatment Intake Form**

#### **Chlamydia**

Name:				DO	3:	
Address:				Pho	ne:	
(Optional) Emerg	gency Contact	: Name:		Eme	ergency Con	tact Phone:
(Optional) Emerg	gency Contact	: Relationship:				
Relevant Past Me	edical and Soc	cial History:				
<b>Current comorbi</b>	dities includiı	ng mental status	:			
<b>Blood Pressure:</b>		Pulse:	Tempera	ature:	Wei	ght:
Sex Assigned at	Birth: Male	Female	Unknown	Choose not to	disclose	Uncertain
Gender: Male	Female	Transgender Female	Transgender Male	Non- Binary	Other	Choose not to disclose
Female	Pregnant	or Br	eastfeeding			Male
Current Medicat Allergies:	ions:					
Positive test for	Chlamydia	or Go	norrhea			

10 state test for chiamydia of donormea

If Patient has symptoms --> Do you have a regular health care provider?

If not, we can provide you with resources for local providers.

Do you have any problem with taking your medication at the same time every day? (Recommend azithromycin instead of doxycycline)

Patient is excluded from pharmacy treatment due to one or more of the following reasons

- Immunocompromised state
- History of rheumatic fever, rheumatic heart disease, scarlet fever, or GAS-induced glomerulonephritis
- Clinical instability based on the pharmacist's clinical judgment or ANY of the following conditions-REFER
  - Acute altered mental status
  - Systolic blood pressure <90 mmHg or diastolic blood pressure <60 mmHg</li>
  - Pulse > 125 BPM
  - Temperature >102F (temporal), >103F (oral), or >104F (tympanic)
  - Symptoms of PID, for any female persons or persons with uterus, fallopian tubes, or ovaries (e.q. lower bilateral abdominal pain, abnormal uterine bleeding, urinary frequency, vaginal discharge, pain during intercourse, etc.)
- 2. Patient meets inclusion to treat in pharmacy criteria

#### Chlamydia

Patient has a positive chlamydia test, has no contraindications to and will be adherent to doxycycline per previous medical record, will be given #14 Doxycycline monohydrate capsules 100 mg orally BID for 7 days

Patient has contraindication to or is likely to be non-adherent to doxycycline, will be given Azithromycin 1 gram (#2 500 mg tabs) tablets orally as a single dose (Take 2 azithromycin 500 mg tablets together by mouth as one dose.)

**Date** 

INSERT SIGNATURE HERE

**AUTHORIZING PHYSICIAN** 

#### **Pharmacy STI Treatment Intake Form**

#### Gonorrhea

Name:				DO	В:	
Address:				Pho	one:	
(Optional) Emer	gency Contact	: Name:		Em	ergency Con	tact Phone:
(Optional) Emer	gency Contact	: Relationship:				
Relevant Past Me	edical and Soc	cial History:				
Current comorbi	idities includii	ng mental status:	:			
Blood Pressure:		Pulse:	Tempera	ature:	Wei	ght:
Sex Assigned at	Birth: Male	Female	Unknown	Choose not to	disclose	Uncertain
Gender: Male	Female	Transgender Female	Transgender Male	Non- Binary	Other	Choose not to disclose
Female	Pregnant	or Bro	eastfeeding			Male

**Current Medications:** 

**Allergies:** 

Positive test for Chlamydia or Gonorrhea

If Patient has symptoms --> Do you have a regular health care provider?

If not, we can provide you with resources for local providers.

- 3. Patient is excluded from pharmacy treatment due to one or more of the following reasons
  - Immunocompromised state
  - History of rheumatic fever, rheumatic heart disease, scarlet fever, or GAS-induced glomerulonephritis
  - Clinical instability based on the pharmacist's clinical judgment or ANY of the following conditions-REFER
    - · Acute altered mental status
    - Systolic blood pressure <90 mmHg or diastolic blood pressure <60 mmHg</li>
    - Pulse > 125 BPM
    - Temperature >102F (temporal), >103F (oral), or >104F (tympanic)
    - Symptoms of PID, for any female persons or persons with uterus, fallopian tubes, or ovaries (e.q. lower bilateral abdominal pain, abnormal uterine bleeding, urinary frequency, vaginal discharge, pain during intercourse, etc.)
- 4. Patient meets inclusion to treat in pharmacy criteria

#### Gonorrhea

Patient tests positive for gonorrhea, has no contraindications to and does not refuse injectable medication and can return, will be given Ceftriaxone at a dose of:

500 mg (1.43 mL) IM gluteally single dose < 150 kg (<330 lbs)

1 gm (2.86 mL) IM gluteally single dose  $\geq$  kg ( $\geq$ 330 lbs)

If unable to return for treatment, may call a prescription to the preferred pharmacy for Cefixime 800 mg tablets (#2 400 mg tabs) PO as a single dose.

