GUIDANCE FOR THE USE OF PRE-EXPOSURE PROPHYLAXIS (PrEP) TO PREVENT HIV TRANSMISSION

What's New – October 2015
• PrEP Payment Options have been compiled by the New York State Department of Health (see Appendix D). The options include Medicaid, PrEP Assistance Program (PrEP-AP), the Gilead Co-Pay Coupon Card, the Gilead Medication Assistance Program, the Patient Access Network, and most private insurances. • Updated information about prescribing PrEP for adolescents is provided (see Section II). • Updated information about managing patients on PrEP who present with a positive HIV screening test or with symptoms suggestive of acute HIV infection is provided (see Section VIII).

Important Announcements:

- On April 29, 2015, Governor Andrew Cuomo unveiled the *Blueprint to End AIDS Epidemic by 2020*, which contained the statewide task force's recommended strategies to end the AIDS epidemic in New York State by reducing the number of annual new HIV infections to 750 by the year 2020. The three-point plan calls for efforts to identify those with undiagnosed HIV infection and to link and retain them in care, including providing antiretroviral therapy to maximize viral suppression. The third point outlined in this plan is to provide access to pre-exposure prophylaxis (PrEP) as part of a strategy to prevent HIV infection among individuals at high risk. By including access to PrEP as a major element in this bold initiative, New York State emphasizes the importance of PrEP as a safe and effective method to prevent HIV infection, demonstrating the use of PrEP as a strategy that should be adopted by all interested in ending the epidemic. It is the intention of this guidance document to give all New York State providers the information needed to successfully manage patients on PrEP.

- This document provides ***guidance*** for delivery of HIV prevention that includes the use of PrEP. This document includes information on service delivery and program implementation and *does not* contain recommendations that are rated to indicate the strength of the recommendation and the quality of the supporting evidence, as is customary for NYS DOH AIDS Institute formal guidelines.

  The Medical Care Criteria Committee is now developing an evidence-based, clinically-focused ***guideline*** for administration and management of PrEP for prevention of HIV infection. As soon as the ***PrEP clinical guideline*** is finalized (expected November 2015), it will be posted on this website and disseminated in an e-mail to website subscribers, and this guidance document will be archived.

New York State Summary Statement on Pre-Exposure Prophylaxis to Prevent HIV Infection

The New York State Department of Health AIDS Institute (NYSDOH AI) and the Centers for Disease Control and Prevention (CDC)[1,2] recommend pre-exposure prophylaxis (PrEP) as an evidence-based intervention to prevent HIV transmission. Throughout its history, the NYSDOH AI has been a leader in recommending biomedical interventions to prevent HIV infection, beginning with establishing a standard of care for the prevention of mother-to-child HIV transmission using antiretroviral agents during pregnancy, labor and delivery, and as prophylaxis for the newborn. Since 1991, NYSDOH AI has recommended a combination of antiretroviral agents for post-exposure prophylaxis (PEP) to prevent HIV transmission in the context of occupational and non-occupational exposures. NYSDOH AI recommends that antiretroviral therapy (ART) be initiated in all patients with a diagnosis of HIV infection. This recommendation is based on increasing evidence that patients with established HIV infection benefit from ART at all stages of disease[3,4] and on data that demonstrate a dramatic reduction of HIV transmission risk among ART-treated patients with viral suppression,[5] which is a strategy commonly known as "treatment as prevention."

Several clinical trials have demonstrated the efficacy of PrEP.[6, 7] In July 2012, the Food and Drug Administration approved tenofovir + emtricitabine (TDF/FTC, Truvada) for use as PrEP in adults. This regimen consists of one pill taken once per day; when taken consistently, it has demonstrated a high level of protection against HIV infection.

New York State continues to promote effective use of this biomedical intervention through this clinical guidance document, provider implementation protocols, and ongoing educational programs. The NYSDOH AI recognizes that a comprehensive system-wide approach is necessary to ensure that patients are effectively managed on PrEP and that individuals throughout the State who will most benefit have access to PrEP. Key populations that are most at risk for HIV should be prioritized for outreach and access to ensure that they are aware of PrEP and its benefits; such populations include men who have sex with men (MSM), injection drug users, and serodiscordant couples, particularly couples with an HIV-infected partner who is not virally suppressed or whose viral suppression is unknown.

Following is a summary of the key principles that are described in this document.

Key Principles for Prescribing PrEP

- **PrEP should not be offered as a sole intervention** for HIV prevention. PrEP should only be prescribed **as part of a comprehensive prevention plan.**

- PrEP may **help protect the HIV seronegative partner in a serodiscordant relationship during attempts to conceive.**

- PrEP is indicated for individuals who have **a documented negative HIV test result** and are at **ongoing high risk for HIV infection.** A negative HIV test result needs to be confirmed as close to initiation of PrEP as possible, ideally on the same day the prescription is given. **Clinicians should wait to prescribe PrEP until confirmation of a negative test result is available.**

- **Efficacy of PrEP is dependent on adherence.** PrEP should only be prescribed to those who are able to adhere to the regimen and express a willingness to do so.

- Although consistent condom use is a critical part of a prevention plan, **lack of use of barrier protection is not a contraindication to PrEP.**

- PrEP is contraindicated in individuals with **documented HIV infection** or **creatinine clearance <60 mL/min,** and in **those who are not ready to adhere to daily PrEP.**

- **The first prescription of PrEP** (Truvada 1 tablet PO daily) **should only be for 30 days** to allow for a follow-up visit to assess adherence, tolerance, and commitment. At the 30-day visit, a prescription for 60 days may be given; the **patient should then return for 3-month HIV testing** and other assessments. After that visit, **prescriptions can be given for 90 days, provided that the patient is adherent**.

- Patients receiving PrEP require **regular visits, at least every 3 months, to monitor HIV status, adherence, and side effects**. Follow-up and monitoring of patients receiving PrEP also includes prevention services that are part of a comprehensive prevention plan, such as risk-reduction counseling, access to condoms, STI screening, and mental health and substance use screening, when indicated.

