Pre-Exposure Prophylaxis (PrEP)

Clinic Resource Manual

2022

VDH VIRGINIA DEPARTMENT OF HEALTH

Promoting & Protecting the Health of All Virginians
www.vdh.virginia.gov

This document is a product of the Virginia Department of Health (VDH) and should only be used by entities affiliated with the Division of Disease Prevention (DDP) HIV and Hepatitis Prevention and its PrEP programs. This manual is a resource for internal use only. Should questions about content or process arise, please contact:

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For information about the VDH **nPEP** program (non-occupational post-exposure prophylaxis), please contact Eric Mayes or visit the website for the **nPEP Protocols for Local Health Departments** and additional resources.

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ACRONYMS

ART - antiretroviral therapy
CAB – cabotegravir (brand name Apretude)
CBO - community-based organization
CDC – Centers for Disease Control and Prevention
DAP – Drug Assistance Program
DDP – Division of Disease Prevention
DPS - Division of Pharmacy Services
eCrCl - estimated creatinine clearance
F/TAF – emtricitabine/tenofovir alafenamide (brand name Descovy®)
F/TDF – emtricitabine/tenofovir disoproxil fumerate (brand name Truvada®)
MI - motivational interviewing
MSM – men who have sex with men
nPEP – non-occupational post-exposure prophylaxis
NSAIDs - nonsteroidal anti-inflammatory drugs
PrEP – pre-exposure prophylaxis
PWH – persons with HIV
PWID – persons who inject drugs
SSP – syringe service program
STI – sexually transmitted infection
TASP - treatment as prevention
TGM – transgender man
TGW – transgender woman
U=U - undetectable equals untransmittable
VDH – Virginia Department of Health

INTRODUCTION

The Virginia Department of Health's (VDH) guidance for the use of HIV pre-exposure prophylaxis (PrEP*)* provides comprehensive information for the use of antiretroviral medications to reduce the risk of acquiring HIV infection. This document has been updated to reflect the most recent CDC (Centers for Disease Control and Prevention) 2021 PrEP Guidelines, which were released in December 2021. These guidelines apply to oral PrEP use, including emtricitabine/tenofovir disoproxil fumerate (F/TDF, brand name Truvada®) and emtricitabine/tenofovir alafenamide (F/TAF, brand name Descovy®), and the first FDA-approved long-acting injectable for HIV prevention, cabotegravir (CAB, brand name Apretude).

New recommendations to be aware of:

- All sexually active adults and adolescents over the age of 15 and weighing at least 35 kg (77 lbs.) should receive information about PrEP, as daily oral PrEP has been shown to be safe and effective in reducing the risk of sexual HIV acquisition.

- Clients who request PrEP should be offered it, even when no specific risk is identified. They may not feel comfortable reporting sexual or injection behaviors to avoid anticipated stigmatizing responses in health care settings.

- Renal function should be assessed by estimated creatinine clearance (eCrCl) at baseline for PrEP clients taking daily oral F/TDF or F/TAF, and monitored periodically so that persons in whom clinically-significant renal dysfunction is developing do not continue to take it.
    - eCrCl should be assessed every six months for clients over age 50 or those who have an eCrCl <90 ml/min at initiation.
    - For all other daily oral PrEP clients, eCrCl should be assessed at least every 12 months.

Reaffirming the following important messaging:

- Acute and chronic HIV infection must be excluded by symptom history and HIV testing immediately before any PrEP regimen is prescribed. Acute symptoms of HIV may include: fever, fatigue, muscle aches, joint aches, skin rash, headache, sore throat, cervical adenopathy, night sweats, and/or diarrhea.

- HIV infection should be assessed at least every three months for clients taking daily oral PrEP, so that persons with incident infection do not continue taking it. The 2-drug regimens of F/TDF or F/TAF are inadequate therapy for established HIV infection, and their use in persons with early HIV infection may cause resistance to one or more of the PrEP medications.

- When PrEP is prescribed, clinicians should provide access, directly or by facilitated referral, to:
    - Support for medication adherence and continuation in follow-up PrEP care; high medication adherence and persistent use are critical to PrEP effectiveness in preventing HIV acquisition.
    - Risk reduction services for safer sex practices and/or comprehensive harm reduction measures for injection drug use.

Good to know:

- F/TDF has been available for PrEP since 2012, and an equivalent generic medication became available October, 2020.

- F/TAF was approved for PrEP use in 2019.

- For most clients, there is no need to switch from F/TDF to F/TAF. While incremental difference in laboratory markers of bone metabolism and renal function have been seen in some studies, no differences in clinically meaningful adverse events have been seen. Either F/TDF or F/TAF can be used when eCrCl $\geq$60 ml/min. Clinicians may prefer F/TAF for persons with previously documented osteoporosis or related bone disease but routine screening for bone density is not recommended for PrEP clients.
- Please click the links for more details about PrEP including a summary of the CDC's 2021 PrEP Guidelines with introduction and evidence of need.

Resources included in this manual:

- **Checklist for Oral PrEP (Appendix A)**
- **VDH Lab Guidelines for Oral PrEP (Appendix B)**
- **VDH Lab Guidelines for nPEP (Appendix C)**
- **Checklist for Injectable PrEP (Appendix D)**

CLINICAL PrEP GUIDELINES

IDENTIFYING INDICATIONS FOR PrEP

The 2021 CDC guidelines have simplified the indications for PrEP and include offering PrEP to all sexually active adults and adolescents as well as providing PrEP for those who request it, even when no specific risk is identified. Table 1 below summarizes the indications for PrEP followed by the rationale for the recommendations. .

Table 1: PrEP Indications: Identifying Substantial Risk of Acquiring HIV Infection

PrEP Indications	
Sexually-Active Adults and Adolescents without HIV who have had anal or vaginal sex in the past six months **AND** any of the following:	• HIV-positive partner (especially if partner has unknown or detectable viral load) • Bacterial STI in past six months • History of inconsistent or no condom use with sexual partner(s)
Persons Who Inject Drugs (PWID) Who:	• Have an HIV-positive injecting partner; **or** • Share injection equipment

Source: CDC

- All sexually active adults and adolescents over the age of 15 and weighing at least 35 kg (77 lbs.) should receive information about PrEP as daily oral PrEP has been shown to be safe and effective in reducing the risk of sexual HIV acquisition.

- Clients who request PrEP should be offered it, even when no specific risk is identified. They may not feel comfortable reporting sexual or injection behaviors to avoid anticipated stigmatizing responses in health care settings.

Informing all sexually active adults and adolescents about PrEP will enable clients to both respond openly to risk assessment questions and to discuss PrEP with persons in their social networks and family members who might benefit from its use. Studies have shown that clients often do not disclose stigmatized sexual or substance use behaviors to their health care providers (especially when not asked about specific behaviors).

Taking a brief, targeted sexual history is recommended for all adult and adolescent clients as part of ongoing primary care and is the best way to determine their testing, treatment and prevention needs. We know that the sexual history is often deferred because of urgent care issues, provider discomfort, or anticipated client discomfort. This deferral is common among providers of

primary care as well as STI care and HIV care. To make the process easier, the clinician can explain that:

- Taking a brief sexual history is routine practice for all clients;
- Having a sexual history is necessary to provide individually appropriate sexual health care; and
- Reaffirm confidentiality of their client information.

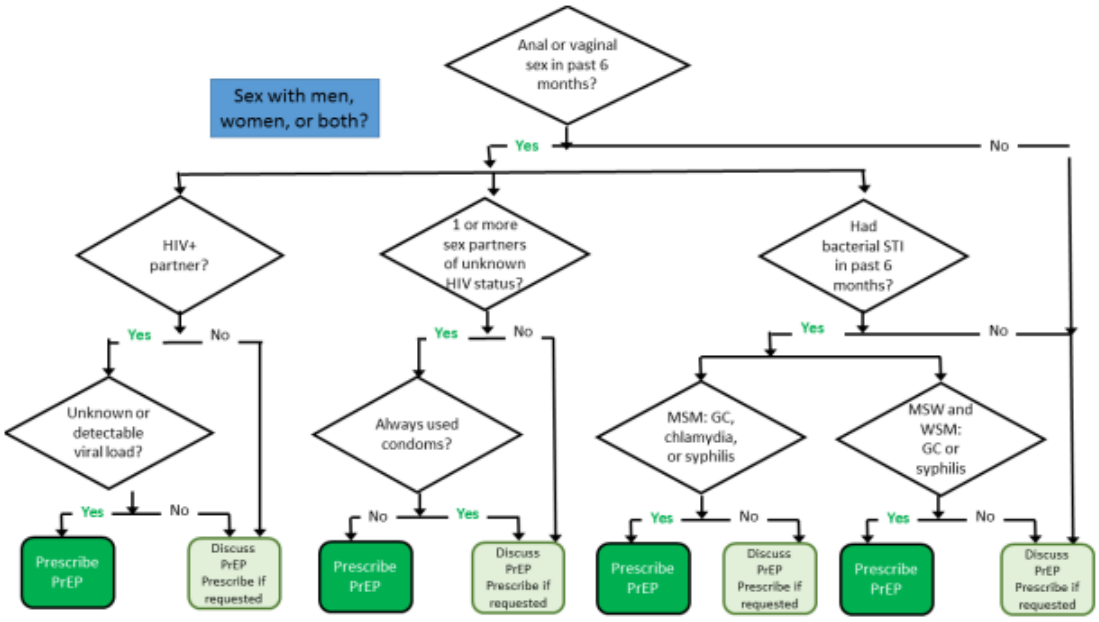
Only a few questions are needed to establish whether indications for PrEP are present. However, clinicians may want to ask additional questions to obtain a more complete sexual history that includes information about a client's gender identity, partners, sexual practices, HIV/STI protective practices, past history of STIs, and pregnancy intentions/preventive methods. For more information on how to discuss the client's sexual health and history, visit: https://www.cdc.gov/std/treatment/sexualhistory.pdf.

Clinicians should become familiar with the evolving terminology referring to sex, gender identity, and sexual orientation. See **Appendix E**, which describes the evolving terminology.

Clinicians should also briefly screen all clients for alcohol use disorder (especially before sexual activity), and the use of illicit non-injection drugs (e.g., amyl nitrite, stimulants). The use of these substances may affect sexual risk behavior, hepatic or renal health, or medication adherence, any of which may affect decisions about the appropriateness of prescribing PrEP medication. In addition, if a substance use disorder is identified, the clinician should provide referral for appropriate treatment or harm-reduction services acceptable to the client.

Figure 1 below outlines a set of brief questions designed to assess a key set of sexual practices that are associated with the risk of HIV acquisition.

Figure 1: Assessing Indications for PrEP in Sexually Active Persons



Source: CDC

ASSESSING RISK OF SEXUAL HIV ACQUISITION

Partner(s) with HIV or Unknown HIV Status

A client who reports that one or more regular sex partners is of unknown HIV status should be offered HIV testing for those partners, either in the clinician's practice or at a confidential testing site (see zip code lookup on CDC website).

When a client reports that one or more regular sex partners is known to have HIV, the clinician should determine whether the client being considered for PrEP knows if the HIV-positive partner is receiving antiretroviral therapy (ART) and has had an undetectable viral load (<200 copies/ml) for at least the prior 6 months. Persons with HIV (PWH) who have an undetectable viral load pose effectively no risk for HIV transmission to sexual partners (see section below on considerations for HIV discordant couples). PrEP for an HIV-uninfected client may be indicated if a sexual partner with HIV has been inconsistently virally suppressed or his/her viral load status is unknown. In addition, PrEP may be indicated if the partner without HIV seeking PrEP either has other sexual partners or wants the additional reassurance of protection that PrEP can provide.

Persons with History of a Bacterial STI in the Past 6 Months

Clinicians should ask all sexually-active clients about any diagnoses of bacterial STIs (chlamydia, syphilis, gonorrhea) during the past 6 months, because they provide evidence of sexual activity that could result in HIV exposure. For heterosexual women and men, risk of HIV exposure during condomless sex may also be indicated by recent pregnancy of a female client or a female sexual partner of a male client considering PrEP.

Persons with Inconsistent or No Condom Use
Reported consistent ("always") condom use is associated with an 80% reduction in HIV acquisition among heterosexual couples and 70% among MSM. Inconsistent condom use is considerably less effective, and studies have reported low rates of recent consistent condom use among MSM and other sexually active adults. Especially low rates have been reported when condom use was measured over several months rather than during most recent sex or the past 30 days. Therefore, unless the patient reports confidence that consistent condom use can be achieved, PrEP should be prescribed while continuing to support condom use for prevention of STIs and unplanned pregnancy.

ASSESSING RISK OF HIV ACQUISITION THROUGH INJECTION PRACTICES

Persons Who Inject Drugs
PWID should be offered PrEP. Studies using F/TDF with PWID show an efficacy of at least 74% and up to 86%. Additionally, other harm reduction services should be offered including drug treatment and relapse prevention services; refer to syringe exchange services; and refer for mental health or social services as needed.

Risk behaviors reported by PWID in 2018 to the National HIV Behavioral Surveillance System (NHBS) include:

- Receptive sharing of syringes (33%)
- Receptive sharing of injection equipment (55%)
- Few (1%) reported using PrEP in the previous 12 months

Most PWID report sexual behaviors that confer risk of HIV acquisition among HIV-negative PWID males.

- 69% reported having had condomless vaginal sex in the prior 12 months
- 4% reported having had condomless anal sex with a male partner

Among HIV-negative PWID females:

- 79% reported having had condomless vaginal sex
- 27% reported having had condomless anal sex.

Among HIV negative PWID, 33% reported their most recent sex was condomless sex with a partner known to have HIV. Because most PWID are sexually active, and many acquire HIV from sexual exposures, they should be assessed for both sexual and injection behaviors that indicate HIV risk. Based on clinical trials, PWID are likely to benefit from PrEP with any FDA-approved medication with or without an identified sexual behavior risk of HIV acquisition.

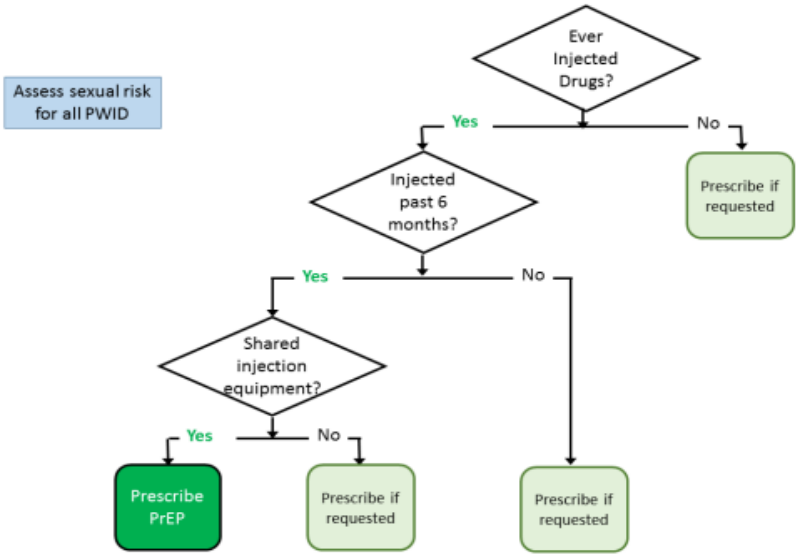
Non-sterile injection with shared syringes or other injection equipment sometimes occurs among transgender persons while administering non-prescribed gender-affirming hormones or among persons altering body shape with silicone or other "fillers." Providing PrEP to persons who

report non-sterile injection behaviors that can place them at substantial risk of acquiring HIV will contribute to HIV prevention efforts.

PrEP and other HIV prevention should be provided and integrated with prevention and clinical care services for the other non-HIV health threats PWID may face (e.g., hepatitis B and C infection, abscesses, septicemia, endocarditis, overdose). In addition, referrals for treatment of substance use disorder, mental health services, harm reduction programs, syringe service programs (SSPs) where available or access to sterile injection equipment, and social services may be indicated.