Patient is contraindicated for ceftriaxone will be given Azithromycin 2 g tablets (#4 500 mg tabs) orally as a single dose and gentamicin 240 mg (6 mL) IM gluteally single dose. (Give two 3 mL doses of gentamicin IM gluteally at a concentration of 40 mg/mL)

Patient refuses injectable medication or is unable to return for treatment and needs delivery, will be given Cefixime 800 mg tablets (#2 400 mg tabs) PO single dose

**INSERT SIGNATURE HERE** 

Date

**AUTHORIZING PHYSICIAN** 

## **Appendix D. Patient Education Materials**

Below are printable educational materials about chlamydia and gonorrhea. Some can be given directly to the patient, while others are directed towards you as a health care provider. There are many resources available online to fit the needs of your patient population.

#### **Disease State Resources**



#### National Library of Medicine<sup>24</sup>

Printable, patient friendly overview of sexually transmitted illnesses.



#### CDC Chlamydia Basic Fact Sheet<sup>25</sup>

Printable overview of chlamydia regarding treatment, spread, signs and symptoms, and more for patient education



#### **CDC Gonorrhea Basic Fact Sheet**<sup>26</sup>

Printable overview of gonorrhea regarding treatment, spread, signs and symptoms, and more for patient education



#### **CDC Chlamydia Brochure**<sup>27</sup>

Printable education guide with more detail about chlamydia infections geared towards patients. Available to print in Spanish.



#### **CDC Gonorrhea Brochure** 28

Printable education guide with more detail about gonorrhea infections geared towards patients. Available to print in Spanish.



#### **Partner Resources**

Discussing a STI diagnosis with partner(s) can induce anxiousness or embarrassment. In addition to using motivational interviewing to encourage your patients to tell their partner and educate them on expedited partner therapy, *Tell Your Partner* is a resource you can provide to assist in this process.



#### **Tell Your Partner** 29

A secure, anonymous text service that alerts partners to get tested and provides resources to find a nearby testing center.

#### **QR Codes**

Education materials can be made available via QR codes to increase anonymity for patients. Materials can be scanned while the patient is still in the pharmacy and saved/bookmarked to their phone to view on their own time.

Use free resources below to generate your own educational materials or QR codes to share resources with your patients. Whichever app or website you use, make sure that the QR code does not expire.



QR Code Monkey 30

Adobe Express 31 \*Requires Free Account

Canva 32 \*Requires Free Account



# What You Need to Know About AZITHROMYCIN

This medication is used to cure an infection.

<u>Contact your healthcare provider</u>, if your symptoms do not improve or get worse.

#### **HOW TO TAKE AZITHROMYCIN:**

Take two tablets by mouth as a single dose

#### TIPS TO HELP YOU TAKE AZITHROMYCIN

- ▼ Take this medication with a full glass of water to avoid throat irritation
- ▼ Take this medication with food to help with upset stomach
- ◆ Do not take antacids that contain aluminum or magnesium within 2 hours before or after taking azithromycin

#### **CAUTION**

- Tell your healthcare provider if you have any heart, liver, muscle, or skeletal disorders
- If you are taking any prescription, non-prescription, herbal, or recreational products, please discuss with your healthcare provider

#### **POSSIBLE SIDE EFFECTS**

- You may experience mild stomach upset, nausea, or diarrhea
- You may experience headache, or abnormal vision
- If any of these effects persist or worsen, please contact your healthcare provider

#### AFTER TAKING THIS MEDICATION

- Do not have sex for one week after you and your partner(s) have completed treatment and all symptoms have resolved
- ◆ Cover up when going out in the sun and wear sunscreen (SPF 30+) this medication can make you sunburn more easily
- Tell your healthcare provider if symptoms do not improve or resolve in 5 days



ALERT your healthcare provider if you have any of the issues below:

- Diarrhea that is watery or bloody
- Are pregnant or may become pregnant
- Develop a skin rash, have trouble breathing, or notice swelling in your face or throat
- O Develop chest pain or irregular heart beat
- Develop yellowing of the skin or eyes and/or notice upper right abdominal pain



For more information, please scan this QR code:





# What You Need to Know About GENTAMICIN + AZITHROMYCIN

This medication is used to cure you of an infection.

<u>Contact your healthcare provider</u>, if your symptoms do not improve or get worse.