- **For patients who receive a reactive HIV screening test result or for whom acute infection is suspected, initiate fully active ART and see Section VIII: *HIV Acquisition During PrEP*.**

I. METHODOLOGY

In September 2012, the New York State Department of Health convened a PrEP Advisory Panel to develop clinical guidance on the use of PrEP. The Panel consisted of primary care providers caring for high-risk populations, clinicians experienced in the treatment of HIV, obstetricians, adolescent care providers, pharmacists, program administrators, social workers, policy makers, representatives from the New York City Department of Health and Mental Hygiene, and consumer representatives.[*]

The following document provides guidance for delivery of an HIV prevention program that includes the use of PrEP. This guidance is based on the results of the clinical trials of PrEP, a review of published data, and the guidelines of the Centers for Disease Control and Prevention.[1,2] Available data are limited regarding the best practices for monitoring the use of TDF/FTC in non-HIV-infected individuals in the clinical setting. When there were no data on which to base recommendations, recommendations were formulated based on both expert opinion and experience with use of these agents in the HIV-infected population.

This PrEP guidance document is intended for practitioners in all clinical practice settings where PrEP will be prescribed and monitored, including primary care, HIV care, STI clinics, and community-based centers. The information has been formatted as a series of tables and checklists for ease of use at the point of care in a variety of settings. This guidance document will be updated regularly as new data are published and more experience is accumulated with the use of PrEP.

II. BACKGROUND

HIV prevention through PrEP involves the use of antiretroviral medications by non-HIV-infected individuals to reduce their risk of acquiring HIV. In July 2012, the Food and Drug Administration (FDA) approved the use of tenofovir + emtricitabine (TDF/FTC) for HIV PrEP in adults who are at high risk for becoming HIV-infected.

Use of tenofovir alone and tenofovir + emtricitabine as PrEP has been studied in clinical trials in several populations, including men who have sex with men,[8] heterosexual discordant couples,[9] heterosexual men and women,[10-12] transgender women,[8] and injecting drug users.[13] All of the trials found PrEP to be safe. Four trials found PrEP to be effective for preventing HIV infection when taken as prescribed. The FEM-PrEP[11] and VOICE trials[12] did not show a benefit, likely because of poor adherence to the daily PrEP regimen. See Appendix A for a summary of results from the clinical trials.

Studies of other antiretroviral agents for use as PrEP, such as maraviroc, rilpivirine, and dapivirine, are underway.

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[*] Prior to participation, each panel member submitted a financial disclosure form in accordance with the program's conflict of interest policy. Two panel members reported potential conflicts with Gilead, manufacturer of Truvada. JB-M, Speaker's Bureau; AU, Speaker's Bureau.

Recommendation: PrEP should be offered to adolescents at high risk for HIV infection. To date, no efficacy or safety studies have been published on the use of PrEP in individuals younger than 18 years of age, but studies in this population are underway. Since the time of licensing for treatment of HIV in adolescents, TDF/FTC has been used without any indication of unique toxicity in this population. Off-label use of TDF/FTC as part of a PEP regimen is recommended for adolescents 13-18 years of age to prevent HIV infection after a high-risk exposure. The CDC and the International Antiviral Society-USA have now extended the use of TDF/FTC to include PrEP for adolescents in sexual or other behavioral situations that put them at high risk for HIV infection.[1,14] In addition to known concerns about renal complications associated with tenofovir use, theoretical concerns from osteopenia have been proposed, particularly in younger age groups.

Providers should carefully weigh the potential benefits and risks, including acquiring HIV infection, before prescribing PrEP to a younger adolescent and should make clear that the efficacy of PrEP is highly dependent on strict adherence. Clinicians should refer to their institution's policy or consult with the institution's legal department about consent to care for adolescents under 18 years of age according to New York State law (for additional information, see *HIV Disclosure to Parents and Consent to HIV Treatment Among Adolescents*).

PrEP should not be offered as a sole intervention for HIV prevention. PrEP should only be prescribed as part of a comprehensive prevention plan that includes counseling and education about the following:

- Consistent and correct condom use
- Safer-sex practices and risk-reduction counseling
- Adherence to PrEP
- Importance of frequent HIV testing and screening for other sexually transmitted infections (STIs) that can facilitate HIV transmission
- For individuals in serodiscordant relationships, the importance of suppressive ART (treatment as prevention) for HIV-infected partners

III. Candidates for Pre-Exposure Prophylaxis

PrEP is indicated for individuals who have a documented negative HIV test result and are at ongoing high risk for HIV infection. A negative HIV test result needs to be confirmed as close to initiation of PrEP as possible, ideally on the same day the prescription is given (see Section V: *Pre-Prescription Assessments, Education, and Laboratory Tests*). PrEP should only be prescribed to those who are able to adhere to the regimen and express a willingness to do so.

PrEP is not meant to be used as a lifelong intervention, but rather as a method of increasing prevention during periods when people are at greatest risk of acquiring HIV. The length of use will depend on the individual's behaviors, which may change over time. Providers need to obtain a thorough sexual and drug use history and regularly discuss risk-taking behaviors with their patients to assess candidacy for PrEP, encourage safer-sex practices and safer injection techniques (if applicable), and assist in the decision of when to use PrEP and when to discontinue use.

TABLE 1. POTENTIAL CANDIDATES FOR PREP
Clinicians should discuss PrEP with the following non-HIV-infected individuals who have substantial and ongoing risk: • **Men who have sex with men (MSM)** who engage in unprotected anal intercourse[15,16] • Individuals who are in a **serodiscordant sexual relationship** with a known HIV-infected partner • Male-to-female and female-to male **transgender individuals** engaging in high-risk sexual behaviors • Individuals engaging in **transactional sex,** such as sex for money, drugs, or housing • **Injection drug users** who report any of the following behaviors: sharing injection equipment (including to inject hormones among transgender individuals), injecting one or more times per day, injecting cocaine or methamphetamine, engaging in high-risk sexual behaviors[13] • Individuals who use **stimulant drugs associated with high-risk behaviors,** such as methamphetamine[15-18] • Individuals diagnosed with at least one anogenital **sexually transmitted infection** in the last year[19,20] • Individuals who have been prescribed **non-occupational post-exposure prophylaxis** (nPEP) who demonstrate continued high-risk behavior or have used multiple courses of nPEP[21]

Other individuals may qualify for PrEP who may not fit within the above risk categories. Decisions to initiate PrEP should be individualized by weighing patients' personal risk of acquiring HIV infection against the potential benefits and risks of TDF/FTC.

Individuals who do not necessarily have continued risk for acquiring HIV but may have episodic exposures may be good candidates for non-occupational post-exposure prophylaxis (nPEP) rather than PrEP. For example, nPEP may be a better option for an individual who uses condoms regularly, but may experience an occasional broken condom or lapse in use. These individuals should be educated about nPEP and the need to receive medication within 36 hours of the exposure.

A 7-item screening index has been developed to identify MSM who are at risk of HIV seroconversion (see Appendix B).

