

PROTOCOL: PRE-EXPOSURE PROPHYLAXIS

Vanderbilt Comprehensive Care Clinic

Facilities

PrEP Providers	Call for Appointments	Clinic Address
[List names of providers]	[Clinic number]	[Clinic address]

Personnel:

Designated and experienced PrEP providers at the [clinic name] will professionally staff the PrEP Clinic.

Medical Oversight:

The Medical Director for the PrEP Clinic will be [provider name].

Laboratories:

[List name of lab(s) running tests]

Eligibility

CDC Recommended Indications for PrEP Use:

As recommended by the CDC (1) the following are indications for PrEP use by MSM, Heterosexually Active Men and Women, and Injecting Drug Users.

Recommended Indications for PrEP Use by MSM:

- Adult man
- Without acute or established HIV infection
- Any male sex partners in past 6 months
- Not in a monogamous partnership with a recently tested, HIV-negative man

AND at least one of the following

- Any anal sex without condoms (receptive or insertive) in past 6 months
- Any STI diagnosed or reported in past 6 months
- Is in an ongoing sexual relationship with an HIV-positive male partner

Recommended Indications for PrEP Use by Heterosexually Active Men and Women:

- Adult person
- Without acute or established HIV infection

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- Any sex with opposite sex partners in past 6 months
- Not in a monogamous partnership with a recently tested HIV-negative partner

AND at least one of the following

- Is a man who has sex with both women and men (behaviorally bisexual)
- Infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be at substantial risk of HIV infection (IDU or bisexual male partner)
- Is in an ongoing sexual relationship with an HIV-positive partner

Recommended Indications for PrEP Use by Injection Drug Users:

- Adult person
- Without acute or established HIV infection
- Any injection of drugs not prescribed by a clinician in past 6 months

AND at least one of the following

- Any sharing of injection or drug preparation equipment in past 6 months
- Been in a methadone, buprenorphine, or suboxone treatment program in past 6 months
- Risk of sexual acquisition

Payment Options

As the PrEP Clinic is NOT a demonstration project or clinical trial, clients are asked to cover the costs of the medication, lab work, and provider visits. The patient can choose to pay out-of-pocket, utilize their insurance, or apply for assistance with Gilead's Medication Assistance Program. Clients utilizing their insurance are also able to apply for a Gilead Copay Assistance card which covers up to \$7,200 per calendar year of the copay for medication used for PrEP (Truvada® or Descovy®).

Eligibility for PrEP Clinic may also be affected by the individual's income and insurance status.

For Patients with Insurance:

The clinic **can** accept most insurance plans (ex. Blue Cross Blue Shield, Medicare, etc.):

The clinic can accept insurance plans offered by the following companies **conditionally**:

- [INSERT INSURANCE PROVIDER]

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Commercially-insured patients can use a Gilead Copay card for their medication copay but are responsible for the copay for visits and lab work.

For Uninsured Patients:

The clinic **cannot** accept insurance plans offered by the following companies (ex. Blue Cross Blue Shield, Medicare, etc.):

- [INSERT INSURANCE PROVIDER]
- [INSERT INSURANCE PROVIDER]

The clinic may be able to see individuals who are uninsured through use of Gilead's Patient Assistance Program. Please see below for conditions regarding this program. These patients would be responsible for provider visits and laboratory costs.

Gilead's Medication Assistance Program: The PrEP Clinic provider is available to help individuals apply for Gilead's Patient Assistance Program which covers the cost of Truvada for eligible individuals. Individuals must have an income less than 500% the federal poverty level to qualify and can be employed or unemployed. <https://www.gileadadvancingaccess.com/financial-support/uninsured>

Screening

Procedure:

The PrEP Clinic provider screens all interested individuals by phone or in person. The provider speaks with the individual regarding their interest in PrEP and their knowledge of how PrEP works, answering any questions and correcting any misinformation. The provider also explains how the PrEP clinic works. For any interested patients, patient information and insurance/income information are collected before setting up an initial appointment. Uninsured individuals will be informed of low-cost options that are available in the community if the PrEP Clinic presents a significant financial barrier.