#### **HOW GENTAMICIN IS ADMINISTERED:**

Two injections as a single dose into two different muscles

#### **HOW TO TAKE AZITHROMYCIN:**

Take four tablets by mouth as a single dose

#### **CAUTION**

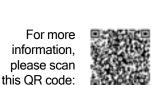
- Tell your healthcare provider if you have any electrolyte abnormalities, sensitivities to sulfa drugs or macrolides, neuromuscular, heart, liver disorders, or kidney disease
- ◆ If you are taking any prescription, non-prescription, herbal, or recreational products, please discuss with your healthcare provider
- Do not take antacids that contain aluminum or magnesium within 2 hours before or after taking azithromycin

#### POSSIBLE SIDE EFFECTS

- For gentamicin injections, you may experience discomfort, redness or swelling at the injection site
- You may experience slight stomach upset, nausea, or diarrhea
- You may experience headache or abnormal vision
- If any of these effects persist or worsen, please contact your healthcare provider

#### AFTER TAKING THESE MEDICATIONS

- Do not have sex for one week after you and your partner(s) have completed treatment and all symptoms have resolved
- Drink plenty of water
- ◆ Cover up when going out in the sun and wear sunscreen (SPF 30+) this medication can make you sunburn more easily
- ▼ Tell your healthcare provider if symptoms do not improve or resolve in 5 days



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ALERT your healthcare provider if you have any of the issues below:

- O Diarrhea that is watery or bloody
- Are pregnant or may become pregnant
- Develop a skin rash, have trouble breathing, or notice swelling in your face or throat
- Develop ringing in the ear or hearing loss
- Develop yellowing of the skin or eyes, and/or notice upper right abdominal pain
- Swelling in legs or ankle, or change in urination





# What You Need to Know About CEFTRIAXONE

This medication is used to cure you of an infection.

<u>Contact your healthcare provider</u>, if your symptoms do not improve or get worse.

#### **HOW CEFTRIAXONE IS ADMINISTERED:**

Single dose injection into a muscle

#### **CAUTION**

- ▼ Tell your healthcare provider if you have any gallbladder, liver, kidney, pancreas or bleeding disorders, or a history of stomach dysfunction (such as colitis)
- ✔ If you are taking any prescription, non-prescription, herbal, or recreational products, please discuss with your healthcare provider

#### POSSIBLE SIDE EFFECTS

- You may get discomfort, redness or swelling at the injection site
- You may experience mild diarrhea
- If any of these effects persist or worsen, please contact your healthcare provider

#### AFTER TAKING THIS MEDICATION

- Do not have sex for one week after you and your partner(s) have completed treatment and all symptoms have resolved
- ▼ Tell your healthcare provider if symptoms do not improve or resolve in 5 days
- Drink plenty of water
- Do not take Oral Typhoid vaccine (Vivotif®) with ceftriaxone
- Ceftriaxone may interfere with certain urine glucose test (Clinitest®)



ALERT your healthcare provider if you have any of the issues below:

- Diarrhea that is watery or bloody
- Are pregnant or may become pregnant
- Develop a skin rash, have trouble breathing, or notice swelling in your face or throat
- 10 Have a seizure



For more information, please scan this QR code:





# What You Need to Know About CEFIXIME

This medication is used to cure you of an infection.

<u>Contact your healthcare provider</u>, if your symptoms do not improve or get worse.

#### **HOW TO TAKE CEFIXIME:**

Take two tablets by mouth as a single dose

#### **CAUTION**

- Tell your healthcare provider if you have any kidney or liver diseases, bleeding disorders, or disorders that result in the build up of diet amino acid
- ✔ If you are taking any prescription, non-prescription, herbal, or recreational products, please discuss with your healthcare provider
- Use a condom, as this medication can interact with hormonal birth control and make them less effective

#### POSSIBLE SIDE EFFECTS

- You may experience mild diarrhea, abdominal pain or nausea
- If any of these effects persist or worsen, please contact your healthcare provider

#### AFTER TAKING THIS MEDICATION

- Do not have sex for one week after you and your partner(s) have completed treatment and all symptoms have resolved
- ▼ Tell your healthcare provider if symptoms do not improve or resolve in 5 days
- Drink plenty of water
- Cefixime may interact with certain urine glucose or ketone tests
- Cefixime may affect the result of certain lab tests



ALERT your healthcare provider if you have any of the issues below:

- Diarrhea that is watery or bloody
- Are pregnant or may become pregnant
- Develop a skin rash, have trouble breathing, or notice swelling in your face or throat
- Worsening of joint pain, fever, or enlarged lymph nodes
- Mave a seizure



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# What You Need to Know About DOXYCYCLINE

This medication is used to cure an infection.

It is important to <u>take the entire prescription even if you are not having symptoms or your symptoms have resolved</u> to treat your infection and protect your partner(s).