Use of PrEP to Prevent HIV Transmission During Attempts to Conceive

PrEP may be one option to help protect the HIV seronegative partner in a serodiscordant relationship during attempts to conceive. Risk of HIV transmission may be further reduced in serodiscordant sexual relationships when the HIV-infected partner is receiving suppressive ART. Data supporting treatment as prevention are strongest for heterosexual couples based on the findings of HPTN 052.[22] These data have been extrapolated to MSM although primary data supporting "treatment as prevention" in this population are lacking.

IV. PrEP: Contraindications and Considerations

Although consistent condom use is a critical part of a prevention plan for all people prescribed PrEP, lack of use of barrier protection is not a contraindication to PrEP.

Table 2. Contraindications to PrEP
Medical Contraindications: ➢ **Documented HIV infection**   ➢ Drug-resistant HIV has been identified in patients with undetected HIV who subsequently received TDV/FTC for PrEP ➢ **Creatinine clearance <60 mL/min** **Lack of readiness to adhere** to a daily PrEP regimen is also a contraindication. Efficacy of PrEP is dependent on adherence to ensure that plasma drug levels reach a protective level.

The considerations outlined in Table 3 are not absolute contraindications to prescribing PrEP. Clinicians should consider these factors and proceed with caution.

Table 3. Important Considerations when Prescribing PrEP
Does the patient have chronic active hepatitis B virus (HBV) infection? TDF/FTC is active against HBV infection. ➢ Although not FDA-approved for the treatment of HBV, TDF/FTC may be used simultaneously as treatment for HBV infection and as PrEP. ➢ Discontinuation of TDF/FTC requires close monitoring in patients with chronic hepatitis B infection because of the concern for rebound viremia. **Is the patient pregnant or attempting to conceive?** PrEP may be one of several options to help protect the HIV seronegative partner from acquiring HIV infection in serodiscordant couples during attempts to conceive. ➢ If a woman is pregnant when starting PrEP or becomes pregnant while on PrEP, discuss the known risks and benefits of taking TDF/FTC during pregnancy (see bottom of Table 5) ➢ After discussing the potential risks of TDF/FTC, recommend continuation of PrEP during pregnancy or breastfeeding for those with ongoing risk for HIV. ➢ Providers should report information regarding use of PrEP during pregnancy to the Antiretroviral Pregnancy Registry **Is the patient an adolescent?** To date, no studies have been published on the use of PrEP in individuals younger than 18 years of age, but studies in this population are underway. In addition to the use of TDF/FTC in HIV treatment, and PEP for adolescents 13-18 years of age, the CDC and the International Antiviral Society-USA have now extended the use of TDF/FTC to include PrEP for adolescents at high sexual or other behavioral risk for HIV infection.[1,14] ➢ Consider PrEP for adolescents at high risk for HIV.

- Carefully weigh the potential benefits and risks, including acquiring HIV infection, before prescribing PrEP to a younger adolescent. In addition to known concerns about renal complications associated with tenofovir use, there are theoretical concerns from osteopenia, particularly in younger age groups.
- Make clear that the efficacy of PrEP is highly dependent on strict adherence.
- Refer to the institution's policy or consult with the institution's legal department about consent to care for adolescents under 18 years of age according to New York State law.

Is the patient at risk for chronic kidney disease (>65 years of age, black race, hypertension, or diabetes)?

- Discuss possibility of kidney disease with individuals who have pre-existing risk factors.

Is the patient taking concomitant nephrotoxic drugs or drugs that have interactions with TDF/FTC?

- Obtain a thorough medication history

Does the patient have osteopenia/osteomalacia/osteoporosis? There may be a risk of bone loss associated with tenofovir.

- Discuss risk of bone loss with individuals with pre-existing risk factors or demonstrated osteoporosis/osteomalacia/osteopenia.

V. PRE-PRESCRIPTION ASSESSMENTS, EDUCATION, AND LABORATORY TESTS

Following is a series of tables, formatted as checklists, that outline what this Panel believes are the essential assessments, patient education, and laboratory tests that need to be performed *before* a prescription for PrEP is given.

Pre-Prescription: Assessments

Once it is decided that the patient is a candidate for PrEP according to the criteria in Table 1, further assessments (listed in Table 4) are needed to clearly understand the prevention needs of the individual patient and whether initiation of PrEP is an appropriate option. Patient education is critical to shared decision-making and the success of PrEP as part of the prevention plan. Tables 4 and 5 provide the basis from which shared decision-making about initiation of PrEP can occur, providing the clinician with the opportunity to educate the patient about risks, benefits, and options, while providing the patient with the opportunity to discuss preferences, needs, and individual circumstances. Medication adherence may be improved when patients participate in treatment decisions.[23]

TABLE 4. PRE-PRESCRIPTION: ASSESSMENT CHECKLIST

Assess the following:

Symptoms of Acute HIV Infection

- ☐ Febrile, "flu"-, or "mono"-like illness in last 6 weeks

Medication List

- ☐ Evaluate for potential drug-drug interactions

Substance Use and Mental Health Screening *

- ☐ See the following quick-reference guides: Mental Health Screening and Substance Use Screening

Knowledge about PrEP

- ☐ Patient understanding of PrEP
- ☐ Misconceptions about PrEP
- ☐ Health literacy in general

For patients who ask to receive PrEP, ask:

- ☐ *Why do you want PrEP?*
- ☐ *What is your understanding of what it will do for you?*

Readiness and Willingness to Adhere to PrEP

- ☐ Potential barriers to daily adherence

Primary Care

- ☐ Does the patient have a primary care provider? If not, provide referral.

Note: Substance use and mental health disorders are not exclusionary criteria. Identifying these disorders allows the clinician to provide appropriate referrals and offer a tailored prevention plan. Substance use and mental health disorders may be barriers to adherence.

Partner Information

- ☐ Determine whether partners are known to be HIV-infected

For patients with an HIV-infected partner, ask:

- ☐ *Is partner(s) receiving ART?*
- ☐ *Is a resistance profile available?*

Domestic Violence Screening, see New York State Office for the Prevention of Domestic Violence

Housing Status

- ☐ Housing status and contact information should be closely monitored for patients with unstable living situations

Means to Pay for PrEP

- ☐ Does the patient have insurance? If not, assess eligibility for Medicaid and refer to case worker for assistance with obtaining insurance

For payment assistance, refer to Appendix D: *Payment Options for Pre-Exposure Prophylaxis (PrEP)*, the PrEP Patient Assistance Program (PrEP-AP), and Truvada for PrEP Medication Assistance Program

For Women:

Reproductive Plans – provide preconception counseling when indicated

- ☐ Is the patient currently using contraception? If not, is the patient interested in using hormonal contraception or other effective method of contraception in addition to condoms?
- ☐ Is the patient trying to conceive?
- ☐ Is the patient currently pregnant?
- ☐ Is the patient currently breastfeeding?