Figure 2 outlines a set of brief questions designed to assess a key set of injection practices that are associated with the risk of HIV acquisition.

Figure 2: Assessing Indications for PrEP in Persons Who Inject Drugs



ASSESSING RISK OF HIV IN SPECIFIC POPULATIONS

Transgender Persons

PrEP medications do not impact the effect of feminizing hormones. Some studies show that the feminizing hormones at doses taken by transgender women (TGW) may result in the lowering of tenofovir diphosphate levels in rectal tissue. It is unclear if this may affect PrEP effectiveness, but this observance suggests that daily adherence is especially important in TGW.

No data is currently available about the prevention effectiveness of either F/TDF or F/TAF for PrEP in transgender men.

It is important to ask transgender persons about non-sterile injection with shared syringes or other injection equipment while administering non-prescribed gender-affirming hormones. Providing PrEP to persons who report non-sterile injection behaviors that can place them at substantial risk of acquiring HIV will contribute to HIV prevention efforts.

Persons with Renal Disease
The appropriate medication should be prescribed based on the following eCrCl table:

Table 2: PrEP Medication Options Based on Estimated Creatinine Clearance

Estimated Creatinine Clearance	PrEP Medication
eCrCl ≥60 ml/min	F/TDF, F/TAF or CAB
eCrCl <60 ml/min and ≥30 ml/min	F/TAF or CAB
eCrCl <30 ml/min	CAB; no oral option at this time

Important to know:

- Dose reduction of either F/TDF or F/TAF is not recommended for PrEP prescribed to patients with significant renal disease.
- If other threats are present, e.g. hypertension or diabetes, they may need more frequent monitoring or additional tests, e.g. urinalysis for proteinuria.
- A rise in serum creatinine is not a reason to withhold treatment with PrEP if eCrCl remains > 60 ml/min for F/TDF or > 30 ml/min for F/TAF.
- If eCrCl is declining steadily but still above the cutoffs, ask client if they are taking high doses of NSAIDs or using protein powders; further evaluation may be needed.

Adolescents
The CDC recommends o PrEP for adolescents (who are at least 15 years old and weigh at least 35kg or 77lb) who report sexual or injection behaviors that indicate a risk for HIV acquisition. As defined in the Virginia Code, VDH requires parental consent to prescribe PrEP to adolescents (< 18 years old). See **Appendix F** for the required consent form signed by parents.

Women Who Become Pregnant or Breastfeed While Taking PrEP
Studies so far have only included cisgender women. There is an increase of HIV acquisition during periods of conception, pregnancy and breastfeeding. CDC recommends offering F/TDF to women seeking to conceive and pregnant or breastfeeding. Pregnant women can receive PrEP through VDH if initially prescribed/recommended by their prenatal care provider.

HIV Discordant Partnerships
When assessing indications for PrEP use in an HIV discordant couple, clinicians should ask about the treatment and viral load status of the partner with HIV (if the negative partner knows

it). PWH who achieve and maintain a plasma HIV RNA viral load <200 copies/ml with ART have effectively no risk of sexually transmitting HIV. This is sometimes referred to as "undetectable equals untransmittable" (U=U) or "treatment as prevention" (TASP). However, some partners who know they have HIV may not be in care, may not be receiving ART, may not be receiving highly effective regimens, may not be adherent to their medications, or for other reasons may not consistently have viral loads that are associated with the least risk of transmission to an uninfected sex partner. In addition, studies have shown that client-reported viral load status may not be accurate, but clinicians providing care to the HIV-negative client may not have access to the medical records of the HIV-positive partner to document their recent viral load status and the consistency of their viral suppression over time. In the HIV discordant couples studies, reported sex with outside partners was not uncommon and HIV infections occurred that were genetically unlinked to the partner in the couple with HIV.

PrEP may be indicated if the partner with HIV has been inconsistently virally suppressed or their viral load status is unknown, if the partner without HIV has other sexual partners (especially if of unknown HIV status), or if the partner without HIV wants the additional reassurance of protection that PrEP can provide. PrEP should not be withheld from HIV-uninfected clients who request it even if their sexual partner with HIV is reported to have achieved and maintained a suppressed viral load. Several studies, using viral genotyping, have documented HIV infection in a previously uninfected client that was acquired from a partner outside the relationship with the partner known to have HIV.

Persons with Documented HIV Infection

See CDC guidance for persons with documented HIV infection.

CLINICIANS CAN CALL THE NATIONAL CLINICIANS CONSULTATION CENTER PREPLINE AT 855-448-7737 FOR ADVICE ABOUT INTERPRETATION OF HIV TEST RESULTS AND MANAGEMENT OF PATIENTS WHO ACQUIRE HIV INFECTION WHILE TAKING PREP MEDICATION.

Table 3: Summary of CDC Guidance for Daily Oral PrEP Use

Summary of CDC Guidance for Daily Oral PrEP Use	
Clinically Eligible	**ALL OF THE FOLLOWING CONDITIONS ARE MET:** • Documented negative HIV Ag/Ab test result **within seven days** before initially prescribing PrEP • No signs/symptoms of acute HIV infection • Estimated creatinine clearance ≥30 ml/min for F/TAF; ≥60 ml/min for F/TDF • No contraindicated medications
Dosage	• Daily, continuing, oral doses of F/TDF, ≤90-day supply **or** • For men and transgender women at risk for sexual acquisition of HIV: daily, continuing oral doses of F/TAF, ≤90-day supply
Follow-up care	**Follow up visits at least every three months to provide the following:** • HIV Ag/Ab test **and** HIV-1 RNA assay, medication adherence and behavioral risk reductions support • Bacterial STI screening for MSM and transgender women who have sex with men - oral, rectal, urine blood • Access to clean needles/syringes and drug treatment services for PWID **Follow up visits every six months to provide the following:** • Assess renal function for clients aged >50 years or who have an eCrCl <90 ml/min at PrEP initiation • Bacterial STI screening for all sexually active clients - (vaginal, oral, rectal, urine - as indicated), blood **Follow up visits every 12 months to provide the following:** • Assess renal function for all clients • For clients on F/TAF, assess weight, triglyceride and cholesterol levels

Source: CDC

LABORATORY TESTING

HIV Testing

The 2021 CDC PrEP Guidelines point out that the performance of HIV tests in those who become infected with HIV while on PrEP is different than for those not on PrEP. PrEP medications can suppress early viral replication which can delay antibody development. People who become infected with HIV during active or recent PrEP or non-occupational post-exposure prophylaxis (nPEP) use are likely to experience delayed antibody production. Clinical trials found that the average delay was 34 days for someone on oral PrEP/nPEP and 62 days for

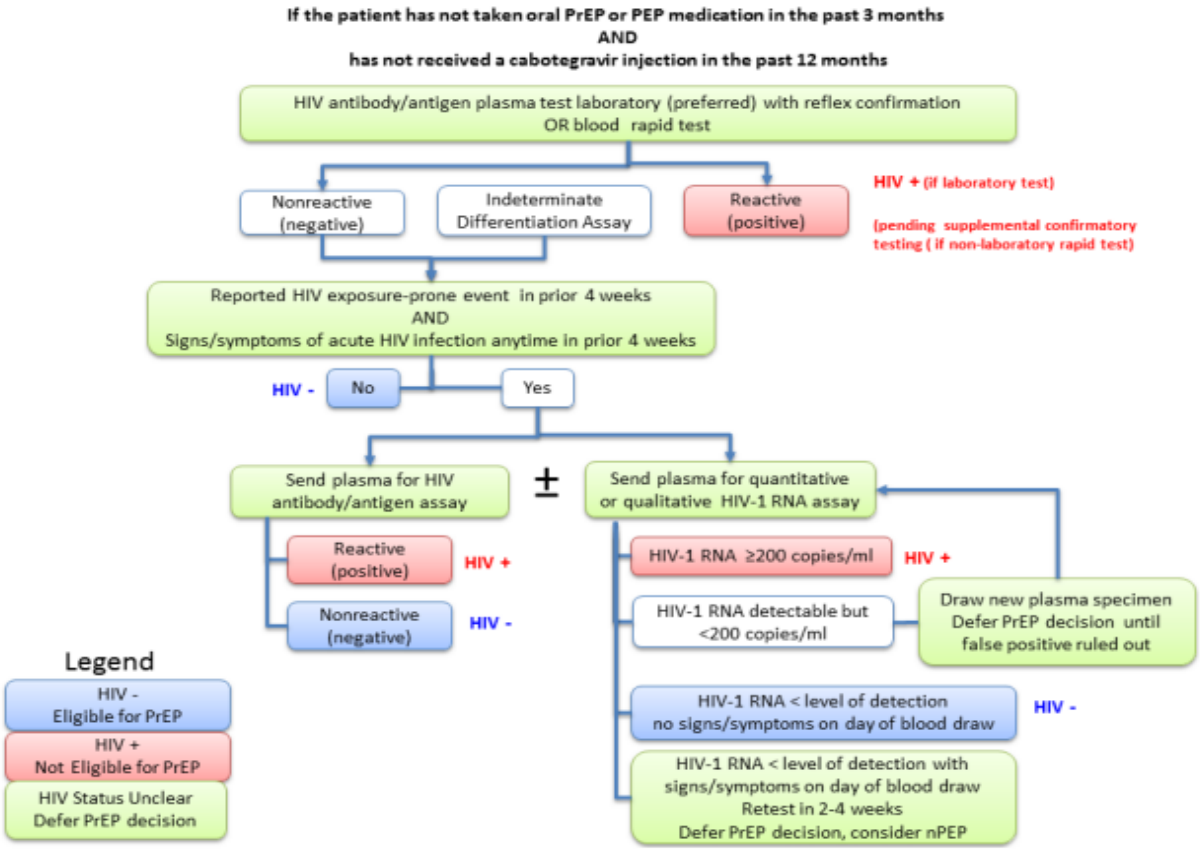
someone who had received cabotegravir (Apretude), the long acting injectable for PrEP. Based on these guidelines, VDH now recommends:

- Adding the qualitative HIV-1 RNA test to the HIV Ag/Ab 4th generation test for those who:
  - have taken oral PrEP or nPEP medication in the past 3 months or
  - have received a cabotegravir injection in the past 12 months
- The HIV-1 RNA test detects HIV genetic material from the virus itself, not antibodies, so the results are not affected by taking PrEP medications.
- Rapid tests that use oral fluid should not be used to screen for HIV infection because they are less sensitive for the detection of acute or recent infection than blood tests.
- While on PrEP, HIV testing should be repeated at least every 3 months after oral PrEP initiation (preferably before prescriptions are refilled).

See Figures 3 and 4 for CDC's recommendations for HIV testing for persons with and without recent PrEP uses.

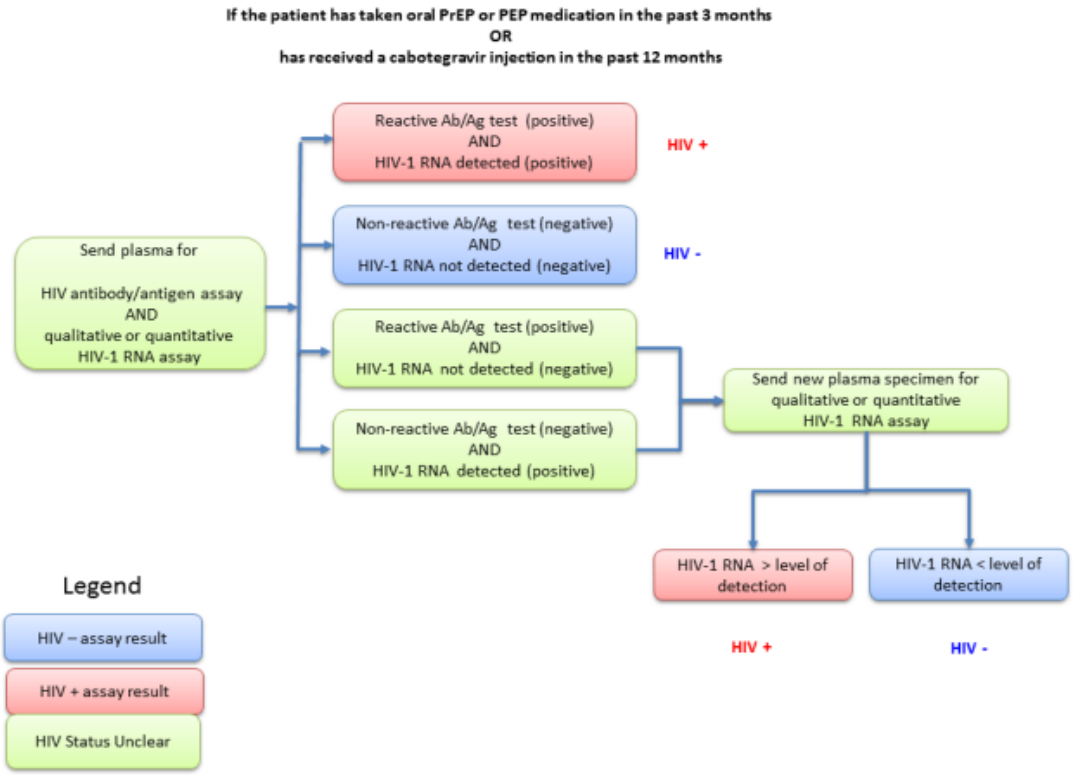
See http://www.cdc.gov/hiv/testing/laboratorytests.html for FDA-approved HIV tests, specimen requirements, and time to detection of HIV infection.

Figure 3: Determination of HIV Status for Persons without Recent PrEP Use



Source: CDC

Figure 4: Determination of HIV Status for Persons with Recent PrEP Use



Acute HIV Infection Assessment

Everyone should be screened for acute HIV infection, especially if there was a possible exposure in the four weeks prior to initiating PrEP. The most common clinical signs and symptoms of acute HIV infection listed in order of occurrence are:

- Fever
- Fatigue
- Myalgia – muscle pain
- Skin rash
- Headache
- Pharyngitis – sore throat
- Cervical adenopathy – swollen lymph nodes in neck
- Arthralgia – joint pain
- Night sweats
- Diarrhea

STI Testing

STIs are strong bio markers of HIV exposure risk. The importance of extragenital testing for gonorrhea and chlamydia is important, especially for MSM. Research has shown that:

- 70-88% of rectal chlamydia and gonorrhea infections in MSM have no concurrent urethral infection.
- 85% of rectal gonorrhea infections are asymptomatic in MSM.
- MSM are significantly more likely to demonstrate antimicrobial resistant gonorrhea.

Additionally, client self-collected samples have equivalent performance as clinician-obtained samples and can help streamline clinic flow. Please see the VDH Laboratory Screening in the Clinical Setting manual for self-collection instructions. See Table D below for the recommended schedule for syphilis, gonorrhea and chlamydia screening.

Renal Function

In addition to confirming that any client starting PrEP medication is not infected with HIV, a clinician must assess renal function since decreased renal function is a potential safety issue for the use of F/TDF or F/TAF as PrEP.

Obtain a serum creatinine to use for estimated creatinine clearance calculation using the **Cockgroft-Gault formula** below:

Figure 5: Cockgroft-Gault Formula to Determine eCrCl

eCrCl = [[(140-age) x IBW x 0.85 for females] ÷ (serum creatinine x 72)]

IBW = ideal body weight

Males: IBW = 50kg + 2.3kg for each inch over 5 feet

Females: IBW = 45.5kg + 2.3kg for each inch over 5 feet

Age in years, weight in kg, and serum creatinine in mg/100mL

Lipid Profile for F/TAF Users

All persons prescribed F/TAF (Descovy) for PrEP should have their weight, triglycerides and cholesterol levels done before medication initiation and then monitored every 12 months. If the values are abnormal, refer for primary care follow-up and consider prescribing F/TDF if there are no medical contraindications.