#### **HOW TO TAKE DOXYCYCLINE:**

Take one capsule by mouth twice a day for seven days

#### WHILE ON THIS MEDICATION

- Do not have sex while taking this medication, and until all symptoms have resolved to prevent spreading the infection to your partner(s)
- Use a condom as this medication can interact with hormonal birth control and make them less effective
- Do not take supplements containing iron or calcium, multivitamins, antacids, or laxatives within 2 hours before or after taking doxycycline
- Drink plenty of water
- Cover up when going out in the sun and wear sunscreen (SPF 30+)— this medication can make you sunburn more easily
- Tell your health care provider if symptoms do not improve or resolve in 5 days

#### **POSSIBLE SIDE EFFECTS**

- You may experience mild diarrhea, upset stomach, or nausea
- If any of these effects persist or worsen, please contact your healthcare provider

#### TIPS TO HELP YOU TAKE DOXYCYCLINE

- Take this medication with a full glass of water and do not lay down for 30 minutes after to avoid throat irritation
- Take this medication with food to help with upset stomach
- Place a reminder note on an object or set an alarm on your phone to remind you to take your medication at the same time every day
- Mark off on a calendar that you have taken your medication.

#### IF YOU FORGET TO TAKE A DOSE

- Take the missed dose as soon as you remember
  - **UNLESS** it is almost time for your next dose, **THEN SKIP** the missed dose and take the next one at the scheduled time
- **DO NOT** take any extra capsules to make up for the missed dose



STOP taking your medicine right away if you have any of the issues below:

- Diarrhea that is watery or bloody
- Are pregnant or may become pregnant
- Develop a skin rash, have trouble breathing, or notice swelling in your face or throat
- Develop rapid headache, blurred vision, double vision, or vision loss



For more information, please scan this QR code:



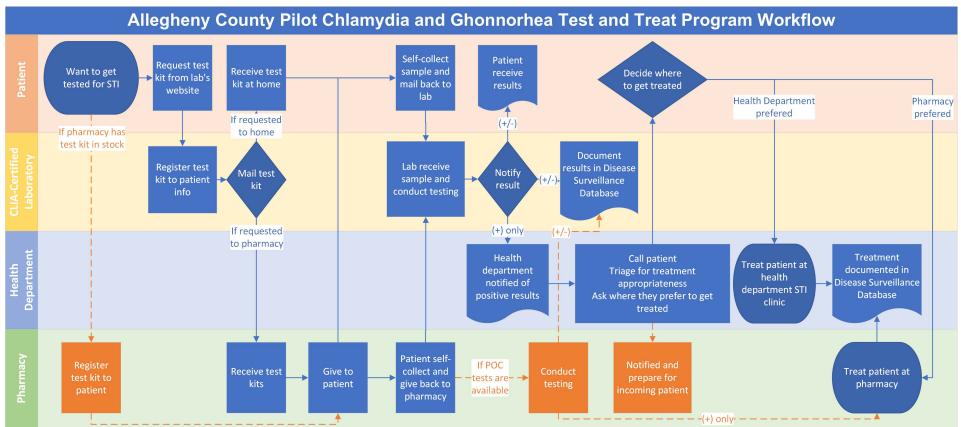


## **Appendix E. Pharmacy Supply List**

	Medications				
Quantity	Item				
	Doxycycline monohydrate 100 mg capsules				
	Azithromycin 500 mg capsules				
	Ceftriaxone 500 mg vials				
	Gentamicin 80mg/2mL vials				
	Cefixime 400 mg tablets				
	1% Lidocaine Solution (without epinephrine) Alternatives: Sterile Water for Injection, 5% Dextrose Solution, 0.9% Sodium Chloride Solution				
	Epinephrine auto-injectors				
	Pharmacy Supplies				
Quantity	Item				
For injection					
	Syringes (3-5 mL)				
	Needles (1" and 1.5"; 22-25 gauge) Gauze				
	Gloves				
	Band-aids/Inject-safe adhesive barrier strips				
	Alcohol wipes				
	Sharps containers				
For screen	ing and vitals:				
	Wi-Fi-enabled computer access				
	Blood pressure cuff				
	Stethoscope				
	Thermometer				
Miscellane	ous:				
	Chairs and/or cot				
	Privacy barriers				
	Intake forms				
	Patient education materials				
	Dispensing supplies (vials, caps, counting tray, spatula)				
	Office supplies (pens, paper, printer)				

### Appendix F. Workflow

This swim lane workflow diagram demonstrates the steps that a patient takes to acquire a test kit, receive test result, and access treatment provided by the Allegheny County pilot program. Each colored lane represents a partner in the program. This is one example of a workflow that could be adapted. It's important to think about the pharmacist, provider, and patient perspective when designing the workflow for your program.



<sup>\*</sup>Blue workflow - Carried out in NACCHO Allegheny county pilot program
\*Orange workflow - Plan for expansion or potential area of improvement

For future iteration of this pilot program, patients can pick up test kit directly at the pharmacy which can decrease delays with testing access. Once more point-of-care (POC) testing options are available and feasible within workflow, this can prevent delays with patients knowing their STI status and enable receiving treatment within the same pharmacy visit.

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