Pre-Prescription: Education

Patients need to understand how PrEP works, including risks and benefits, the need for strict adherence to maintain protective drug levels, and what it will and will not do for them. Explanations should be given in the patient's native language and should be easy to understand. For example: *The pill Truvada has two drugs in it that are commonly used to treat HIV in persons who are HIV-positive. When taken daily by people who are HIV-negative, they can block HIV from infecting the body. The pill needs to be taken every day in order for the body to build up sufficient drug levels to block HIV. It cannot be expected to work if it is only taken just before or just after sex. PrEP reduces but does not eliminate HIV transmission risk. You still need to use condoms even if you are taking PrEP because PrEP does not protect against other sexually transmitted diseases.*

Table 5 lists the areas to educate patients about before prescribing PrEP.

TABLE 5. PRE-PRESCRIPTION: PATIENT EDUCATION CHECKLIST

Educate about the following:

How PrEP works

- ☐ Explain how PrEP works in language that is easy to understand
- ☐ Explain how PrEP works as part of a comprehensive prevention plan

Limitations of PrEP

- ☐ Efficacy is dependent on adherence
- ☐ PrEP reduces but does not eliminate HIV transmission risk
- ☐ PrEP does not protect against other STIs

PrEP use

- ☐ Dosing and need for daily adherence
- ☐ Number of sequential doses to achieve protective effect[a]
- ☐ What to do when doses are missed, and reinforcement of condom use in period following missed dose

Common side effects

- ☐ Headache, abdominal pain, weight loss; side effects usually resolve or improve after first month

Long-term safety of PrEP[b]

- ☐ 24-month follow-up data suggest clinical safety of oral TDF in non-HIV-infected individuals

Baseline tests and schedule for monitoring

- ☐ Tests that need to be taken before prescribing PrEP (see Table 6)
- ☐ Elements of and schedule for follow-up monitoring (see Table 8), including HIV testing at least every 3 months

Criteria for discontinuing PrEP

- ☐ Positive HIV test result
- ☐ Development of renal disease
- ☐ Use of medication for unintended purposes
- ☐ Non-adherence to medication or appointments
- ☐ Change in risk behaviors (i.e., PrEP is no longer needed)

Possible symptoms of seroconversion

- ☐ Instruct patients to contact their healthcare provider if they experience any of the following symptoms: fever, rash, joint pain, oral ulcers (mouth sores), fatigue, night sweats, sore throat, malaise, pain in muscles, loss of appetite

For Women: Potential Benefits/Risks if Pregnancy Occurs During Use of PrEP

Benefits

- ☐ Decreased risk of acquisition of acute HIV infection during pregnancy, which is a significant risk factor for mother-to-child HIV transmission[24]

Potential toxicity

- ☐ Available data suggest that TDF/FTC does not increase risk of birth defects; however, there are not enough data to exclude the possibility of harm

Note: For women who become pregnant while using PrEP, continuation of PrEP during pregnancy is an individualized decision based on whether there are ongoing risks for HIV during pregnancy

[a] Available data suggest that it takes less time to accumulate protective drug concentrations in the rectum than the female genital tract[25-27] Based on modeling, 7 days of daily dosing is needed to achieve protective concentrations for receptive anal sex and 21 days of daily dosing is needed for receptive vaginal sex. There are no data for injection drug use or insertive vaginal or anal sex.

[b] Although long-term safety has not been established in non-HIV-infected individuals, TDF/FTC has been used safely in HIV-infected individuals since 2004. 24-month follow-up data show clinical safety of oral TDF in uninfected MSM.[28]

Pre-Prescription: Laboratory Tests

The laboratory tests listed in Table 6 should be obtained at the pre-prescription visit. **It is imperative that a negative HIV test result is confirmed as close to initiation of PrEP as possible, ideally on the same day the prescription is given.** Clinicians should wait to prescribe PrEP until confirmation of a negative test result is available. Drug-resistant HIV has been found in patients with undiagnosed HIV who were using TDF/FTC as PrEP. If the HIV test result is not immediately available, it may be necessary to inform the patient of a negative test result by phone with the option for the clinician to either call in the prescription or schedule another visit.

When patients are engaged in care to receive PrEP, providers should use the opportunity to administer vaccinations for HAV, HBV, HPV, and meningococcus as indicated.[†]

TABLE 6. PRE-PRESCRIPTION: LABORATORY TESTS

Obtain the following tests before prescribing PrEP:

- **Baseline HIV Test**
  - Obtain 4th generation (recommended) or 3rd generation (alternative) rapid HIV test (list of 3rd and 4th generation tests is available here)
  - Perform nucleic acid amplification test (NAAT, viral load) for HIV for:
    - Patients with symptoms of acute infection
    - Patients whose antibody test is negative but who have reported unprotected sex with an HIV-infected partner in the last month[8]

Drug-resistant HIV has been found in patients with undiagnosed HIV who were using TDF/FTC as PrEP.

- **Basic Metabolic Panel**
  - Do not initiate PrEP in patients with creatinine clearance <60 mL/min
- **Urinalysis**
  - Proteinuria is an early warning sign of tenofovir toxicity; baseline urinalysis is necessary to identify pre-existing proteinuria
- **Serology for Viral Hepatitis A, B, and C**
  - Immunize against hepatitis A and B in non-immune patients
- **Screening for Sexually Transmitted Infections**
  - NAAT for gonococcal and chlamydial infection — test sites of exposure (genital, rectal, pharyngeal)
  - Rapid plasma reagin (RPR) for syphilis
- **Pregnancy Test**
  - If a woman is pregnant when starting PrEP or becomes pregnant while on PrEP, discuss the known risks and benefits

[†] See the Centers for Disease Control and Prevention's adult schedule for immunizations for non-HIV-infected adults. See New York State Department of Health recommendations for vaccinating against meningococcal disease.

VI. PRESCRIBING PrEP

Table 7 provides the recommended regimen for TDF/FTC when used for a PrEP indication. The first prescription should only be for 30 days to allow for a follow-up visit to assess adherence, tolerance, and commitment. At the 30-day visit, a prescription for 60 days may be given; the patient should then return for 3-month HIV testing and other assessments (see Table 8). After that visit, prescriptions can be given for 90 days, provided that the patient is adherent.