Hepatitis B Testing and/or Vaccination

F/TDF (Truvada) is also used to treat chronic HBV infections. When these drugs are discontinued, clients with HBV infection may experience clinically significant hepatitis flares. HBV screening is recommended before initiating oral PrEP, so clients can be informed of the danger of stopping PrEP medications without appropriate monitoring for potential hepatitis flares. Clients who are not immune and do not have HBV infection should be vaccinated.

Hepatitis C Testing
VDH recommends Hepatitis C screening for all clients who have not been screened and/or have risk factors.

Testing Not Indicated Routinely for Oral PrEP Clients:
Bone mineral density testing
Liver function tests
Hematologic assays
Urinalysis
Medication adherence monitoring

Table 4: Timing of Oral PrEP-associated Laboratory Tests

Timing of Oral PrEP-associated Laboratory Tests					
Test	**Screening/ Baseline Visit**	**Every 3 months**	**Every 6 months**	**Every 12 months**	**When stopping PrEP**
HIV test*	X*	X*			X*
eCrCl	X		If age ≥50 or eCrCl <90 ml/min at PrEP initiation	If age <50 and eCrCl ≥90 ml/min at PrEP initiation	X
Syphilis	X	MSM/TGW	X		MSM/TGW
Gonorrhea	X	MSM/TGW	X		MSM/TGW
Chlamydia	X	MSM/TGW	X		MSM/TGW
Hep B serology	X				
Hep C serology	X			MSM,TGW and PWID only	
Lipid panel (F/TAF only)	X			X	

*Assess for acute HIV infection and add HIV-1 RNA testing to HIV-1 Ag/Ab as indicated
Source: CDC

PRESCRIBING PrEP and DOCUMENTING VISITS

- Staff at local health departments should use the PrEP/nPEP Flow Sheet for documentation of visits. See **Appendix G** for the PrEP/nPEP Flow Sheet instructions and **Appendix H** for the PrEP/nPEP Flow Sheet.
- A complete STI visit using the STI Clinic Visit Form is required at the initial and every 12 month visits. Interim visits may be provided as needed for problems, complaints, issues with drug adherence, etc.
- Medication may be dispensed and delivered for 30-60 days at a time depending on their adherence history.
- Schedule follow-up appointments so that the client does not run out of medication waiting for their next medical evaluation.
- Medications can be ordered 25-35 days from the previous order date.
- If a client does not pick up medication within 10 days, they may need repeat HIV testing before receiving their medication.
- After 30 days, undelivered medication must be promptly returned to Division of Pharmacy Services (DPS). See **Appendix I** for the Returning Drugs to Pharmacy Procedure and form.
- If a client is lost to care or no longer interested in the program, return their medication to DPS and complete a withdrawal form (see **Appendix J**) and fax to PrEP staff at **(804) 864-8053**. File the withdrawal form in the client's chart.
- If a client is traveling or temporarily away from their pick up site (college student, vacation, work, etc.), they may arrange for an alternate pick up site or ship to an alternate address.
- One 30-day emergency supply is available annually, in the event that a client loses his/her bottle of medication etc. The decision to provide additional refills is made on a case-by-case basis by VDH's Division of Disease Prevention (DDP), Central Pharmacy, clinician, and PrEP navigator.
- All options for the provision of medication should be exhausted before requesting medication from DPS. VDH PrEP DAP can be used as a bridge if the client is between coverage options.
- Please see **Appendix K** for a list of oral PrEP medication drug interactions.

Table 5 below details who can benefit from which oral medication:

Table 5: Comparison of F/TDF and F/TAF

Product	**Oral Daily F/TDF** (Truvada/generic)	**Oral Daily F/TAF** (Descovy)
Status for PrEP	FDA approved 2012	FDA approved 2019
Recommended for	• Cisgender men • Transgender women • Cisgender women • Transgender men • Pregnant and breastfeeding women	• Cisgender men • Transgender women
Efficacy data for what type of HIV exposure	• Anal sex • Vaginal sex • Injection drug use	• Anal sex only • NOT approved for receptive vaginal sex
Active ingredients	emtricitabine 200mg with tenofovir disoproxil fumarate 300mg	emtricitabine 200mg with tenofovir alafenamide 25mg
How do you use it?	1 pill once a day	1 pill once a day
How effective is it when taken as directed?	99% for sexual exposure 74% for injection drug use	99% for sexual exposure
Short-term side effects (at initiation)	Nausea, vomiting, diarrhea, abdominal pain, fatigue for usually less than a week reported by 3-5% of clients	Nausea, abdominal pain, fatigue for usually less than a week reported by 4% of clients
Clinical considerations	Extremely rare clinically significant decrease in kidney function that usually resolves when F/TDF is stopped Counseling for clients positive for Hepatitis B	On average: 2 lbs. increase in weight; 2% higher cholesterol than F/TDF Counseling for clients positive for Hepatitis B
Recommended visit frequency	3 months	3 months

*Adapted from BLUPrInt

Managing Side Effects of Oral PrEP
Clients taking PrEP should be informed of potential side effects. Some (<10%) of clients prescribed F/TDF or F/TAF experience a "start-up syndrome" that usually resolves within the first month of taking PrEP medication. This may include headache, nausea, or abdominal discomfort. Clinicians should discuss the use of over-the-counter medications should these temporary side effects occur. Clients should be counseled about signs or symptoms that indicate a need for urgent evaluation when they occur between scheduled follow-up visits (e.g., those suggesting possible acute renal injury or acute HIV infection). Weight gain is a reported side effect of F/TAF for PrEP.

Time to Achieving Protection with Daily Oral PrEP
The time from initiation of daily PrEP use to maximal protection against HIV infection is unknown. Data from studies so far with F/TDF show that maximum concentrations of tenofovir are reached after approximately 7 days of daily oral dosing in:

- Rectal tissue ~ 7 days = receptive anal sex
- Cervicovaginal tissue ~ 20 days = receptive vaginal sex
- F/TAF data is not yet available
- Data is also not available for F/TDF or F/TAF PrEP in penile tissue = insertive anal or vaginal sex

Starting and Stopping Daily Oral PrEP
People may discontinue PrEP for several reasons, including:

- Client choice
- Changed life situation resulting in lowered HIV risk
- Intolerable toxicities
- Chronic non-adherence to daily dosing or schedule follow-up visits, or
- Acquisition of HIV

How to safely discontinue and restart daily PrEP should be discussed with clients when starting and discontinuing PrEP medication.

- Protection from HIV infection will wane over 7-10 days after ceasing daily use
- Discuss how to access nPEP if needed
- Clients with Hepatitis B infection should be monitored closely for hepatitis flares

Restarting someone on PrEP requires the same pre-prescription evaluation as a person being newly prescribed PrEP, including an HIV test. Also discuss the changed circumstances and confirm their commitment to take the medication and follow up as prescribed.

To Manage PrEP Clients with Ambiguous HIV Test Results

Please see CDC guidance for managing PrEP clients with ambiguous HIV test results and/or contact the PrEPline below:

CLINICIANS CAN CALL THE NATIONAL CLINICIANS CONSULTATION CENTER PREPLINE AT 855-448-7737 FOR ADVICE ABOUT INTERPRETATION OF HIV TEST RESULTS AND MANAGEMENT OF PATIENTS WHO ACQUIRE HIV INFECTION WHILE TAKING PREP MEDICATION.

CABOTEGRAVIR (CAB, brand name Apretude)

Cabotegravir is the first long-acting injectable for HIV prevention. Approved by the FDA in December 2021, CAB is also the first of more options to become available for PrEP in the future. The following guidelines are taken from the CDC's 2021 PrEP Guidelines. For full prescribing information, visit the manufacturer's website: ViiV Apretude for Healthcare Professionals. The VDH Apretude protocol is under development which will include ordering, storage and handling, and administration information.

Prescribing Cabotegravir PrEP Injections

Clients considering PrEP should be informed of all FDA-approved options. CAB injections may be especially appropriate for clients:

- with significant renal disease
- who have had difficulty with adherent use of oral PrEP
- who prefer injections every 2 months to an oral PrEP dosing schedule

CAB should not be administered to persons with a history of hypersensitivity reaction to cabotegravir.

Recommended Medication

- 600 mg of CAB injected into the gluteal muscle every 2 months is recommended for PrEP in adults at risk of acquiring HIV after initial two doses given one month apart.
- 30 mg daily oral CAB is optional for a 4-week lead-in prior to injections.

Other than those recommended in this guideline, no other injectable antiretrovirals, injection sites, or dosing schedules should be used as their efficacy is unknown.

- Do not administer or prescribe other antiretroviral medications in combination with CAB for PrEP
- Do not administer CAB injections at any site other than gluteal muscle because the pharmacokinetics of drug absorption with injection at other sites is unknown
- Do not dispense CAB injections for use by clients for home administration (unless and until self-administration is FDA approved)
- Do not prescribe ongoing daily oral CAB (other than for lead-in prior to initiating or restarting injections)

Table 6: CAB PrEP Drug Interactions (https://www.hiv-druginteractions.org/)

Rifampicin, rifapentin	Do not co-administer with CAB Rifampicin and rifapentine increase metabolism of CAB and may result in significantly reduced exposure to protective levels of CAB
Rifabutin	Co-administer with caution Rifabutin moderately increases metabolism of CAB and may result in somewhat reduced exposure to protective levels of CAB
Hormonal contraceptives	No significant effect
Feminizing hormones (Spironolactone, estrogens)	No data yet available
Carbamazepine, oxcarbazepine, phenytoin, phenobarbital	Do not co-administer with CAB Concern that these anticonvulsants may result in significantly reduced exposure to protective levels of CAB, but strength of evidence is weak

Source: CDC

CAB PrEP Initiation Visit

In the clinical trials of CAB injections for PrEP, clients were provided oral CAB 30 mg tablets daily for 5 weeks prior to receiving the first injection. Because there were no safety concerns identified during this lead-in period or during the injection phase of the studies, an oral lead-in is not required when initiating CAB PrEP. It may be optionally used for clients who are especially worried about side effects to relieve anxiety about using the long-acting CAB injection. However, continued daily oral CAB is not recommended or FDA-approved for PrEP.
Clients who have been taking daily oral PrEP can initiate CAB injections as soon as an HIV-1 RNA test results confirm that they remain HIV negative.

Laboratory Testing for CAB PrEP Clients

Clients whose HIV test results indicate that they do not have acute or chronic HIV infection can be considered for initiation of CAB injections (see Figure 4). Because of the long duration of drug exposure following injection, exclusion of acute HIV infection is necessary with the most sensitive test available, an HIV-1 RNA assay. Ideally, this testing will be done within 1 week prior to the initiation visit. If clinicians wish to provide the first injection at the first PrEP evaluation visit based on the result of a rapid combined antigen/antibody assay, blood should always be drawn for laboratory confirmatory testing that includes an HIV RNA assay. All PrEP clients should have baseline STI tests (see Table 7).

Testing Not Indicated Routinely for CAB PrEP Clients
Based on the results of the CAB clinical trials, the following laboratory tests are NOT indicated before starting CAB injection or for monitoring clients during its use: creatinine, eCrCl, hepatitis B serology, lipid panels, or liver function tests.

Table 7: Timing of Injectable CAB PrEP-associated Laboratory Tests

Timing of Injectable CAB PrEP-associated Laboratory Tests							
Test	**Screening / Baseline Visit**	**1 month visit**	**Every 2 months**	**Every 4 months**	**Every 6 months**	**Every 12 months**	**When stopping CAB**
HIV test* (HIV Ag/Ab & HIV-1 RNA)	X	X	X	X	X	X	X
Syphilis	X			MSM/ TGW	Heterosexual men & women	X	MSM/ TGW
Gonorrhea	X			MSM/ TGW	Heterosexual men & women	X	MSM/ TGW
Chlamydia	X			MSM/ TGW	Heterosexual men & women	X	MSM/ TGW

*Assess for acute HIV infection
Source: CDC

Recommended CAB Injection

- 3 ml suspension of CAB 600 mg IM in gluteal muscle (gluteus medius or gluteus maximus); administer by Z-track method – ventrogluteal preferred and recommended; dorsagluteal acceptable as an alternative
- The use of a 2-inch needle is recommended for intramuscular injection for participants with a body-mass index (BMI) of 30 or greater, and a 1.5-inch needle for participants with a BMI of less than 30

Managing Injection Site Reactions
In the clinical trials, injection site reactions (pain, tenderness and induration) were frequent following CAB injections. These reactions were generally mild or moderate, lasted only a few days, and occurred most frequently after the first 2-3 injections. Clients should be informed that these reactions are common and transient. In addition, they should be provided with proactive management advice.

For the first 2-3 injections:

- Take an over-the-counter pain medication within a couple of hours before or soon after the injection and continue as needed for one to two days
- Apply a warm compress or heating pad to the injection site for 15-20 minutes after the injection (e.g., after arriving back at home)
- Thereafter, as needed for subsequent injections

Client Education/Counseling

Clients should be provided an appointment for the next injection one month after the initial one. Clients should be educated about:

- The long "tail" of gradually declining drug levels when discontinuing CAB injections and the risk of developing a drug-resistant strain if HIV infection is acquired during that time
- The importance of keeping their follow-up appointments if they have decided not to continue with CAB injections for PrEP

Clinical Follow-up and Monitoring for CAB Injections

See Table 8 below for clinical follow-up care for CAB injections.

Table 8: Summary of CDC Guidance for Injectable PrEP Use

Summary of CDC Guidance for Injectable PrEP Use	
Clinically Eligible	**ALL OF THE FOLLOWING CONDITIONS ARE MET:** • Documented negative HIV Ag/Ab and HIV-1 RNA test results **within seven days** before initial CAB injection • No signs/symptoms of acute HIV infection • No contraindicated medications
Dosage	600mg CAB administered as one 3ml IM injection in the gluteal muscle • Initial dose • Second dose 4 weeks after first dose (month 1 follow-up visit) • Every 8 weeks thereafter (month 3, 5, 6, follow-up visits, etc.)
Follow-up care	**At follow-up visit 1 month after first injection:** • HIV Ag/Ab test **and** HIV-1 RNA assay **At follow-up visits every 2 months:** • HIV Ag/Ab test and HIV-1 RNA assay • Access to clean needles/syringes and drug treatment services for PWID **At follow-up visits every 4 months:** • Bacterial STI screening for MSM and TGW who have sex with men – oral, rectal, urine, blood

	<u>At follow-up visits every 6 months:</u> • Bacterial STI screening for all heterosexually-active women and men **<u>At follow-up visits every 12 months:</u>** • Assess desire to continue injections for PrEP **<u>At follow-up visits when discontinuing CAB injections:</u>** • Re-educate clients about the "tail" and the risks during declining CAB levels • Assess ongoing HIV risk and prevention plans • If PrEP is indicated, prescribe daily oral F/TDF or F/TAF within 8 weeks after last injection • Continue follow-up visits with HIV testing quarterly for 12 months

Source: CDC

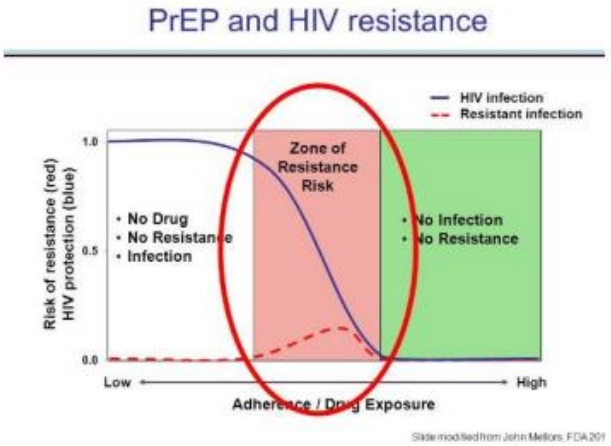
Discontinuing or Restarting CAB PrEP

On a follow-up visit, clients without HIV who wish to discontinue CAB injections for PrEP or those who are a month or more late for an injection should be counseled about:

- How to safely discontinue or restart CAB injections for PrEP
- The risk of developing drug-resistant HIV during the period of waning drug levels (the "tail period")
- Need for daily oral PrEP or other effective HIV prevention methods if ongoing risk of HIV exposure is anticipated.