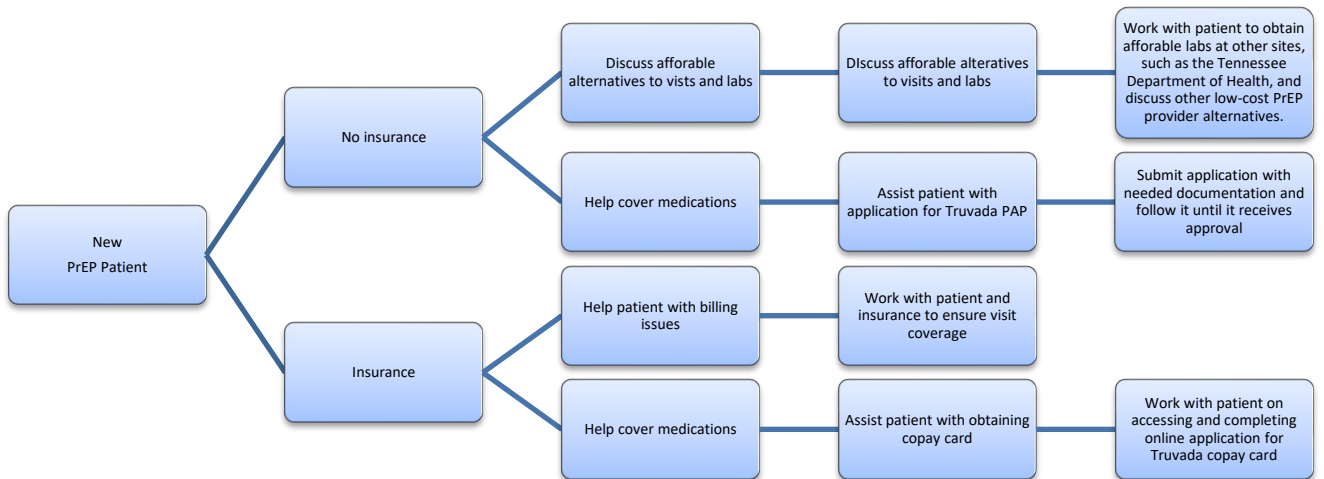
Screening:

The provider will screen the patient for reasons for wanting PrEP, knowledge of how PrEP works, eligibility information, and need for assistance along with any other relevant notes.

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Administrative Considerations and Process:



Initial Visit

Procedure:

Patient may self-refer to the PrEP Clinic. PrEP provider discusses the PrEP Clinic in detail with the patient. Readiness and willingness to adhere to PrEP are assessed. The patient’s PCP is documented and a medical release form is signed if the provider is not within the EMR system. If the patient does not have a PCP, they are given a list of PCP options. PrEP payment method is confirmed. If the patient has an HIV-positive partner, their ART, viral load, and CD4 status are discussed. Referrals are made if domestic or intimate partner violence is indicated in the risk assessment. Housing status is assessed for stability. Reproductive plans are discussed with female patients. An HIV test (Fourth-generation HIV antibody/antigen test) is conducted in concordance with a risk assessment and risk reduction counseling. If a positive result is indicated, linkage-to-care procedures are followed. Upon documenting a negative result, a prescription for PrEP is created for eligible patients. Medication counseling is provided.

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Patient Packet:

At the initial visit, the PrEP provider will provide the individual with a PrEP Clinic Patient Packet which includes the following:

- An informational sheet on how the clinic works
- A flow-chart indicating the schedule of PrEP clinic events/components
- A sheet of PrEP basic information
- A PrEP Clinic FAQ
- A medication guide

PrEP Clinic Components

Schedule of Visits:

The clinic operates [hours].

Once a client has completed their initial PrEP Clinic visit, their next visit will be about three months later. Clients will then attend PrEP Clinic once every three months.

At every visit, PrEP Clinic clients will have vital signs recorded and specimens collected for lab at [lab] and see a PrEP Clinic provider. These components of the PrEP Clinic lab are detailed below.