TABLE 7. PrEP: PRESCRIBING RECOMMENDATIONS
Prescription for PrEP should not be given until the patient is confirmed to have a negative HIV test result: If a negative result is not immediately available, a follow-up phone call to discuss test results may be necessary with the option for the clinician to either call in the prescription or schedule another visit
First Prescription: 30-day supply with no refills **Second Prescription given at 30-day visit:** 60-day supply with no refills ➢ 3-month HIV test is needed before a 90-day supply can be given **Subsequent Prescriptions:** no more than 90-day supply, confirmed negative HIV test result required for refill
Recommended Regimen*: **Truvada 1 tablet PO daily** (Tenofovir 300 mg + Emtricitabine 200 mg) * PrEP with antiretroviral agents other than TDF/FTC cannot be recommended at this time
Common Side Effects: Headache, abdominal pain, weight loss but side effects usually resolve or improve after first month

Figure 1 provides a general guide for the schedule of visits and follow-up assessments in the first year of receiving PrEP.

Figure 1. PrEP Management

Pre-Prescription Visit:

- Discuss PrEP use; clarify misconceptions
- Perform following laboratory tests:
  - HIV test (see Table 6 for guidance on what type of test to use)
  - Metabolic panel
  - Urinalysis
  - Hepatitis A, B, and C serology
  - STI screening
  - Pregnancy test

After confirmation of negative HIV test:
Prescribe 30-day supply of PrEP
Follow up in 2 weeks to assess side effects
(in person or by phone)

Adherence and commitment should be assessed at **each visit**. Schedule visits every 30 days for patients who report poor adherence or intermittent use.

30-day visit:

Assess:

- Side effects
- Serum creatinine and calculated creatinine clearance for patients with borderline renal function or at increased risk for kidney disease (>65 years of age, black race, hypertension, or diabetes)
- Discuss risk reduction and provide condoms

Prescribe 60-day refill; patient must come in for 3-month visit for HIV test and follow-up assessments, then 90-day schedule can begin

3-month visit

- HIV test
- Ask about STI symptoms
- Discuss risk reduction and provide condoms
- Serum creatinine and calculated creatinine clearance
- Pregnancy test

6-month visit

- HIV test
- Obtain STI screening tests (see Table 8)
- Pregnancy test
- Discuss risk reduction and provide condoms

9-month visit

- HIV test
- Ask about STI symptoms
- Discuss risk reduction and provide condoms
- Serum creatinine and calculated creatinine clearance
- Pregnancy test

12-month visit

- HIV test
- Obtain STI screening tests (see Table 8)
- HCV serology for MSM, IDUs, and those with multiple sexual partners
- Discuss risk reduction and provide condoms
- Pregnancy test
- Urinalysis

VII. PrEP Follow-Up Management and Monitoring

Patients receiving PrEP require regular visits, at least every 3 months, to monitor HIV status, adherence, and side effects. Follow-up and monitoring of patients receiving PrEP also includes prevention services that are part of a comprehensive prevention plan, such as risk-reduction counseling, access to condoms, STI screening, and mental health and substance use screening, when indicated.

Table 8 lists the elements of a follow-up visit for patients receiving PrEP.

Table 8. PrEP: Follow-Up Visits

At each visit:

- Assess **adherence**
- Provide **risk-reduction counseling**
- Offer **condoms**
- Manage **side effects**, *follow up 2 weeks after initiation to assess side effects (in person or by phone)*

Laboratory Testing: Follow-Up and Monitoring	
Laboratory Test	**Frequency**
HIV Testing	
• 4th generation (recommended) or 3rd generation (alternative) HIV screening test *List of 3rd and 4th generation tests is available here.*	o Every 3 months, *and* o Whenever there are symptoms of acute infection (serologic screening test + HIV RNA test)
STI screening	
• Ask about symptoms	o Every visit
• NAAT to screen for gonorrhea and chlamydia, based on sites of exposure • Rapid plasma reagin (RPR) for syphilis • Inspection for anogenital lesions	o At least every 6 months, even if asymptomatic (*Note:* Monogamous discordant couples may not need STI screening as frequently), *and* o Whenever symptoms are reported
Hepatitis C screening	
• Hepatitis C IgG	o At least annually for injection drug users, MSM, and those with multiple sexual partners
Renal function	
• Serum creatinine and calculated creatinine clearance	o 3 months after initiation, then every 6 months
• Urinalysis	o Annually
Pregnancy testing	o Every 3 months

Adherence and Retention in Care

In all studies of PrEP, efficacy is highly dependent on adherence. For patients who report intermittent use, more frequent visits may be necessary to reinforce adherence. Some providers use patient contracts to reinforce adherence to medication and appointments. Some providers may contact the pharmacy to confirm that medication is being refilled at time intervals consistent with adherence (e.g., every 30 days if 30-day supply given). If patients are consistently unable to adhere to the regimen, PrEP should be discontinued, and tailored risk-reduction messages should be delivered.

For patients who are not receiving routine primary care, PrEP is an opportunity for engagement and retention in care. Engagement in primary care should be strongly encouraged, and health maintenance, such as immunizations and standard age-appropriate prevention screening should be offered. Clinicians should partner with providers within or outside of their organization to provide services, including subspecialty services, mental health and substance use treatment, case management, navigation and linkage services, housing assistance, and income/benefits assessments. Referrals should also be made to support groups if indicated. See the HIV Patient Resources Directory for services listed by region.

Risk-Reduction Counseling

Discussions about risk reduction should be tailored according to the patient's individual needs (see Appendix C for a detailed listing of AIDS-Institute-funded HIV prevention programs that provide risk-reduction counseling). Clinicians should provide condoms at every visit, and should discuss use of effective contraception and desire to use contraception. PrEP users should be counseled to continue use of condoms while using PrEP (see *Prevention with Positives*, Appendix B, for more information about types of condoms and proper use).

For patients in serodiscordant relationships with HIV-infected partners who are not receiving ART, clinicians should recommend treatment for the HIV-infected partner and should reinforce this message at each visit.

For injection drug users, clinicians should make referrals for substance use treatment and should prescribe clean syringes and needles and refer to needle-exchange programs. New York State's two syringe access initiatives are the Expanded Syringe Access Demonstration Program and Syringe Exchange Programs.

HIV Testing

Routine HIV testing is an integral component of safe use of PrEP. Frequent screening is meant to prevent the development of resistance in PrEP users who become HIV-infected while using PrEP, as well as protect transmission to HIV-negative partners. Quarterly testing with a 4th generation (recommended) or 3rd generation (alternative) HIV screening test is recommended (see list of available 3rd and 4th generation HIV tests).