CAB levels slowly wane over many months after injections are discontinued. In the HPTN 077 trial, the median time to undetectable CAB plasma levels was 44 weeks for men and 67 weeks for women with a wide range for both sexes. At some point during this "tail" phase, CAB levels will fall below a protective threshold and persist for some time at non-protective levels, exposing the client to the risk of HIV acquisition. These lower levels of CAB may however be sufficient to apply selective pressure that selects for existing or de-novo viral strains with mutations that confer resistance to CAB or to other INSTI medications. Infection with INSTI-resistant virus may complicate HIV treatment.

Figure 6: PrEP and HIV Resistance



For these reasons, clients discontinuing CAB injections who may be at ongoing risk of sexual and injection HIV exposure should be provided with another highly effective HIV prevention method during the months following their last injection. As with daily oral PrEP, CAB PrEP has been associated with delayed seroconversion and detection of HIV acquisition. CAB injections can be restarted at any point after determining HIV status with HIV-1 RNA testing.

When helping clients discontinue CAB PrEP safely, clinicians should:

- Re-educate clients about the "tail" and the risks during declining CAB levels
- Assess ongoing risk/indications
- If PrEP is indicated, prescribe daily oral F/TDF or F/TAF beginning within 8 weeks after last injection
- Educate about nPEP
- Continue follow-up visits quarterly for 12 months
- Conduct HIV-1 RNA tests at each quarterly follow-up visit after discontinuing CAB injections

Time to Protection with CAB PrEP

No data are yet available from clinical trials in men or women to estimate the time from initiation of CAB injections to maximal protection against HIV acquisition.

Table 9: Overview of Cabotegravir for PrEP

Product	**Injectable cabotegravir (CAB)** (Apretude)
Status	FDA-approved
Recommended for	• Cisgender men • Transgender women • Cisgender women • Transgender men
Efficacy data for what type of HIV exposure	• Anal sex • Vaginal sex
Active ingredients	cabotegravir
How do you use it?	Initiation: optional 4 weeks oral pills, first injection, then 2nd injection 4 weeks later *Followed by maintenance of 1 injection every 8 weeks*

How effective is it when taken as directed?	As effective as daily oral PrEP (non-inferiority trial)
Short-term side effects (at initiation)	Among clinical trial participants, injection site reactions were reported by 82% of cisgender men and transgender women and 38% of cisgender women; real world data from clients are not yet available. Headache, nausea, vomiting, diarrhea, fatigue, abdominal pain, dizziness, sleep disorders, fever, myalgia, rash, decreased appetite were reported between 2-4% of trial participants; real world data from clients are not yet available.
Clinical considerations	CAB persists at low (subtherapeutic) levels in the body for up to 12 months. When discontinuing CAB, starting 8 weeks post-injection, client should continue another form of PrEP while risk of HIV remains, to protect against acquiring drug-resistant virus. Depressive disorders are listed in package insert; data were not reported in any clinical trial publications. Contraindicated for anticonvulsants, some antimycobacterials; dose adjustment of cabotegravir necessary for some antimycobacterials; dose adjustment for methadone may be necessary.
Recommended visit frequency	Every 8 weeks

Adapted from BLUPrInt

PrEP 2-1-1 OR PrEP ON DEMAND FOR MSM

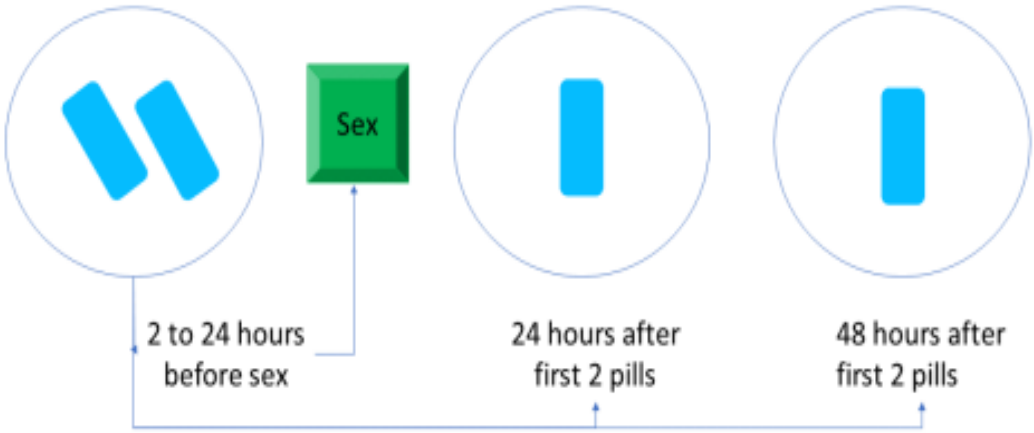
MSM – PrEP on demand, also known as 2-1-1, is a nondaily PrEP regimen that times F/TDF doses to sexual intercourse events. This dosing is currently not FDA-approved, but is recommended by IAS-USA. In two clinical trials with MSM, there was up to 86% efficacy. Dosing was designed for MSM who have infrequent sex (less than once/week) and can anticipate or delay sex so that the dose can be taken at least two hours before sex.

As demonstrated in Figure 7, the instructions for dosing are:

- 2 pills in the 2-24 hours before sex (closer to 24 hours is preferred)
- 1 pill 24 hours after the initial two-pill dose
- 1 pill 48 hours after the initial two-pill dose

Clinicians should prescribe no more than 30 pills without follow-up and documentation of another negative HIV test. Clients having sex less than once weekly will have sufficient medication to cover up to 7 intermittent sexual events.

Figure 7: PrEP 2-1-1 Dosing



Based on the timing of subsequent sexual events, MSM should be instructed to take additional doses as follows:

- If sex occurs on the consecutive day after completing the 2-1-1 doses, take 1 pill per day until 48 hours after the last sexual event.
- If a gap of ≥ 7 days occurs between the last pill and next sexual event, start again with 2 pills.

Clinicians who elect to provide the 2-1-1 regimen should also discuss with clients:

- The importance of taking both pre-sex and post-sex doses of F/TDF to achieve good protection;
- The importance of using PrEP for all sexual encounters, not for only some partners or events;

- The possibility of recurrent "start-up" symptoms with infrequent PrEP dosing;
- The possibility of inadvertent disclosure of same-sex behavior to peers or family members since 2-1-1 dosing is only used by MSM;
- How to change between daily and 2-1-1 dosing;
- The continued need for follow-up visits for HIV and STI testing; and
- The possibility that this off-label use will not be covered by insurance.

2-1-1 dosing should not be prescribed:

- For populations other than adult MSM because it has been studied only in adult MSM;
- For MSM who it is anticipated will have difficulty adhering to a complex dosing regimen (e.g., adolescents, clients with an active substance use disorder);
- With F/TAF because its use for pericoital dosing has not been studied; or
- For MSM with active hepatitis B infection because of the danger of hepatic flares with episodic T/TDF exposure.

Table 10: PrEP 2-1-1

Product	**2-1-1 F/TDF** (TRUVADA/generic)
Status	Off-label use endorsed by the WHO and regional U.S. health departments
Recommended for	Cisgender men
Efficacy data for what type of HIV exposure	Anal sex only for men who have sex with other men
Active ingredients	Emtricitabine with tenofovir disoproxil fumarate
How do you use it?	• 2 pills 2-24 hours before sex • 1 pill 24 hours after that • 1 pill 24 hours after that *Client should continue 1 pill every 24 hours until client has taken 2 pills 48 hours after last sexual activity*
How effective is it when taken as directed?	86%
Short-term side effects (at initiation)	Nausea, vomiting, diarrhea, abdominal pain reported by 6% of clients
Clinical considerations	Contraindicated with Hepatitis B ~ flares
Recommended visit frequency	3-6 months

Source: CDC

SAME DAY PrEP PRESCRIBING

For all clients, safely initiating PrEP requires determination of HIV status and assessment of renal function. Safely shortening the time to initiation of PrEP may be useful for some clients due to time or work constraints and/or risk behaviors between visits.

To use a same-day PrEP initiation protocol, the clinic must be able to:

- Conduct point-of-care HIV testing, ideally with an antigen/antibody finger stick or other blood test
- Where same-day results can be obtained, laboratory-based antigen/antibody test or an HIV-1 RNA test can be used (and is preferred)
- Oral fluid HIV testing should not be used when initiating PrEP
- Draw blood for laboratory creatinine and HIV testing when same-day HIV and creatinine test results are not available
- Where available, a point-of-care blood creatinine test may be used
- Provide assistance for eligible clients to enroll in health insurance, medication copayment assistance, or medication assistance programs for those who are uninsured or underinsured
- Provide rapid follow-up contact for clients whose laboratory test results indicate HIV infection or renal dysfunction
- Provide scheduled follow-up care appointments
- Have clinicians available to dispense or prescribe oral PrEP medication
- Optimally, clinics would be able to provide STI specimen collection for laboratory testing on the first day

Same-day PrEP initiation is not appropriate for:

- Clients who express ambivalence about starting PrEP (e.g., need more time to think)
- Clients for whom blood cannot be drawn for laboratory testing
- Clients with signs/symptoms and sexual history indicating possible acute HIV infection
- Clients with history of renal disease or associated conditions (e.g., hypertension, diabetes)
- Clients without insurance or a means to pay when picking up the prescribed medication that day
- Clients who do not have a confirmed means of contact should laboratory tests indicate a need to discontinue PrEP (e.g., HIV infection, unanticipated renal dysfunction)

Same-day PrEP initiation may not be appropriate for:

- Clients with a very recent possible HIV exposure but no signs and symptoms of acute infection (should be evaluated for nPEP before PrEP)
- Clients who may not be easily contacted for return appointments
- Clients with mental health conditions that are severe enough to interfere with the understanding of PrEP requirements (adherence, follow-up visits)

PROGRAMMATIC PrEP GUIDELINES

ADHERENCE COUNSELING

PrEP is only useful as a prevention tool if the client takes the medication as prescribed. This is particularly true for oral medication regimens. Adherence is also a factor with other forms of PrEP but the interval will be greater.

For some, PrEP is a long-term commitment, so helping the client form strategies that ensure adherence may be useful. Strategies may include formulation of a client-centered adherence plan, which accounts for time of day to take the drug, storage of the drug, what to do if the client misses a dose, and what to do if side effects occur, etc.

Adherence is often compromised by other factors such as mental illness, alcohol or substance use, lack of stable housing, and interpersonal violence. Forgetfulness and stigma are also common causes of non-adherence. In addition, adherence has been shown to vary widely according to age. It is important to take these factors into consideration when providing adherence counseling.

Clinical staff and the client should discuss barriers to adherence and possible means of overcoming barriers before the client is prescribed PrEP and throughout the course of therapy.

Examples of Subjective Assessment of Adherence for Oral Medication:

- How often do you take your PrEP pill?
- What time of day do you take your PrEP pill?
- How often do you [miss, skip] doses or take doses late?
- How many doses do you [estimate, guess] you have missed in the last [week, month]?
- What situations make it difficult to take your PrEP pill on time every day?
- What helps you remember to take your PrEP pill on time?
- How often do you have pills left in the bottle when your next med pick up is due?
- How many tablets are usually in the bottle when your next med pick up is due?
- What can we do to help you take your PrEP pills on time every day?

Examples of Objective Assessment of Adherence:

- Pill bottle counts (in clinic or on home visits)
- Tracking medication pick up dates
- Urine screening for PrEP medication

If there has been a significant lapse in treatment with potential for exposure, the client should be evaluated for nPEP treatment.

Some community-based organizations (CBOs) provide interventions that may help increase adherence to an oral regimen. If the clinical staff feels these would be useful to the client, they

can make a referral. To obtain information about local CBOs, please contact DDP's HIV/STD/Hepatitis Hotline (1-800-533-4148).

THE ROLE OF THE PrEP NAVIGATOR

PrEP navigators are key members of the multi-disciplinary team for PrEP clients. PrEP navigators may also be known as PrEP caseworkers, community health workers or case managers.

Core Skills

- Knowledge of HIV, STIs, risk reduction, prevention and care issues
- Ability to manage multiple clients' needs
- Ability to stay organized and manage and track a large amount of information
- Ability to fill out screening tools, data forms and maintain good documentation practices
- Ability to support clients in accessing a wide range of services
- Ability to use a client-centered counseling approach and motivational interviewing (MI)
- Ability to adhere to a strict code of client confidentiality
- Ability to demonstrate cultural and linguistic sensitivity, comfort and ability to work with diverse populations

Activities

PrEP navigators are expected to help clients obtain clinical services related to PrEP, access medication (through any one of the following: Virginia's PrEP Drug Assistance Program, relevant client assistance program, Medicaid, Medicare, their insurance company), ensure that clients are able to maintain the ongoing regimen of testing and care related to PrEP, and help clients with adherence to daily therapy.

For PrEP-specific medical management, tasks include:

- Reading and understanding the most updated version of this manual.
- Ensuring clients have completed a behavioral screening for PrEP. This can be done with the STI history form (at the local health department – see (**Appendix L**) or comparable sexual history form.
- Providing PrEP education - specific education regarding individual PrEP medications.
- Introducing clients to Virginia's program and educating potential clients on the programmatic aspects of the DDP program.
- Helping clients make and keep appointments based on the cyclical timeline outlined in Virginia's PrEP protocols, which should include appointment reminders and any follow-up needed. For example, if an STI is found during routine lab testing, the navigator should assist in scheduling a follow-up appointment and ensure that the client receives treatment.

- Helping clients with medication pick-up, where applicable, through reminders to the client and submission of appropriate forms to the PrEP team at Central Office and Central Pharmacy.
- Providing appropriate adherence counseling. This entails ensuring clients are taking their medication as prescribed. For clients who have difficulty with adherence, this also involves using motivational interviewing to help clients understand their barriers to adherence, and helping clients develop adherence plans.
- Follow-up on client withdrawal. The navigator is responsible for notifying central office staff of the client's withdrawal (see PrEP Withdrawal Form, **Appendix J**) and helping ensure the medication is returned to pharmacy within 30 days.

Service Navigation for PrEP clients may also include:

- Knowing where regional PrEP clinics are located.
- Obtaining specific contact information for PrEP navigators at each PrEP clinic and have it readily available to give to clients.
- Coordinating the referral process with other PrEP clinics to efficiently assist clients. Even if navigators work in a PrEP clinic, it is still important to make connections with other sites in case clients prefer a clinic elsewhere.
- Assessing clients for service needs in addition to PrEP.
- Making referrals to services and PrEP providers based on need.
- Following up on referrals to see if clients were linked with a provider.
- Documenting client encounters, referrals, and linkages appropriately.

For additional information on Service Navigation, please contact DDP or refer to the VDH Service Navigation Manual.

APPLICATION FOR THE VDH PrEP DRUG ASSISTANCE PROGRAM (DAP)

Contact Information

- Central Pharmacy Phone Number: (804) 786-4326
- Central Pharmacy Fax Number: (804) 371-0236

Procedures

1. Complete the VDH PrEP DAP application form in its entirety (see **Appendix N** – English, **Appendix O** – Fillable Version).
    - If necessary, please use the No Income Verification Letter (see **Appendix P**).
2. Fax the application form to the PrEP Eligibility Specialist at Central Office Richmond: (804) 864-8053
3. After the application form is received at Central Office, the PrEP Eligibility Specialist will review the application and ensure that all needed documentation is present and sufficient to approve the application. Once the application is approved, the PrEP Eligibility Specialist will inform the PrEP navigator, at which point the PrEP Eligibility

Specialist will fax the approved application. Upon approval, the provider will fax the prescription, along with the corresponding completed PrEP Medication Order Form (see **Appendix Q**) to Central Pharmacy: (804) 371-0236.