Labs:

Schedule of Laboratory Tests

	0	3	6	9	12	15	18	21	24
HIV Ab	X	X	X	X	X	X	X	X	X
HIV Ag/Ab [†]	X								
Serum Cr [‡]	X	X	X		X		X		X
U/A	X				X				X
Preg	X	X	X	X	X	X	X	X	X
HBV sAg*	X				X				X
HBV sAb	X								
HCV Ab**	X				X				X
STI symptom assessment	X	X	X	X	X	X	X	X	X

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RPR [†]	X		X		X		X		X
Urine [†] GC/CT (Males)	X		X		X		X		X
Rectal [†] GC/CT	X		X		X		X		X
Pharyngeal [†] GC/CT	X		X		X		X		X
Vaginal GC/CT (Females)	X		X		X		X		X

*If HBV sAb reactive, do not perform annual sAg.

**If reactive, refer to VHC.

[†]More frequently as indicated.

Patient Social History:

At each visit, an in-depth social history will be conducted by the provider, which includes the following topics.

Social History Topics:

- Alcohol Use
- Other Recreational Drug Use
- Sexual Behavior
- Personal Safety
- Travel
- Medication Adherence

The provider who sees the patient that day has the ability to address anything of concern. If suicidal ideation or intimate partner violence are indicated, those respective protocols go into effect and appropriate referrals are made. Providers make notes about the responses and their conversations with the client in the EHR.

Patient Education:

Education should be provided for all PrEP Clinic patients. Prior to initiating PrEP, each patient will receive general information on PrEP, HIV basics, HIV prevention and other prevention practices, counseling on risk reduction of other sexually transmitted infections, the importance of adherence, and more information on how the clinic functions.

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If applicable, providers should discuss available information about risks and benefits of PrEP during pregnancy with patients. See CDC PrEP guidelines for more information (1).

Topics covered are documented in the EHR by the PrEP Clinic Provider.

Provider Visit:

PrEP Clinic clients are seen by a provider at every PrEP Clinic visit. PrEP Clinic providers are Nurse Practitioners or Infectious Disease Physicians who practice at the clinic.

Providers are tasked with reviewing lab results, reinforcing educational messages around adherence and safer sex, conducting targeted examinations, and addressing the responses. Based on the conversations between the provider and the client, they will jointly decide whether to initiate or continue Truvada® or Descovy® as PrEP. If initiating or continuing, the provider will write or renew a prescription for Truvada® or Descovy® as PrEP.

Providers document the visit in the EHR.

Discontinuation of PrEP

Discontinuation of PrEP is a decision that is made between the client and the PrEP clinic providers for various reasons. Clients who chose to discontinue PrEP have safer sex messages reinforced and are still welcome to come to the clinic for regular HIV testing and counseling.

PrEP will be discontinued if the client tests positive for HIV at any of their regular appointments.

Discontinuation of PrEP provision is additionally recommended:

- If a low creatinine clearance is recorded (Creatinine clearance as calculated by the Cockcroft-Gault equation <60ml/min for Truvada® or <30mL/min for Descovy®) that does not improve with increased hydration.
- If any severe effects are noted (lactic acidosis, sever liver problems)
- If the client demonstrates poor adherence behaviors (<3 pills per week, stops coming to appointments, etc.)

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Billing

Lab work:

Most visits are generally billed under the following ICD-10 diagnosis codes:

- Z20.6 “Contact with and (suspected) exposure to HIV”
- Z17.1 “Human immunodeficiency virus [HIV] counseling”
- Z11.3 “Encounter for screening for infection with a predominantly sexual mode of transmission”
- Z79.899 “Other long term (current) drug therapy”

Other potential billing codes are listed in the CDC Guidelines... Provider’s Supplement.

Provider Visits:

Provider visits are billed at Level 2-4 depending on medical complexity and counseling time involved in the visit.

Other Resources:

- A. Patient Packet
 1. How the Clinic Works
 2. PrEP Clinic Flow Chart
 3. PrEP Basics
 4. PrEP Clinic FAQ
- B. Confidentiality Agreement
- C. PrEP Clinic Informational Materials
- D. CDC Guidelines for PrEP: <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>
- E. Gilead Truvada for PrEP Link: <https://start.truvada.com/>

References:

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1. Centers for Disease Control and Prevention (CDC). Preexposure Prophylaxis for the Prevention of HIV Infection in the United States: 2021 Update. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf> Accessed January 6, 2021.