HIV testing should also occur whenever patients present with symptoms consistent with acute HIV infection. If acute HIV infection is suspected, an HIV serologic screening test should be used in conjunction with a plasma HIV RNA assay; a fourth-generation HIV antigen/antibody combination test is the recommended serologic screening test if available. Detection of HIV RNA in the absence of serologic evidence of HIV infection should be considered a preliminary positive result. More detailed recommendations for testing for acute HIV infection are available (see *Diagnosis and Management of Acute HIV Infection*).

For information about what to do when the HIV test of a patient receiving PrEP is positive, see Section VIII: *HIV Acquisition During PrEP*.

Side Effects

The most common side effects of TDF/FTC are headache, abdominal pain, and weight loss; however, these side effects usually resolve or improve after the first month. Two weeks after initiation of PrEP, clinicians should follow up either in person or by phone to assess side effects. Standard measures, such as antidiarrheal agents, anti-gas medications, and antiemetics, should be used to alleviate gastrointestinal side effects as needed.

Use of TDF/FTC in HIV-infected patients has shown that side effects, such as renal impairment or bone density loss, can occur. Although uncommon, regular laboratory monitoring for these parameters is necessary (see Table 8). If a decrease in serum creatinine and calculated creatinine clearance is observed, potential causes should be evaluated.

Pregnancy Screening and Management

Pregnancy tests should be obtained at each follow-up visit for women. Clinicians should discuss the known risks and benefits of taking TDF/FTC during pregnancy. Continuation of PrEP during pregnancy is an individualized decision based on patient preference and whether there are ongoing risks for HIV during pregnancy. The patient's obstetrical provider should be informed of the use of TDF/FTC during pregnancy.

VIII. HIV ACQUISITION DURING PREP

For patients who receive a reactive HIV screening result while on PrEP:

- Initiate fully active ART or consult with a provider experienced in HIV treatment to discuss treatment
- Perform supplemental diagnostic testing according to the CDC HIV testing algorithm; ART should be initiated while awaiting confirmatory results
- Assess for interruption in medications and duration of such interruption, and discuss any access or adherence barriers
- If supplemental laboratory testing confirms HIV infection
    - Perform HIV RNA testing (if not already obtained as part of the diagnostic algorithm for suspected acute HIV infection) to measure viral load
    - Perform HIV genotypic resistance testing; adjustments to the current ART regimen can be made once genotypic resistance results are available or when considering side effects (see current ART guidelines regarding treatment)
- If supplemental laboratory testing does not confirm HIV infection, PrEP may be resumed

For patients who present with symptoms of acute retroviral illness (see Table 5) and for whom acute HIV infection is suspected:

- A plasma HIV RNA assay should always be performed in conjunction with an HIV screening test (refer to current guidelines on acute infection for testing)
- For patients who receive a *reactive* HIV screening result, manage as described above for reactive screening
- For patients who receive a *nonreactive* screening result with HIV RNA ≥5,000 copies/mL:
    - Initiate fully active ART and perform HIV genotypic resistance testing; adjustments to the current ART regimen can be made according to genotypic resistance results or side effects (see current ART guidelines regarding treatment)
- A presumptive diagnosis of HIV infection can be made*For patients who receive a nonreactive HIV screening result but detectable low-level HIV RNA (<5,000 copies/mL), repeat HIV RNA to exclude a false-positive result; ART may be offered as described above while awaiting results from repeat HIV RNA testing
- If diagnostic laboratory testing does not confirm HIV infection, PrEP may be resumed

**If a presumptive diagnosis of HIV infection is made on the basis of HIV RNA testing alone, a new specimen should be collected 3 weeks later and HIV diagnostic testing should be repeated according to the CDC HIV testing algorithm.*

Clinicians should be vigilant for signs of potential HIV seroconversion in patients receiving PrEP (see Table 5 for a list of signs and symptoms of acute seroconversion). For information regarding testing and diagnosis of acute HIV infection, see *Diagnosis and Management of Acute HIV Infection* for guidance on screening for acute infection.

IX. DISCONTINUATION OF PrEP REGIMEN

Indications for discontinuation of PrEP are listed in Table 9. **When discontinuing PrEP in patients who have chronic hepatitis B virus, close monitoring for rebound hepatitis B viremia is recommended.**

TABLE 9. PrEP: DISCONTINUATION OF REGIMEN
Discontinue PrEP if patient receives a positive HIV test result and: ➢ recommend ART in consultation with a provider with extensive experience in HIV treatment ➢ obtain genotypic testing; adjustments may be made to the ART regimen once resistance results are available
Important Note: Discontinuation of TDF/FTC in patients with chronic active hepatitis B virus can cause exacerbations of hepatitis B.
Discontinue in patients who: ➢ develop renal disease ➢ are non-adherent to medication or appointments after attempts to improve adherence ➢ are using medication for purposes other than intended ➢ reduce risk behaviors to the extent that PrEP is no longer needed ➢ request discontinuation, with referral to risk-reduction support services and documentation of referral *Note: For women who become pregnant while using PrEP, continuation of PrEP during pregnancy is an individualized decision based on whether there are ongoing risks for HIV during pregnancy.*

X. RESOURCES

Centers for Disease Control and Prevention (CDC) guidelines for the use of daily pre-exposure prophylaxis (PrEP) for the prevention of HIV infection:

- Centers for Disease Control and Prevention. Preexposure prophylaxis for the prevention of HIV infection in the United States – 2014: A clinical practice guideline. Atlanta: Department of Health and Human Services, 2014. Available at www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf
- Centers for Disease Control and Prevention. Preexposure prophylaxis for the prevention of HIV infection in the United States – 2014: Clinical providers' supplement. Atlanta: Department of Health and Human Services, 2014. Available at www.cdc.gov/hiv/pdf/guidelines/PrEPProviderSupplement2014.pdf

Find a PrEP Provider Near You: The Greater Than AIDS website provides a directory of PrEP providers throughout the US. http://www.greaterthan.org/get-prep

World Health Organization. Guidance on oral pre-exposure prophylaxis (PrEP) for serodiscordant couples, men and transgender women who have sex with men at high risk of HIV: Recommendations for use in the context of demonstration projects; July 2012. Available at: www.who.int/hiv/pub/guidance_prep/en/index.html

Truvada Risk Evaluation and Mitigation Strategy (REMS) Materials:
Available at: www.truvadapreprems.com/truvadaprep-resources

Truvada Package Insert:
Available at: www.accessdata.fda.gov/drugsatfda_docs/label/2013/021752s042lbl.pdf

AIDS Vaccine Advocacy Coalition (AVAC) website: Pre-Exposure Prophylaxis

PrEP Watch: www.prepwatch.org

REFERENCES

1. Centers for Disease Control and Prevention. Preexposure Prophylaxis for HIV Prevention in the United States – 2014. A Clinical Practice Guideline. Available at: http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf.