- Orders faxed to Central Pharmacy before 1pm will ship the same day. Orders received after 1pm will ship the following day. **DO NOT e-mail client information to Central Pharmacy.**

4. Central Pharmacy will fill and ship the medication, along with the PrEP Medication Order Form (see **Appendix Q**) to the pick-up site designated for the client. The medication will be in a brown paper bag with a **"P"** on it so that it is easily distinguishable from other medications stored at the pick-up site.
5. When the client picks up the medication, the site must obtain the client signature and date on the PrEP Medication Order Form that accompanied the medication. If the pickup site is different from the program site, the PrEP Medication Order Form will need to be faxed back to the program site fax number, found at the top of the form, so that the program site knows when to reorder medication from Central Pharmacy. Completed PrEP Medication Order Forms are to be faxed to (804) 864-8053, no later than the end of each month.
6. All refills must be tracked and submitted by the program site PrEP navigator. If the prescription sent to DPS contains multiple refills, after the initial fill, only the completed PrEP Medication Order Form is required to be faxed to Central Pharmacy. If there are no remaining fills, a prescription will need to accompany the PrEP Medication Order Form. Medication will not be filled earlier than 14 days from the date that it is due. Central Pharmacy will only fill a 30-day supply at a time.
7. If a client does not pick up medication within 10 days, they may need repeat HIV testing before receiving their medication. A Supplemental HIV Test Result Form should be submitted to verify that the client remains HIV negative (see **Appendix R**).
8. *If a client withdraws, or is otherwise deemed ineligible, after a prescription has been filled by Central Pharmacy, please fax a completed withdrawal form to both the PrEP Eligibility Specialist and Central Pharmacy.*

CLIENT WITHDRAWAL FROM PROGRAM

Clients may withdraw from the program at any time, for any reason or no reason. DDP requests that clinicians ask clients to contact the clinic or DDP if they choose to withdraw from the program.

The local health department or provider site may also choose to stop providing PrEP services for a client if the client fails to return for the 30 day follow-up appointment or any subsequent appointment required for PrEP maintenance. Before discontinuing services, the agency should try to contact the client by telephone with three total attempts, one of which must be outside of regular business hours. These attempts should be documented in the client's records. A new set of calls is made if new telephone contact information for the client is obtained.

Once withdrawal has been determined, the provider site will complete a PrEP Withdrawal form (See **Appendix J**), and fax this form to the PrEP Services Team (See DDP Contact Information). DDP uses this form to monitor client withdrawal, to include the reasons clients withdraw for program planning purposes.

PrEP MAIL DELIVERY PROGRAM AND PROTOCOL

If a client proves adherent, they may be eligible to have medication sent to their home after consultation with the PrEP navigator.

The decision to allow home delivery is made collaboratively by the site PrEP navigator, clinician, VDH-DDP and DPS, and is based on the client's prior adherence, accessibility, and any possible barriers. A client must provide a physical address for shipment by DPS. For clients without a physical shipping address, DDP will work with the client and Central Pharmacy to determine a solution.

PrEP Mail Delivery Protocol

Clients are eligible for delivery upon completion of their first 90-day prescription (one 30- day fill with two refills). Delivery may be initiated when the client returns for the 90-day follow-up visit. At this visit, the clinician or navigator should discuss the delivery option with the client, and review several factors that will help determine if mail delivery is an option.

In order to participate in the mail delivery program, the client must have a physical mailing address where they are able to safely receive mail; PO boxes will not be accepted for mail delivery. Additionally, UPS must be able to deliver the medication to the provided physical address.

When deciding if a client is a good candidate for mail delivery, consider past adherence and barriers to picking up medication. It is also important to discuss with the client if the address that has been provided is a shared address with others, who may receive the package, and if the package may be delivered to an address where it could be taken or misplaced easily. Clients may opt to require a signature for delivery. Emphasize that with this option, someone must be present when the package is delivered and able to pick up the medication from a UPS store if delivery is missed.

Delivery does not completely eliminate visits to the health department. Clients will continue to come in for 90-day tests, results, and subsequent prescription renewals for a 30-day fill with two refills. In order for the mail delivery program to be successful and operate smoothly, it is imperative that all prescriptions be written for a thirty day fill with two refills and that the 90-day cycle is maintained.

Eligibility for mail delivery should be determined at a clinical visit to ensure the prescription fills and delivery cycle are synchronized.

The following procedures provide guidance for clients who would like this option:

- The PrEP navigator or staff member acting will complete the request on the Request for Alternate Delivery of Medications (Ship to Home) form (see **Appendix S**). The ship to home form should be used for **refills** (indicate refills on the form) **and must accompany all new prescriptions.** If there are refills or future requests, the health department will need to fill out a new form. Do not re-fax previously used forms.

  Reminders for verifying the client's address:
  - The PrEP navigator or staff member acting as navigator must verify the client's address **EVERY** time medications are shipped to home or alternate site; **do not assume the address is the same as before** (e.g., the client may have moved).
  - Print the client's address legibly and correctly, including apartment number if applicable, and make sure spelling is correct (e.g.: 211 31st Street vs 211 31st OR South Klein St vs S Klein St).
  - There will be a checkbox on the form that states "current client address has been verified;" if it is not checked, Pharmacy will have to call to verify.
  - Ensure that the correct address is sent to Pharmacy **before** faxing the request.

- New prescriptions may be transmitted electronically or submitted via fax. Faxed prescriptions can be submitted on a LHS-181 or can be the original prescription(s); prescriptions must have a manual signature on them if faxed (otherwise, the pharmacist must take as a verbal order to be valid).
  - Prescriptions must be legible, not cut off or missing information (uniform prescription), not slanted or obscured.

- The pharmacy staff will review, order and dispense medication, then ship.

- The pharmacy staff will fax the Request for Alternate Delivery of Medications (Ship to Home – see **Appendix S**) form back to the navigator at the PrEP site with the tracking number.

- The site may track the package and verify receipt of delivery as needed.

The navigator should give the client his/her contact information in case the medication is not received, is damaged or misplaced. It is the navigator's responsibility to follow-up with the client to ensure receipt of medication.

If a client does not receive the medication within 7 days of delivery, the client should notify DPS immediately. An appointment for the client to have a medical evaluation will be necessary, and home delivery will be suspended unless a resolution is reached which satisfies VDH-DDP, DPS and partner site to ensure safe and timely deliveries.

QUALITY ASSURANCE AND EVALUATION

DDP will evaluate the PrEP program in order to determine program effectiveness and to assist in similar future projects. Evaluation will include activities such as assessing progress towards goals and objectives, tracking PrEP program enrollment, and using data to understand and improve adherence rates. DDP will also conduct chart reviews on a regular basis for quality assurance purposes.

PrEP clinic staff are encouraged to conduct their own internal PrEP quality assurance activities and chart reviews on a regular basis. A recommended schedule is to review at least 5 charts quarterly.

Clients receiving DDP-funded medications must consent to be involved in the evaluation process. This process involves:

1. Permission for the local health department to share information on behavioral risks, HIV/STD/Hepatitis status, and drug adherence with VDH-DDP PrEP project staff.
2. Completion of periodic short client satisfaction surveys. Permission to contact client if they withdraw without notification to ascertain their reason for stopping PrEP.

HOW TO ORDER PrEP EDUCATIONAL MATERIALS

VDH makes PrEP educational materials, such as client brochures and posters, available at no cost through the HIV/STD/Hepatitis Hotline. Please call (800) 533-4148 or email hiv-stdhotline@vdh.virginia.gov to order materials. To view or request educational materials, please visit the resources page.

PROVIDER TRAINING AND CONSULTATION RESOURCES

VDH-DDP can provide training, consultation and technical assistance on a variety of topics. Please reach out to DDP staff to discuss how DDP can meet your needs. Listed below are other training and consultation resources related to HIV prevention:

<table>
<tr><th colspan="2">Virginia and Nearby Resources</th></tr>
<tr><td>Mid-Atlantic AIDS Education Training Center
https://www.maaetc.org/

The MAAETC provides HIV/AIDS education, consultation and resources throughout Pennsylvania, Maryland, Virginia, West Virginia, and DC.</td><td>Virginia HIV/AIDS Resource and Consultation Center (VHARCC)
https://vharcc.com/
Virginia Commonwealth University
Eastern Virginia Medical School
Inova Juniper Program</td></tr>
<tr><th colspan="2">National Resources</th></tr>
<tr><td>National LGBT Health Education Institute
A Program of the Fenway Institute
https://www.lgbthealtheducation.org/</td><td rowspan="2">National Clinician Consultation Center
University of California, San Francisco

PrEP Warmline

(855) 448-7737 or (855) HIV-PrEP
Monday – Friday, 9 am – 8 pm ET

PEP Warmline

(888) 448-4911</td></tr>
<tr><td>HealthHIV
http://healthhiv.org/

2000 S Street NW
Washington, DC 20009
(202) 232-6750</td></tr>
</table>

PrEP DATA COLLECTION AND SUBMISSION

Organizations that have a contract with VDH to provide PrEP services are required to collect and submit data to VDH on a monthly basis. Please contact the Program Coordinator or Data Manager for instructions.

VDH DIVISION OF DISEASE PREVENTION (DDP) CONTACT INFORMATION

PrEP Services Coordinator Project Support and Financial Qualification Eric Mayes | (804) 763-9506 Eric.Mayes@vdh.virginia.gov	**HIV/STI/Viral Hepatitis Nurse Consultant** Clinical Support Jenny Calhoun, RN | (804) 864-7328 Jenny.Calhoun@vdh.virginia.gov
PrEP Services Support Technician Miles McKemy | (804) 864-8002 Miles.McKemy@vdh.virginia.gov	**Public Relations Coordinator** Chris Barnett | (804) 380-5986 Christopher.Barnett@vdh.virginia.gov
Central Pharmacy Support Stephanie Wheawill, PharmD | (804) 786-4326 Stephanie.Wheawill@vdh.virginia.gov	**HIV Prevention Data Manager** Lori Beck | (804) 864-7903 Lori.Beck@vdh.virginia.gov
Drug User Health Coordinator (Comprehensive Harm Reduction) Bruce Taylor | (804) 584-3651 Bruce.Taylor@vdh.virginia.gov	**HIV & Hepatitis Prevention Director** Felencia McGee | (804) 864-7967 Felencia.McGee@vdh.virginia.gov

APPENDICES

Appendix A: VDH PrEP Clinical Visit Checklist

VDH PrEP Clinical Visit Checklist

Clinic Protocol for Oral PrEP

☐	1. Confirm HIV-negative status and clinical eligibility

	• HIV-negative result using HIV antibody/antigen blood test within 7 days of prescribing PrEP
	• Conduct HIV-1 RNA test in patients who:
	  ○ Have had symptoms of acute HIV in the past 4 weeks
	  ○ Report condomless anal or vaginal sex during the previous 4 weeks
	  ○ Have shared injection drug needles in the past 4 weeks
	  ○ Have been on oral PrEP in the past 3 months or injectable PrEP in the past 12 months
	• Estimated creatinine clearance ≥30 ml/min
	• No contraindicated medications
	• Completed sexual history, medical history and/or physical exam, if indicated
	• nPEP, if possible HIV exposure in past 72 hours

☐	**2. Confirm program eligibility (link to application)**
	• Resident of VA • Completed PrEP DAP application with documentation of residence, proof of income and insurance • Seek assistance for medication – Gilead Advancing Access, Ready, Set, PrEP, etc.
☐	**3. Screening tests with LabCorp test numbers**

	• HIV testing
	  ○ HIV Ag/Ab **083935**
	  ○ HIV-1/HIV-2 Qualitative RNA **139825**
	• Serum creatinine **001370** - to calculate estimated creatinine clearance (eCrCl)
	  ○ F/TDF, eCrCl ≥ 60 ml/min
	  ○ F/TAF, eCrCl ≥ 30 ml/min
	• Lipid Profile **303756** – cholesterol and triglycerides for **F/TAF only**
	• Pregnancy testing (for patients who can become pregnant) – in house
	• Hepatitis B serology **144473**
	  ○ Vaccinate as appropriate
	• Hepatitis C serology **144050**
	• Screen for STIs
	  ○ GC/Chlamydia **183194** – urine or genital/vaginal
	  ○ GC/Chlamydia **188672** – rectal
	  ○ GC/Chlamydia **188698** – pharyngeal
	  ○ Syphilis **082345** - T. pallidum screening cascade
	For additional optional testing see VDH Lab Testing Guidelines for Oral PrEP, 2022 (include link)

☐	**3. Screen for additional services/referrals if indicated**
	• Reproductive counseling/contraception • Immunizations • Drug treatment services/syringe services support • Mental Health Counseling • Housing/Food Assistance/Transportation • Primary Care Services

☐ 4. PrEP education and support

- Provide adherence education
  - How PrEP works
  - Importance of dosing schedule
  - Strategies for adherence (establish routine, set a reminder)
- Provide education about side effects and management
- Remind patients of common STI symptoms and importance of screening
- Write PrEP prescription
  - F/TDF daily ≤90 day supply
  - F/TAF daily ≤90 day supply for cisgender men and transgender women only
- Schedule patient for follow-up visit

☐ 5. Follow-Up

- **At ~ 2 weeks by phone or telehealth**
  - Verify that patient picked up prescription and initiated PrEP
  - Check about side effects/adherence/questions
  - Review test results/confirm treatment if indicated
  - Remind patient of next PrEP visit

- **At least every 3 months**
  - HIV Ag/Ab and HIV-1 RNA test
  - Bacterial STI screening for MSM and TGW who have sex with men – all sites
  - Medication adherence and behavioral risk reduction support
  - Access to clean needles/syringes and drug treatment services for PWID

- **Every 6 months**
  - Assess renal function for patients aged ≥50 years or who have an eCrCl <90 ml/min at PrEP initiation
  - Bacterial STI screening for all sexually active clients – blood, all sites as indicated

- **Every 12 months**
  - Assess renal function for all patients
  - For patients on F/TAF, assess weight, triglyceride and cholesterol levels

Timing of Oral PrEP-associated Laboratory Tests

Test	Initial Visit	Every 3 months	Every 6 months	Every 12 months	When stopping PrEP
HIV Ag/Ab **HIV-1 RNA**	X	X X			X X
eCrCl	X		If age ≥50 or eCrCl <90 ml/min at PrEP initiation	If age <50 and eCrCl ≥90 ml/min at PrEP initiation	X
Syphilis	X	MSM/TGW	X		MSM/TGW
Gonorrhea	X	MSM/TGW	X		MSM/TGW
Chlamydia	X	MSM/TGW	X		MSM/TGW
Hep B serology	X				
Hep C serology	X			MSM,TGW and PWID only	
Lipid panel *(F/TAF only)*	X			X	

These guidelines are adapted from the CDC's Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update

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Appendix B: VDH Lab Testing Guidelines for Oral PrEP

2022

VDH Lab Testing Guidelines for Oral PrEP, 2022

LabCorp #/Test	Initial	every 3 months	every 6 months	every 12 months	when stopping PrEP
083935 HIV 1/0/2 4th Generation	X	X			X
	If positive at any point, refer for linkage to care.				
139825 HIV-1/HIV-2 Qualitative RNA NAAT	Only if on oral PrEP in last 3 months	X			X
	If positive at any point, refer for linkage to care.				
144473 Hepatitis B panel HBcAb+HBsAb+HBsAg	X				
	Reassess as indicated by history.				
551610 Hepatitis B Viral Load	If positive HBsAg (144473)			If positive HBsAg (144473)	
144050 Hepatitis C Ab w/ reflex to NAA	X				
	Reassess as indicated by history; refer for treatment of Hep C if acute infection.				
082345 Syphilis (T Pallidum Screening Cascade)	X	MSM/TGW	X		MSM/TGW
183194 Chlamydia/Gonorrhea- Urine, Vaginal, Endocervical, Male Urethral	X	MSM/TGW	X		MSM/TGW
188672 Chlamydia/Gonorrhea NAAT-Rectal	X	MSM/TGW	X		MSM/TGW
188698 Chlamydia/Gonorrhea NAAT-Pharyngeal	X	MSM/TGW	X		MSM/TGW
001370 Serum Creatinine (for estimated calculated creatinine clearance)	X		If age ≥50 **or** eCrCl <90ml/min at PrEP initiation	If age <50 **and** eCrCl >90ml/min at PrEP initiation	X
	Use Cockgroft-Gault formula				
303756 Lipid Profile for F/TAF only Total cholesterol, HDL, LDL, VLDL, triglycerides	X			X	
322755 Liver function tests AST/ALT	As indicated for evaluation of clinical symptoms or in the presence of concurrent hepatitis B/C				
322000 Comprehensive Metabolic Panel (CMP)	Order this test if both creatinine and liver function tests are needed at the same visit.				
003038 OR in-house Urinalysis for protein	As indicated for evaluation of renal safety threat				
Pregnancy Urine in-house	X	As indicated by history.			
	Females at risk for pregnancy				