2. Centers for Disease Control and Prevention. Preexposure Prophylaxis for the Prevention of HIV in the United States – 2014. Clinical Providers' Supplement. Available at: http://www.cdc.gov/hiv/pdf/guidelines/PrEPProviderSupplement2014.pdf.

3. INSIGHT START Study Group. Initiation of Antiretroviral Therapy in Early Asymptomatic HIV Infection. N Engl J Med. 2015 [Epub ahead of print]. [PubMed]

4. TEMPRANO ANRS 12136 Study Group. A Trial of Early Antiretrovirals and Isoniazid Preventive Therapy in Africa. *N Engl J Med* 2015 [Epub ahead of print]. [PubMed]

5. National Institutes of Health. News release: HIV control through treatment durably prevents heterosexual transmission of virus. July 20, 2015. Available at: http://www.niaid.nih.gov/news/newsreleases/2015/Pages/HPTN052results.aspx

6. Martin M, Vanichseni S, Suntharasamai P, et al. The impact of adherence to preexposure prophylaxis on the risk of HIV infection among people who inject drugs. *AIDS* 2015;29:819-824. [PubMed]

7. Grant RM, Anderson PL, McMahan V, et al. Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: a cohort study. *Lancet Infect Dis* 2014;14:820-829. [PubMed]

8. Grant RM, Lama JR, Anderson PL, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *N Engl J Med* 2010;363:2587-2599. [PubMed]

9. Baeten JM, Donnell D, Ndase P, et al. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. *N Engl J Med* 2012;367:399-410. [PubMed]

10. Thigpen MC, Kebaabetswe PM, Paxton LA, et al. Antiretroviral preexposure prophylaxis for heterosexual HIV transmission in Botswana. *N Engl J Med* 2012;367:423-434. [PubMed]

11. Van Damme L, Corneli A, Ahmed K, et al. Preexposure prophylaxis for HIV infection among African women. *N Engl J Med* 2012;367:411-422. [PubMed]

12. Marrazzo J et al. *Pre-exposure prophylaxis for HIV in women: Daily oral tenofovir, oral tenofovir/emtricitabine or vaginal tenofovir gel in the VOICE study (MTN 003).* 20th Conference on Retroviruses and Opportunistic Infections, Atlanta, abstract 26LB, 2013.

13. Choopanya K, Martin M, Suntharasamai P, et al. Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): A randomized, double-blind, placebo-controlled phase 3 trial. *Lancet* 2013;381:2083-2090. [PubMed]

14. Marrazzo JM, del Rio C, Holtgrave DR, et al. HIV prevention in clinical care settings: 2014 recommendations of the International Antiviral Society-USA Panel. *JAMA* 2014;312:390-409. [PubMed]

15. Smith DK, Pals SL, Herbst JH, et al. Development of a clinical screening index predictive of incident HIV infection among men who have sex with men in the United States. *J Acquir Immune Defic Syndr* 2012;60:421-427. [PubMed]

16. Grov C, Rendina HJ, Ventuneac A, et al. HIV risk in group sexual encounters: An event-level analysis from a national online survey of MSM in the U.S. *J Sex Med* 2013;10:2285-2294 [Epub ahead of print]. [PubMed]

17. Buchacz K, McFarland W, Kellogg TA, et al. Amphetamine use is associated with increased HIV incidence among men who have sex with men in San Francisco. *AIDS* 2005;19:1423-1424. [PubMed]

18. Zule WA, Costenbader EC, Meyer WJ Jr, et al. Methamphetamine use and risky sexual behaviors during heterosexual encounters. *Sex Transm Dis* 2007;34:689-694. [PubMed]

19. Zetola NM, Bernstein KT, Wong E, et al. Exploring the relationship between sexually transmitted diseases and HIV acquisition by using different study designs. *J Acquir Immune Defic Syndr* 2009;50:546-551. [PubMed]

20. LaLota M, Beck DW, Metsch LR, et al. HIV seropositivity and correlates of infection among heterosexually active adults in high-risk areas in South Florida. *AIDS Behav* 2011;15:1259-1263. [PubMed]

21. Heuker J, Sonder GJ, Stolte I, et al. High HIV incidence among MSM prescribed postexposure prophylaxis, 2000-2009: Indications for ongoing sexual risk behaviour. *AIDS* 2012;26:505-512. [PubMed]

22. Cohen MS, Chen YQ, McCauley M, et al., HPTN 052 Study Team. Prevention of HIV-1 infection with early antiretroviral therapy. *N Engl J Med* 2011;365:493-505. [PubMed]

23. Johnson MO, Sevelius JM, Dilworth SE, et al. Preliminary support for the construct of health care empowerment in the context of treatment for human immunodeficiency virus. *Patient Prefer Adherence* 2012;6:395-404.

24. Birkhead GS, Pulver WP, Warren BL, et al. Acquiring human immunodeficiency virus during pregnancy and mother-to-child transmission in New York: 2002-2006. *Obstet Gynecol* 2010;115:1247-1255. [PubMed]

25. Anderson PL, Glidden DV, Liu A, et al. Emtricitabine-tenofovir concentrations and pre-exposure prophylaxis efficacy in men who have sex with men. *Sci Transl Med* 2012;4:151ra125. [PubMed]

26. Hendrix CW, Chen BA, Guddera V, et al. MTN-001: Randomized pharmacokinetic cross-over study comparing tenofovir vaginal gel and oral tablets in vaginal tissue and other compartments. *PLoS One* 2013;8:e55013. [PubMed]

27. Patterson KB, Prince HA, Kraft E, et al. Penetration of tenofovir and emtricitabine in mucosal tissues: Implications for prevention of HIV-1 transmission. *Sci Transl Med* 2011;3:112re4. [PubMed]

28. Grohskopf LA, Chillag KL, Gvetadze R, et al. Randomized trial of clinical safety of daily oral tenofovir disoproxil fumarate among HIV-uninfected men who have sex with men in the United States. *J Acquir Immune Defic Syndr* 2013;64:79-86. [PubMed]

APPENDIX A. RESULTS FROM CLINICAL TRIALS OF THE EFFICACY OF DAILY ORAL PREP FOR PREVENTING HIV INFECTION

Results From Randomized, Placebo-Controlled, Clinical Trials of the Efficacy of Daily Oral Antiretroviral Pre-Exposure Prophylaxis (PrEP) for Preventing Human Immunodeficiency Virus (HIV) Infection

Clinical trial	Participants	Type of medication	mITT efficacy*		Adherence-adjusted efficacy based on TDF detection in blood	
			%	(95% CI)	%	(95% CI)
Bangkok Tenofovir Study	Injecting drug users	TDF	49	(10–72)	70	(2–91)
Partners PrEP	HIV discordant couples	TDF	67	(44–81)	86	(67–94)
		TDF/FTC	75	(55–87)	90	(58–98)
TDF2	Heterosexually active men and women	TDF/FTC	62	(22–83)	84	NS
iPrEx	Men who have sex with men	TDF/FTC	42	(18–60)	92	(40–99)
Fem-PrEP	Heterosexually active women	TDF/FTC	NS	—	NA	—
VOICE	Heterosexually active women	TDF	NS	—	NA	—
		TDF/FTC	NS	—	NA	—

Abbreviations: CI, confidence interval; FTC, emtricitabine; mITT, modified intent to treat analysis, excluding persons determined to have had HIV infection at enrollment; NA, data not available; NS, not statistically significant; TDF, tenofovir disoproxil fumarate.

* % reduction in acquisition of HIV infection.

Reprinted from Centers for Disease Control and Prevention. Update to interim guidance for pre-exposure prophylaxis (PrEP) for the prevention of HIV infection: PrEP for injecting drug users. *Morb Mortal Wkly Rep* 2013;62:463-465. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6223a2.htm

APPENDIX B. HIRI-MSM RISK INDEX

The following risk index was predictive of HIV seroconversion in two large prospective cohorts of men who have sex with men in the United States. The index can be used to prioritize patients for PrEP and other intensive HIV prevention efforts.

HIRI-MSM Risk Index*

1	How old are you today (yrs)?	<18 years	score 0
		18–28 years	score 8
		29–40 years	score 5
		41–48 years	score 2
		≥49 years	score 0
2	How many men have you had sex with in the last 6 months?	>10 male partners	score 7
		6–10 male partners	score 4
		0–5 male partners	score 0
3	In the last 6 months, how many times did you have receptive anal sex (you were the bottom) with a man?	1 or more times	score 10
		0 times	score 0
4	How many of your male sex partners were HIV positive?	>1 positive partner	score 8
		1 positive partner	score 4
		<1 positive partner	score 0
5	In the last 6 months, how many times did you have insertive anal sex (you were the top) with a man who was HIV positive?	5 or more times	score 6
		0 times	score 0
6	In the last 6 months, have you used methamphetamines such as crystal or speed?	Yes	score 5
		No	score 0
7	In the last 6 months, have you used poppers (amyl nitrate)?	Yes	score 3
		No	score 0
		Add down entries in right column to calculate total score	Total score†

*To identify sexually active MSM in their practice, we recommend clinicians ask all their male patients a routine question: "In the past (time) have you had sex? (if yes), with men, women, or both?"

†If score is 10 or greater, evaluate for PrEP or other intensive HIV prevention services; If score is 9 or less, provide indicated standard HIV prevention services.

Reprinted from Smith DK, Pals SL, Herbst JH, et al. Development of a clinical screening index predictive of incident HIV infection among men who have sex with men in the United States. *J Acquir Immune DeficSyndr*2012;60:421-427. [PubMed]

APPENDIX C. AIDS INSTITUTE-FUNDED HIV PREVENTION COUNSELING PROGRAMS

The following link contains information about how to contact an **AIDS Institute-funded HIV prevention program that provides risk-reduction counseling:**

www.hivguidelines.org/wp-content/uploads/2014/12/ai-funded-nys-hiv-prevention-counseling-programs-12-22-2014.pdf

See also: www.health.ny.gov/diseases/aids/about/index.htm

APPENDIX D. PAYMENT OPTIONS FOR PRE-EXPOSURE PROPHYLAXIS (PREP)

Health Coverage and NYSDOH Sponsored Programs	
Private Insurance	• Most private insurances cover PrEP. • Coverage varies based on plan. There may be deductibles and co-payments.
Medicaid	• PrEP prescription costs, medical appointments, and lab tests covered. • Prior approval is required and renewed every 3 months. • Helpline (800) 541-2831 • www.health.ny.gov/diseases/aids/general/prep/truvada.htm
PrEP Assistance Program (PrEP-AP)	• PrEP-AP Hotline (800) 542-2437 or visit: www.health.ny.gov/diseases/aids/general/resources/adap • PrEP-AP serves HIV-negative persons who are residents of New York State who are uninsured or underinsured. Financial eligibility is based on 435% of the Federal Poverty Level (FPL). • Covers costs of doctor's visits and lab testing for uninsured and underinsured individuals. Services include HIV, STI/STD testing, counseling, and supportive primary care services consistent with clinical guidelines for PrEP. • PrEP medication will be provided to uninsured or underinsured individuals through the manufacturer patient assistance programs (PAP) (listed below). • Providers that are enrolled in the New York State Medicaid Program are eligible to enroll in PrEP-AP. Please contact the ADAP Provider Relations Section at (518) 459-1641 or email damarys.feliciano@health.ny.gov for more information on becoming a PrEP-AP provider. • Providers are responsible for assisting patients with the PAP application to receive Truvada as indicated for PrEP
Medication Assistance Programs	
Gilead Co-Pay Coupon Card	• Gilead Co-Pay Coupon Card www.gileadcopay.com o Covers up to $300/month in prescription co-payments. o Patient must have insurance. o Patient must NOT be enrolled in Medicare or Medicaid. o No income eligibility requirement.
Gilead Medication Assistance Program	• Gilead Medication Assistance Program (855) 330-5479 http://start.truvada.com/individual o Covers prescription costs. o Patient must be uninsured or their insurance does not cover any prescription cost. o Patient must have annual income less than 500% FPL.
Patient Access Network	• Patient Access Network (866) 316-7263 o Offers help to people with chronic disease for whom cost limits access to critical medical treatment due to rising deductibles and co-pays. o One-time grant to cover up to $4,000 of prescription costs for one year. o Patient must have private insurance, Medicare, or Medicaid. o Patient must have annual income less than 500% FPL. If income is above this amount, patient may still qualify if prescription costs exceed 10% of income.