Appendix C: VDH Lab Testing Guidelines for nPEP

2022

VDH Lab Testing Guidelines for nPEP, 2022

LabCorp Test #/Test	Initial	4-6 weeks	3 months	6 months
083935 **HIV 1/0/2 4th Generation**	X	X	X	X
	If positive at any point, refer for linkage to care.			
139825 **HIV-1/HIV-2 Qualitative RNA NAAT** **If on oral PrEP in past 3 months**	X	X	X	X
	If positive at any point, refer for linkage to care.			
144473 **Hepatitis B** **HBcAb+HBsAb+HBsAg**	X			X (if susceptible at baseline)
	Refer positive for evaluation and treatment. Reassess as indicated by history.			
144050 **Hepatitis C** **HCV Ab w/ reflex to NAA**	X			X (if susceptible at baseline)
	Refer for treatment if acute Hep C infection. Reassess as indicated by history.			
082345 **Syphilis** **T Pallidum Screening Cascade**	X	X		X
	Serial post-treatment RPR titers for positive results per 2021 STI Treatment Guidelines CDC			
183194 **Chlamydia/Gonorrhea** **NAAT-Urine, Vaginal, Endocervial, Male Urethral**	X	X (if not presumptively treated at baseline or symptomatic)		
188672 **Chlamydia/Gonorrhea** **NAAT-Rectal**	X	X (if not presumptively treated at baseline or symptomatic)		
188698 **Chlamydia/Gonorrhea** **NAAT-Pharyngeal**	X	X (if not presumptively treated at baseline or symptomatic)		
001370 **Serum Creatinine** **for estimated calculated creatinine clearance**	X	X		
	If prescribed Truvada/Isentress or Truvada/Tivicay			
322755 **Liver Function Tests** **AST/ALT**	X	X		
	If prescribed Truvada/Isentress or Truvada/Tivicay			
Pregnancy **Urine in-house**	X	X		
	If at risk for pregnancy; Tivicay contraindicated if pregnant or at risk for pregnancy			

Appendix D: VDH Lab Testing Guidelines for Injectable PrEP 2022

VDH PrEP Clinical Visit Checklist

Clinic Protocol for Injectable PrEP

☐	**1. Confirm HIV-negative status and clinical eligibility**

	• HIV-negative result using HIV antibody/antigen blood test within 7 days of prescribing PrEP
	• Conduct HIV-1 RNA test in patients who:
	  ○ Have had symptoms of acute HIV in the past 4 weeks
	  ○ Report condomless anal or vaginal sex during the previous 4 weeks
	  ○ Have shared injection drug needles in the past 4 weeks
	  ○ Have been on oral PrEP in the past 3 months or injectable PrEP in the past 12 months
	• No contraindicated medications
	• Completed sexual history, medical history and/or physical exam, if indicated
	• nPEP, if possible HIV exposure in past 72 hours

☐	**2. Confirm program eligibility (link to application)**
	• Resident of VA • Completed PrEP DAP application with documentation of residence, proof of income and insurance • Seek assistance for medication – Gilead Advancing Access, Ready, Set, PrEP, etc.
☐	**3. Screening tests with LabCorp test numbers**

	• HIV testing
	  ○ HIV Ag/Ab **083935**
	  ○ HIV-1/HIV-2 Qualitative RNA **139825**
	• Pregnancy testing (for patients who can become pregnant) – in house
	• Hepatitis B serology **144473**
	  ○ Vaccinate as appropriate
	• Hepatitis C serology **144050**
	• Screen for STIs
	  ○ GC/Chlamydia **183194** – urine or genital/vaginal
	  ○ GC/Chlamydia **188672** – rectal
	  ○ GC/Chlamydia **188698** – pharyngeal
	  ○ Syphilis **082345** - T. pallidum screening cascade
	If additional testing is indicated, see VDH Lab Testing Guidelines for PrEP, 2022

☐	**3. Screen for additional services/referrals if indicated**
	• Reproductive counseling/contraception • Immunizations • Drug treatment services/syringe services support • Mental Health Counseling • Housing/Food Assistance/Transportation • Primary Care Services
☐	**4. PrEP education and support**

	• Provide adherence education
	  ○ How PrEP works
	  ○ Importance of dosing schedule
	  ○ Strategies for adherence

- Provide education about side effects and management
- Remind patients of common STI symptoms and importance of screening
- Write PrEP prescription
- Schedule patient for follow-up visit

☐ 5. Follow-Up

- **At 1 month visit after first injection**
  - HIV Ag/Ab and HIV-1 RNA testing
- **Every 2 months**
  - HIV Ag/Ab and HIV-1 RNA test
  - Access to clean needles/syrings and drug treatment services for PWID
- **Every 4 months**
  - Bacterial STI screening for MSM and TGW who have sex with men - blood, all sites as indicated
- **Every 6 months**
  - Bacterial STI screening for all heterosexually-active women and men - blood, all sites as indicated
- **Every 12 months**
  - Assess desire to continue injections for PrEP
- **At follow up visits when discontinuing cabotegravir injections –**
  - Re-educate clients about the "tail" and the risks during declining CAB levels
  - Assess ongoing HIV risk reduction plans
  - If PrEP is indicated, prescribe daily oral F/TDF or F/TAF beginning within 8 weeks after last injectioin
  - Continue follow up visits with HIV testing quarterly for 12 months

TIMING OF CAB LABS

Test	Initial Visit	1 month visit	Every 2 months	Every 4 months	Every 6 months	When stopping CAB
HIV Ag/Ab **HIV-1 RNA**	X X	X X	X X	X X	X X	X X
Syphilis	X			MSM/TGW	Heterosexuals	MSM/TGW
Gonorrhea	X			MSM/TGW	Heterosexuals	MSM/TGW
Chlamydia	X			MSM/TGW	Heterosexuals	MSM/TGW
Hep B serology	X					
Hep C serology	X					

These guidelines are adapted from the CDC's Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update

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Appendix E: GLAAD Gender Reference Guide

Sex The assignment of a person as male or female usually based on the appearance of their external anatomy at birth. This is what is written on the birth certificate.

Gender Identity A person's internal, deeply held sense of their gender. Most people have a gender identity of man or woman (or boy or girl). Gender identity is not visible to others.

Sexual Orientation A person's enduring physical, romantic, and/or emotional attraction to another person. Gender identity and sexual orientation are not the same. Persons of varied gender identities may be straight, lesbian, gay, bisexual, or queer

Transgender (adj.)
People whose gender identity differs from the sex they were assigned at birth. Many transgender people are prescribed hormones by their doctors and some undergo surgery to bring their bodies into alignment with their gender identity. A transgender identity is not dependent upon physical appearance or medical procedures. Trans can be used as shorthand for transgender

Cisgender (adj.) People whose gender identity is the same as the sex they were assigned at birth **Cis** can be used as shorthand for cisgender.

Gender Expression External manifestations of gender, expressed through a person's name, pronouns, clothing, haircut, behavior, voice, and/or body characteristics.

Gender Non-Conforming People whose gender expression is different from conventional expectations of masculinity and femininity. Many people have gender expressions that are not entirely conventional – that fact alone does not make them transgender. The term is not a synonym for transgender or transsexual and should only be used if someone self-identifies as gender non-conforming.

Non-binary and/or genderqueer Terms used by some people who experience their gender identity and/or gender expression as falling outside or somewhere in between the categories of man and woman. The term should only be used if someone self-identifies as non-binary and/or genderqueer.

Adapted from GLAAD Media Reference Guide at
https://www.glaad.org/reference/transgender

Appendix F: VDH Patient Consent for General Primary Care

Patient Name:_____ Date of Birth:_____ ID#_____

VIRGINIA DEPARTMENT OF HEALTH

Patient Application and Consent for Health Care

PATIENT CONSENT FOR GENERAL PRIMARY CARE

I hereby authorize the Physicians, Nurses, Nurse Practitioners, and other medical care providers of the Virginia Department of Health (VDH) to examine and/or treat me and/or my dependent, as named above.

NOTICE OF DEEMED CONSENT FOR HIV, HEPATITIS B OR C TESTING

VDH is required by § 32.1-45.1 of the Code of Virginia (1950), as amended, to give you the following notice:

1. If any VDH health care professional, worker or employee should be directly exposed to your blood or body fluids in a way that may transmit disease, your blood will be tested for infection with human immunodeficiency virus (HIV), as well as for Hepatitis B and C. A physician or other health care provider will tell you the result of the test. Under Va. Code § 32.1-45.1(A), you are deemed to have consented to the release of the test results to the person exposed.
2. If you should be directly exposed to blood or body fluids of a VDH health care professional, worker or employee in a way that may transmit disease, that person's blood will be tested for infection with human immunodeficiency virus (HIV), as well as for Hepatitis B and C. A physician or other health care provider will tell you and that person the result of the test.

HIV TESTING

If HIV testing is performed, you will be told ahead of time, be given information about the test, and allowed to decline testing. All results will remain confidential except as allowed by law.

PAYMENT FOR SERVICES

Some services are free, but we charge for many of them. You will be responsible for paying for those services. We have a sliding fee scale, based on your family income and family size, that may lower the charges. You will be liable for any charges not paid by third party payers according to this sliding scale. The percentage you pay will remain the same until your income or family size changes. Some services are charged on a flat fee basis, regardless of income or family size (everyone pays the same price). It is possible that our charges may change. We will try to discuss those changes with you. Your information is being entered into a statewide database that can be accessed from any local health department in the state. Based on the information you have provided, you are responsible for paying _____ % of the charges. If there is a charge for services and you do not pay at the time of visit, we will establish a payment plan for the amount due.

I give my permission for me and/or my dependent (as named above) to be interviewed about family income and family size. I understand that I am responsible for paying the bill.

OUTSIDE LAB SERVICES

If my health care provider orders lab tests, I understand that I may receive a separate bill from an outside lab. If I am insured, my insurance company will determine the amount that I may owe to the lab provider, and I will be responsible for any payment. I understand that the sliding fee scale that may apply to other services provided directly by VDH will not apply to the lab bill from an outside lab provider. Sometimes the lab may have to perform additional testing on a specimen. This will result in extra charges that may be added to my account, and I may receive a bill from VDH. _____

Patient's Initials

Patient Name:_____ Date of Birth:_____ ID#_____

RECEIPT OF THE NOTICE OF PRIVACY PRACTICES

I acknowledge that I have received the Notice of Privacy Practices from the Virginia Department of Health.

CONSENT TO RECEIVE ELECTRONIC APPOINTMENT REMINDERS

VDH does not charge for this service, but standard text messaging rates may apply based on your wireless plan. I understand that this consent will apply to all future appointments unless I request a change in writing.

☐ **I do not consent** to receive text messages to remind me of an appointment.

☐ **I do not consent** to receive email messages to remind me of an appointment.

☐ **I consent** to receive text messages on my cellphone to remind me of an appointment, and I also agree to inform the health department if my cellphone number changes.

My cellphone number is _____

☐ **I consent** to receive email messages at my email address to remind me of an appointment, and I also agree to inform the health department if my email address changes.

My email address is_____

RECORD KEEPING

I understand that medical records will be retained for ten years after the date of the last visit, then destroyed in a manner that assures confidentiality throughout the process and in its results. In the case of a minor, the record will be retained for twenty-eight years after birth, then destroyed in a manner that assures confidentiality throughout the process and in its results. I authorize VDH to release records necessary to support the application for payment by Medicare, Medicaid, insurance or other health care benefits. I request the third party payer to pay any authorized benefits to VDH or its contractors on my behalf.

I understand that this consent will remain in effect as long as my dependent or I receive care from VDH or until I withdraw it.

I certify that the information I have provided is a true and complete statement according to my best knowledge and belief, and that a full explanation of services and charges has been given to me. I understand that if I give false information, withhold information, or fail to report changes promptly, I will be breaking the law and can be prosecuted and/or have services discontinued.

_____ _____

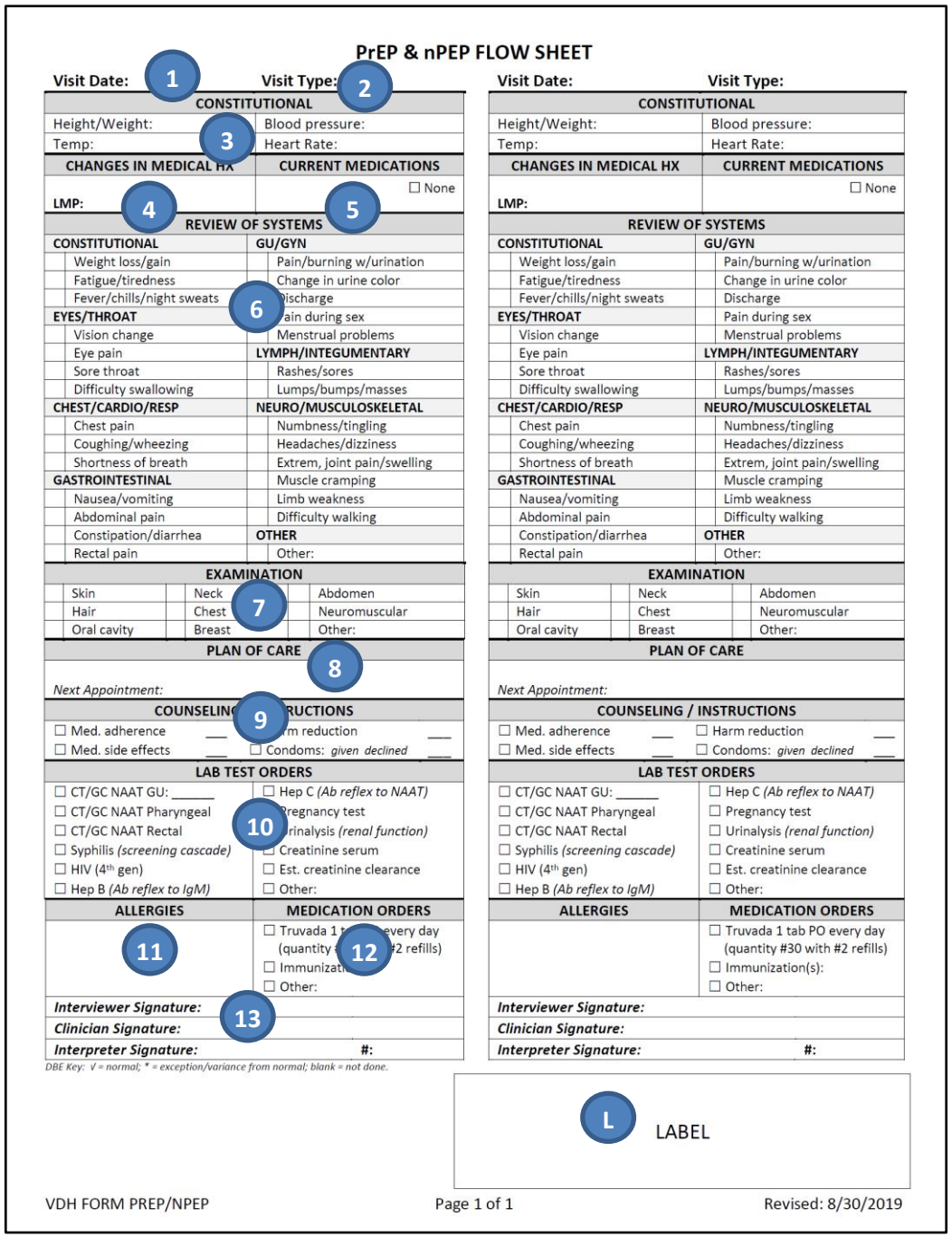
Signature of Patient, Parent/Legal Guardian, or Person Acting in Loco Parentis **Date Signed**

_____ _____

Relationship (if signature is not of Patient) **Signature of Person Obtaining Consent**

Appendix G: PrEP & nPEP Flow Sheet - Instructions

PrEP & nPEP FLOW SHEET – INSTRUCTIONS



PrEP & nPEP FLOW SHEET

Visit Date: (1) Visit Type: (2) | Visit Date: Visit Type:

CONSTITUTIONAL		CONSTITUTIONAL	
Height/Weight:	Blood pressure:	Height/Weight:	Blood pressure:
Temp: (3)	Heart Rate:	Temp:	Heart Rate:
CHANGES IN MEDICAL HX	CURRENT MEDICATIONS	CHANGES IN MEDICAL HX	CURRENT MEDICATIONS
LMP: (4)	☐ None (5)	LMP:	☐ None

REVIEW OF SYSTEMS			
CONSTITUTIONAL		GU/GYN	
☐ Weight loss/gain		☐ Pain/burning w/urination	
☐ Fatigue/tiredness		☐ Change in urine color	
☐ Fever/chills/night sweats		☐ Discharge	
EYES/THROAT		☐ Pain during sex	
☐ Vision change		☐ Menstrual problems	
☐ Eye pain		LYMPH/INTEGUMENTARY	
☐ Sore throat		☐ Rashes/sores	
☐ Difficulty swallowing		☐ Lumps/bumps/masses	
CHEST/CARDIO/RESP		NEURO/MUSCULOSKELETAL	
☐ Chest pain		☐ Numbness/tingling	
☐ Coughing/wheezing		☐ Headaches/dizziness	
☐ Shortness of breath		☐ Extrem, joint pain/swelling	
GASTROINTESTINAL		☐ Muscle cramping	
☐ Nausea/vomiting		☐ Limb weakness	
☐ Abdominal pain		☐ Difficulty walking	
☐ Constipation/diarrhea		OTHER	
☐ Rectal pain		☐ Other:	

(6)

EXAMINATION		
☐ Skin	☐ Neck	☐ Abdomen
☐ Hair	☐ Chest	☐ Neuromuscular
☐ Oral cavity	☐ Breast	☐ Other:

(7)

PLAN OF CARE (8)

Next Appointment:

COUNSELING / INSTRUCTIONS (9)

☐ Med. adherence ___	☐ Harm reduction ___
☐ Med. side effects ___	☐ Condoms: *given declined* ___

LAB TEST ORDERS	
☐ CT/GC NAAT GU: _____	☐ Hep C *(Ab reflex to NAAT)*
☐ CT/GC NAAT Pharyngeal	☐ Pregnancy test
☐ CT/GC NAAT Rectal	☐ Urinalysis *(renal function)*
☐ Syphilis *(screening cascade)*	☐ Creatinine serum
☐ HIV (4th gen)	☐ Est. creatinine clearance
☐ Hep B *(Ab reflex to IgM)*	☐ Other:

(10)

ALLERGIES	MEDICATION ORDERS
(11)	☐ Truvada 1 tab PO every day (quantity #30 with #2 refills) (12)
	☐ Immunization(s):
	☐ Other:

Interviewer Signature:
Clinician Signature: (13)
Interpreter Signature: #:

DBE Key: √ = normal; * = exception/variance from normal; blank = not done.

(L) LABEL

VDH FORM PREP/NPEP | Page 1 of 1 | Revised: 8/30/2019

Purpose: This form is designed for follow-up PrEP and nPEP visits (i.e., <u>after</u> initial visit or re-enrollment visits) and other interim visits as needed. It is only applicable to clinics offering these services.

Status: This form is required for every follow-up PrEP or nPEP visit. This form should be used in conjunction with the client visit health history form, which should be completed by the patient at each PrEP visit. *This form does not need to be completed for routine, non-problematic, monthly medication pick-ups when there is no clinical or counseling component to the visit.*

General Instructions: This form should be completed by the nurse or clinician providing the clinic services. If the client visit entails care for non-routine complaints, concerns, or findings, the regular clinic visit record may be used as indicated. Each page is formatted for two follow-up visits.

Note: The Clinic Visit Record form must be completed for initial and re-enrollment PrEP and nPEP clients. A full visit should also be completed annually for all enrolled PrEP clients.

(L) **Label:** Place patient label on the bottom right of the form (should be done by OSS). This label should be a chart-type label without date.

(1) **Date:** Enter date of visit.

(2) **Visit Type:** Enter type of visit (e.g., “28-day,” “30-day”, “6-week,” “3-month,” “interim,” “problem”) and PrEP or nPEP.

(3) **Vitals:** A minimum of three vital measurements must be recorded for each visit (which three measurements to perform is at the discretion of the local clinic.)

(4) **Current medications:** Document any pharmaceutical or complementary medication the patient is currently using.

(5) **Changes in Medical History:** Document any changes in the medical history since patient’s previous visit. If none, write “none.”

(6) **Review of Systems:** Check all systems reviewed, and then indicate whether there were any normal or abnormal observations using DBE. Leave blank if the system was not

reviewed. Descriptors for abnormalities should be recorded in Exception Notes, unless a full STI Visit is indicated. If the client has any STI symptoms (including symptoms of acute HIV infection) or is experiencing medication side-effects, then a full STI visit should be performed using the normal visit record forms (i.e. the standard Sexual Health History and Visit Record forms).

7 **Physical Exam:** A directed physical exam may be performed as indicated. See the STI Visit Record form instructions for detailed information regarding normal values. If a focused physical exam is conducted during the PrEP follow-up visit, the clinician should complete the box to the left of each item as follows:

- Check mark (✓)means examined and determined to be normal.
- Asterisk (*) means abnormality identified, notation should be made to the right with additional information in Exception Noted as needed.
- Blank (_)means not performed.

8 **Plan of Care:** Document client's plan of care and any relevant medical or counseling orders. Note next appointment date and time. If additional space is needed, utilize Exception Note.

9 **Counseling/Instructions:** Clinician should check the box to the left if counseling/instructions were ordered for client, and the nurse or clinician should initial to right of each item to record who actually provided the counseling/instructions.

10 **Lab Tests Ordered:** Place an "X" by lab tests ordered and performed. If ordered, but not performed, document explanation in Exception Note. Note that the estimated creatinine clearance is a calculated value. Lab tests are ordered by clinician based on PrEP and nPEP guidelines provided by VDH and CDC as well as clinician medical decision-making.

For urogenital CT/GC NAAT testing, document the specimen collection site on the line to the right of the test name.

Note: Bone density testing may be ordered by clinician as clinically indicated. Document this and/or any other testing performed in one of the "Other" rows.

11 **Allergies:** Confirm allergies with client prior to ordering medications. Any allergies should be recorded **in red**. If no allergies, write NKDA. Do not leave blank.

12 **Medication Order:** Date and complete medication dosage for any medication ordered. If medication is not included on the pre-filled list, document it under "Other." If additional space is needed, utilize Exception Note.

Note whether each medication was administered, prescribed, or delivered, as well as the injection site, lot number, and administration date and who administered the medication. Medication can be ordered on this record and dispensed to be given at a later time if necessary. Only injectable medications require the documentation of lot number and injection site.

Immunizations: If any vaccinations are indicated, check the box next to the appropriate vaccine and document whether it was given, declined, or referred (G, D, R) in the right box. If client is eligible for vaccine, but it was not given during the clinic visit, mark an asterisk (*) and document the reason in the Exception Note.

13 **Interviewer Signature:** The nurse or interviewer who takes the orders, performs counseling, etc. should sign here if they provided any care or servicers during the visit.

Clinician Signature: If a clinician sees the client during the visit, or orders medication or laboratory tests for the client, then the clinician should review this form and sign.

Interpreter Signature/Number: If a professional translator or other assistive services are used during the visit, document this per VDH protocol and have the interpreter sign with their name and number here.

Appendix H: PrEP & nPEP Flow Sheet

PrEP & nPEP FLOW SHEET

Visit Date: **Visit Type:**

CONSTITUTIONAL	
Height/Weight:	Blood pressure:
Temp:	Heart Rate:

CHANGES IN MEDICAL HX	CURRENT MEDICATIONS
LMP:	☐ None

REVIEW OF SYSTEMS

CONSTITUTIONAL	GU/GYN
☐ Weight loss/gain	☐ Pain/burning w/urination
☐ Fatigue/tiredness	☐ Change in urine color
☐ Fever/chills/night sweats	☐ Discharge
EYES/THROAT	☐ Pain during sex
☐ Vision change	☐ Menstrual problems
☐ Eye pain	**LYMPH/INTEGUMENTARY**
☐ Sore throat	☐ Rashes/sores
☐ Difficulty swallowing	☐ Lumps/bumps/masses
CHEST/CARDIO/RESP	**NEURO/MUSCULOSKELETAL**
☐ Chest pain	☐ Numbness/tingling
☐ Coughing/wheezing	☐ Headaches/dizziness
☐ Shortness of breath	☐ Extrem, joint pain/swelling
GASTROINTESTINAL	☐ Muscle cramping
☐ Nausea/vomiting	☐ Limb weakness
☐ Abdominal pain	☐ Difficulty walking
☐ Constipation/diarrhea	**OTHER**
☐ Rectal pain	☐ Other:

EXAMINATION

☐ Skin	☐ Neck	☐ Abdomen
☐ Hair	☐ Chest	☐ Neuromuscular
☐ Oral cavity	☐ Breast	☐ Other:

PLAN OF CARE

Next Appointment:

COUNSELING / INSTRUCTIONS

☐ Med. adherence ___	☐ Harm reduction ___
☐ Med. side effects ___	☐ Condoms: *given declined* ___

LAB TEST ORDERS

☐ CT/GC NAAT GU: _____	☐ Hep C *(Ab reflex to NAAT)*
☐ CT/GC NAAT Pharyngeal	☐ Pregnancy test
☐ CT/GC NAAT Rectal	☐ Urinalysis *(renal function)*
☐ Syphilis *(screening cascade)*	☐ Creatinine serum
☐ HIV (4th gen)	☐ Est. creatinine clearance
☐ Hep B *(Ab reflex to IgM)*	☐ Other:

ALLERGIES	MEDICATION ORDERS
	☐ Truvada 1 tab PO every day (quantity #30 with #2 refills) ☐ Immunization(s): ☐ Other:

Interviewer Signature:

Clinician Signature:

Interpreter Signature: **#:**

*DBE Key: √ = normal; * = exception/variance from normal; blank = not done.*

Visit Date: **Visit Type:**

CONSTITUTIONAL	
Height/Weight:	Blood pressure:
Temp:	Heart Rate:

CHANGES IN MEDICAL HX	CURRENT MEDICATIONS
LMP:	☐ None

REVIEW OF SYSTEMS

CONSTITUTIONAL	GU/GYN
☐ Weight loss/gain	☐ Pain/burning w/urination
☐ Fatigue/tiredness	☐ Change in urine color
☐ Fever/chills/night sweats	☐ Discharge
EYES/THROAT	☐ Pain during sex
☐ Vision change	☐ Menstrual problems
☐ Eye pain	**LYMPH/INTEGUMENTARY**
☐ Sore throat	☐ Rashes/sores
☐ Difficulty swallowing	☐ Lumps/bumps/masses
CHEST/CARDIO/RESP	**NEURO/MUSCULOSKELETAL**
☐ Chest pain	☐ Numbness/tingling
☐ Coughing/wheezing	☐ Headaches/dizziness
☐ Shortness of breath	☐ Extrem, joint pain/swelling
GASTROINTESTINAL	☐ Muscle cramping
☐ Nausea/vomiting	☐ Limb weakness
☐ Abdominal pain	☐ Difficulty walking
☐ Constipation/diarrhea	**OTHER**
☐ Rectal pain	☐ Other:

EXAMINATION

☐ Skin	☐ Neck	☐ Abdomen
☐ Hair	☐ Chest	☐ Neuromuscular
☐ Oral cavity	☐ Breast	☐ Other:

PLAN OF CARE

Next Appointment:

COUNSELING / INSTRUCTIONS

☐ Med. adherence ___	☐ Harm reduction ___
☐ Med. side effects ___	☐ Condoms: *given declined* ___

LAB TEST ORDERS

☐ CT/GC NAAT GU: _____	☐ Hep C *(Ab reflex to NAAT)*
☐ CT/GC NAAT Pharyngeal	☐ Pregnancy test
☐ CT/GC NAAT Rectal	☐ Urinalysis *(renal function)*
☐ Syphilis *(screening cascade)*	☐ Creatinine serum
☐ HIV (4th gen)	☐ Est. creatinine clearance
☐ Hep B *(Ab reflex to IgM)*	☐ Other:

ALLERGIES	MEDICATION ORDERS
	☐ Truvada 1 tab PO every day (quantity #30 with #2 refills) ☐ Immunization(s): ☐ Other:

Interviewer Signature:

Clinician Signature:

Interpreter Signature: **#:**

LABEL

Appendix I: Procedures for Health Departments Returning Drugs to Pharmacy

Procedures for Health Departments Returning Drugs to Pharmacy

4/2022

Per agency policies, medications, chargeable vaccines, and some medical supplies should be returned to the Division of Pharmacy Services (DPS). If you have questions regarding the disposal of medications dispensed by a pharmacy other than DPS, please feel free to contact us for assistance. Should you have questions regarding the procedures for returning medications to the pharmacy, please contact us at 804-786-4326 or email pharmacyvisions@vdh.virginia.gov.

General Guidelines

Medications returned in an open manufacturer's sealed bottle or that have been dispensed in an amber vial or bottle will be properly disposed of in the pharmacy and no credit will be issued to the health department. Additionally, **no credit will be given for any products once they have left the health department (with the client, the client's agent, etc.) nor will the medications be returned to stock.**

Products that can be returned to stock by pharmacy will result in a credit to the fund source.

Long Acting Reversible Contraceptives (LARCs): Returns for LARCs follow a slightly different policy. Expired shelf stock LARCs should be returned following instructions the Bulk Mediations & Vaccines. For other LARC returns such as defective issues, improper insertion, etc., please contact the pharmacy for guidance.

If medication/waste is hazardous/waste, please contact the pharmacy for guidance before returning

All medication dispensed by DPS and not delivered to the client on the label must be boxed and returned to DPS.

VA MAP or PrEP Programs

Medications which have never left the health department **and** are returned in the manufacturer's sealed bottle, with a minimum of 4 months (120 days) until expiration, may be returned to stock by pharmacy staff. All medications **not picked up by the client within 60 days of receipt** must be returned to the pharmacy. For viable, in date cold items, see the cold chain procedure. Please include the completed **Returned Drugs to Pharmacy** form.

For Alexandria and Fairfax pharmacy only: if VA MAP replacement medications need to be returned, please contact pharmacy staff.

TB Program

Medications which have never left the health department **and** are returned in the manufacturer's sealed bottle, with a minimum of 4 months (120 days) until expiration, may be returned to stock by pharmacy staff.

Medications which have been dispensed in compliance packaging (through the Pearson packaging machine), in addition to those dispensed in an amber vial or bottle, cannot be returned to stock and will be properly disposed of by the pharmacy.

All medications **not picked up by the client within 60 days of receipt** must be returned to the pharmacy. For viable, in date cold items, see the cold chain procedure. Please include the completed **Returned Drugs to Pharmacy** form.

For Fairfax pharmacy only: if TB replacement medications need to be returned, please contact pharmacy staff.

Controlled Substances
Legally, we cannot accept a controlled substance not originally dispensed by DPS.

Bulk Medications & Vaccines
Products returned in a sealed manufacturer package or unopened units (ex. prefilled syringes, unopened multi dose vials, etc.) with an acceptable expiration date may be returned to stock with credit given to the health department. Acceptable expiration dating will be determined on a case by case basis. There may be exceptions to this where DPS will not be able to issue any credit (ex., large or special orders). To insure maximum credit, products should be returned as soon as possible and do not write on product packaging. Products procured from DPS should be boxed and returned to DPS. For returning viable, in date cold items and vaccines, see the cold chain procedures below. Please include the completed **Returned Drugs to Pharmacy** form.

Expired or non-viable, **chargeable** vaccines that are in unopened units (ex., prefilled syringes and unopened multi dose vials) must be returned to DPS. For expired non-chargeable vaccines (i.e. VFC, EP&R purchased vaccine), please contact the respective program for guidance.

Cold Chain for Viable Medications
Viable vaccines or other refrigerated medications can be returned by the following cold chain to ensure viability and/or stability. **Please contact the pharmacy for further guidance.** Vaccines or refrigerated medications should be shipped in an insulated cooler with the appropriate gel packs or freezer bricks and shipped Monday, Tuesday or Wednesday. Vaccines should be shipped **overnight**. Product should be separated from the gel packs or freezer bricks with layers of paper. Additionally, vaccines should have a warm/cold mark attached to ensure there has been no temperature variance. Whether to use a warm mark or cold mark depends on the outside temperature at the time of shipping.

For all medications returned to DPS, please complete the **Returned Drugs to Pharmacy** form and include it in the box of medications being returned. Please separate items that are being shipped via cold chain versus those that are not. All medications should be shipped to the following address:

VDH Division of Pharmacy Services
101 N. 14th Street
Room S-45
Richmond, VA 23219

Health Departments should retain records for inventory returned to the pharmacy for a minimum of 2 years to meet laws and regulations issued under the Board of Pharmacy. Library of Virginia requires record retention for up to 10 years in some scenarios.

Returned Drugs to Pharmacy Form

Health Department _____

Contact Name _____

Contact Ph# _____

PO# (if applicable) _____

Date Returned _____

Reason for Return
(check all that apply)

- ☐ Expired medications
- ☐ Medications never left health department
- ☐ Medications left health department
  (please place in a separate bag with a note stating as such)

Additional Comments for Pharmacy _____
_____
_____

Include one form per box

Appendix J: PrEP Program Withdrawal Form

PrEP Program Withdrawal Form

Name:_____ **Date of Birth:**_____

Clinical Site:_____ **Date of Enrollment:**_____

Date of Withdrawal:_____

HIV Status:

- □ Reactive
- □ Non-reactive

Date of Test:_____

Withdrawal by Clinician	Self-Withdrawal
☐ Reactive HIV test result	☐ Change in risk behaviors
☐ Development of Renal Disease	☐ Side effects
☐ Use of Medication for unintended purposes	Please explain:_____
☐ Non-adherence to medication or appointments	_____
☐ Other, please	☐ Unable to keep up daily regimen
explain:_____	☐ Other, please
	explain:_____

By signing below, I_____, acknowledge that I will no longer be a participant of the Commonwealth of Virginia's PrEP Program for the uninsured. I understand that I will no longer receive prescriptions for Truvada through the program.

Signature:_____ **Date:**_____

Appendix K: Oral PrEP Medication Drug Interactions

Oral PrEP Medication Drug Interactions

	TDF	TAF
Buprenorphine	No significant effect No dosage adjustment necessary	
Methadone	No significant effect No dosage adjustment necessary	
Oral contraceptives	No significant effect No dosage adjustment necessary	
Feminizing hormones (Spironolactone, estrogens)	Lower tenofovir-diphosphate rectal tissue levels (unknown if it affects PrEP effectiveness). TDF does not affect hormone levels	*No data available*
Acyclovir, valacyclovir, cidofovir, ganciclovir, valganciclovir, aminoglycosides, high-dose or multiple NSAIDS or other drugs that reduce renal function or compete for active renal tubular secretion	Serum concentrations of these drugs and/or TDF may be increased. Monitor for dose-related renal toxicities	*No data available*
Adefovir	**Do not co-administer with TDF** Serum concentration of TDF may be increased, monitor for toxicities	*No data available*
Ledipasvir, sofosbuvir, velpatasvir, voxilaprevir	Serum concentrations of TDF may be increased. Monitor for toxicities	No significant effect
St John's Wort	No significant effect	**Do not co-administer with TAF** Decrease in TAF concentration possible
Rifampin	No significant effect	**Do not co-administer with TAF unless benefits outweigh risks**
Rifabutin, Rifapentine	No significant effect	**Do not co-administer with TAF**

Appendix L: VDH Visit Health History

VISIT HEALTH HISTORY

Instructions: Complete at each visit (except follow-up visits).

Date: ___ / ___ / _____

SECTION 1. SEXUAL HEALTH

- OFFICE USE ONLY -

Date and initial each entry

1. What brings you to the clinic today? *(check all that apply)*
   - ☐ Screening/testing only (NO SYMPTOMS)
   - ☐ I have symptoms that are bothering me
     Please describe your symptoms: _____
   - ☐ I was told to come by a partner or someone else
     Who told you to come? _____
   - ☐ My partner told me he/she has an STI
     Please specify which STI: _____
   - ☐ For birth control or family planning services
   - ☐ Follow-up visit or treatment
   - ☐ Other reason: _____

2. When was the last time you had sex (vaginal, anal, and/or oral) without a condom?
   (Or when the condom broke or fell off during sex?) _____ / _____ / _____

3. How often do you use condoms?
   ☐ Never ☐ Sometimes ☐ Always ☐ Other: _____

4. What types of sex have you had in the ***last year***? *(check all that apply)*
   - ☐ My mouth on my partner's (☐ vagina ☐ penis ☐ anus ☐ other: _____)
   - ☐ My partner's mouth on my (☐ vagina ☐ penis ☐ anus ☐ other: _____)
   - ☐ My vagina on my partner's (☐ vagina ☐ penis ☐ mouth ☐ other: _____)
   - ☐ My partner's vagina on my (☐ vagina ☐ penis ☐ mouth ☐ other: _____)
   - ☐ My penis in/on my partner's (☐ vagina ☐ mouth ☐ anus ☐ other: _____)
   - ☐ My partner's penis in/on my (☐ vagina ☐ mouth ☐ anus ☐ other: _____)
   - ☐ Shared sex toys with my partner

5. How many sex partners have you had ... in the ***last 2 months***? _____
   … in the ***last year***? _____

6. Is your current sex partner with you today for their own visit? ☐ Yes ☐ No

7. Are you or your partner currently using any method(s) to prevent pregnancy?
   ☐ Yes ☐ No ☐ Don't know ☐ Not applicable

   If yes, what method are you using? _____

   If no, would you like to discuss birth control options today? ☐ Yes ☐ No

SECTION 2. IF ASSIGNED FEMALE AT BIRTH

- OFFICE USE ONLY -

Date and initial each entry

8. Are you currently pregnant? ☐ Yes ☐ No ☐ Don't know

9. Do you need emergency contraception today?
   (like the "morning after pill" or Plan B) ☐ Yes ☐ No ☐ Don't know

- OFFICE USE ONLY –

☐ *Interpreter or assistive services used* ☐ *Declined*

Name: _____

Title: _____ Number: _____

LABEL

Date: ___ / ___ / _____

SECTION 3. HEALTH SCREENING QUESTIONS				**- OFFICE USE ONLY -**
Please answer the following questions:	**In the past year**	**In your lifetime**	**Never**	*Date and initial each entry*
10. Have you had sex with a male?	☐	☐	☐	
11. Have you had sex with a female?	☐	☐	☐	
12. Have you had sex with a transgender individual?	☐	☐	☐	
13. Have you had sex with strangers?	☐	☐	☐	
14. Have you had sex with someone who has HIV/AIDS?	☐	☐	☐	
15. Have you had sex with a man who has sex with other men?	☐	☐	☐	
16. Have you had sex for drugs, money, or other things you needed?	☐	☐	☐	
17. Have you had sex with someone who exchanges sex for money, drugs, or other things they need?	☐	☐	☐	
18. Have you stayed in jail or prison?	☐	☐	☐	
19. Have you injected a drug not prescribed by a doctor?	☐	☐	☐	
20. Have you snorted drugs?	☐	☐	☐	
21. Have you shared equipment for injecting or inhaling drugs, steroids, hormones, silicone, or other substances?	☐	☐	☐	
22. Have you gotten a tattoo or piercing outside of a licensed parlor?	☐	☐	☐	
23. Have you had sex with someone who has hepatitis C?	☐	☐	☐	
24. Have you lived with, or had sex with, someone who has hepatitis B?	☐	☐	☐	
25. Have you been hit, slapped, choked, sexually abused, or otherwise physically hurt by anyone, including someone you were dating or going out with?	☐	☐	☐	
26. Has anyone made you have sex (vaginal, oral, or anal) when you didn't want to, including someone you were dating or going out with?	☐	☐	☐	

27. Have you had sex with someone you met through the internet or a mobile app?
☐ Yes ☐ No
If yes, which sites or apps have you used? _____

28. Do you think (or know) that your sex partner has been having sex with someone else?
☐ Yes ☐ No ☐ Don't know

29. Are you interested in medication to prevent HIV (*i.e.* PrEP or nPEP)?
☐ Yes ☐ No ☐ Unsure

30. Have you ever had a HIV test? ☐ No ☐ Yes: Date of last test? _____

31. Have you ever had a syphilis test? ☐ No ☐ Yes: Date of last test? _____

32. Please list any specific questions you have for the provider today:

Reminder*: Record any changes to the client's medical or STI history on the "General Health History" form.*

- OFFICE USE ONLY -

REVIEW NOTES	***INITIALS***	***DATE***
☐ *Reviewed, no changes*		
☐ *Reviewed, changes as noted*		
☐ *Reviewed, no changes*		
☐ *Reviewed, changes as noted*		

LABEL

Appendix M: VDH Visit Health History - Instructions

VISIT HEALTH HISTORY - INSTRUCTIONS

Overview: This form is required for every visit with the exception of follow-up visits such as those for ongoing treatment and/or monitoring (i.e. Depo, wart treatment, etc.). This form should be completed for 3, 6, and 9-month PrEP visits, but not for PrEP medication pick-ups. The purpose of this form is to gather information on relevant sexual health history and risk factors indicating screening needs.

The screening questionnaire should be independently completed by the client before seeing the initial interviewer. The interviewer may be a clinician, nurse, nursing assistant (health care technician), DIS, or other authorized health department staff. The interviewer should review this form with the client.

Using this health history and the client's printed vaccine record, the interviewer should be able to get a preliminary assessment of the client's testing, vaccination, and education needs and to tailor the interview to the individual client.

If the patient cannot read and/or write, this form should be completed via verbal interview. If the patient is of limited English proficiency (LEP), this form should be completed via professional translator with verbal interview, and translator information must be noted per policy. Similarly, note if any other assistive services are required to complete this or any other forms.

Note: The CDC recommends testing of clients seeking services at an STI clinic at least annually for HIV, gonorrhea, chlamydia, and syphilis. Family planning clients should also be offered relevant STI screening, including annual chlamydia screening for all women under 25 years of age. Clients at higher risk, such as those with more than one sex partner, should be offered testing every 3 months.

GENERAL FORM INSTRUCTIONS

LABEL: The client label should be placed on the bottom right corner of each page of the health history.

VISIT DATE: The date of the visit must be completed on each page.

OFFICE USE ONLY: These sections should be used by the interviewer (nurse, DIS, clinician, or other staff) to document any notes or clarification about the client's responses to the visit health history form. The initial interviewer should document any clarification notes about the client's response to the visit health history. At the end of the form, the interviewer should check whether they made any changes or not, and then initial and date. Any subsequent interviewer should note their changes or additions and initial each note, and also initial and date at the end of the form. This form is only used for one visit.

SECTION 1. SEXUAL HEALTH

Question 1: The reason the client gives for attending clinic should be used to guide the visit, including whether the client requires a physical examination and/or testing/counseling.

Question 2: The last date of sex without a condom may be used to determine the accuracy and appropriateness of each STI screening test at the clinic visit. The window periods of tests should be explained to clients in relation to the date of last sex. For biologically female clients not seeking pregnancy, the date of last sex can help identify the appropriate window for emergency contraception and need for pregnancy testing.

Question 3: The frequency of condom use can be used to inform screening recommendations and counseling.

Question 4: Information on the client's current sexual practices should be used to determine appropriate testing and education. Specifically:

a. ***For mouth to partner's vagina:*** educate about dental dams and the HPV vaccine; test for pharyngeal GC/CT, syphilis, and HIV.

For mouth to partner's penis: educate about condoms; test for pharyngeal GC/CT, syphilis, and HIV.
For mouth to partner's anus: educate about dental dams, the risk of enteric illnesses, and the Hepatitis A vaccine; test for pharyngeal GC/CT, syphilis, and HIV.

b. ***For partner's mouth on anus:*** educate about dental dams, the risk of enteric illnesses, and the Hepatitis A vaccine.
For partner's mouth on penis or vagina: educate about dental dams and/or condoms; test for urogenital GC/CT, syphilis, and HIV.
c. ***For vagina on partner's vagina:*** educate about increased risk of bacterial vaginosis and trichomonas; test for GC/CT, syphilis, and HIV; offer trichomonas testing.
d. ***For penis to partner's vagina, mouth, or anus:*** test for urogenital GC/CT, syphilis, and HIV; for those reporting penile-vaginal sex, consider offering trichomonas testing.
e. ***For partner's penis in vagina:*** test for urogenital GC/CT, syphilis, and HIV; offer trichomonas testing.
For partner's penis in mouth: test for pharyngeal GC/CT, syphilis, and HIV.
For partner's penis in anus: test for rectal GC/CT, syphilis, and HIV.
f. ***For shared sex toys:*** It may be appropriate to test for GC/CT, syphilis, and HIV depending on how the toys were shared. Among women who have sex with women, educate about increased risk of bacterial vaginosis and trichomonas. Test for GC/CT, syphilis, and HIV as indicated; consider offering trichomonas testing if available/feasible.

Question 5: The number of recent sex partners can be used to inform screening recommendations and counseling. It may also help the DIS to identify the number of possible contacts if the client tests positive for a reportable STI.

Question 6: If the client's sex partner is also present at the clinic, the nurse/clinician should address any joint screening, intervention, or treatment needs. It is important to clarify whether the partner is only present for company, or for his/her own clinic visit. If the client's partner is present, be sure to maintain HIPAA confidentiality, or ensure that both clients sign a consent to exchange information.

Question 7: This question can help to guide the interviewer's questions regarding family planning and contraceptive needs. If client is interested in discussing birth control, provide them with the mandatory education and counseling as described in the VDH Family Planning manual. If the client is interested in discussing birth control but the clinic cannot provide birth control at that visit, educate client about birth control methods and arrange for appropriate follow-up or referral.

SECTION 2. IF ASSIGNED FEMALE AT BIRTH

Question 8: If the client reports being pregnant, she should be seen by the provider for evaluation of symptoms. If a provider is not available, symptomatic pregnant clients should be referred to local resources. STI screening services may be offered to asymptomatic pregnant clients if a provider is not available. Pregnancy tests can be performed during clinic visit and documented on the visit record. If women indicate they don't know pregnancy status, offer a pregnancy test during the visit or provide information on how to obtain one.

Question 9: If a biologically female client, who is not using birth control and is not seeking pregnancy, has had unprotected vaginal intercourse in the last 72 hours (see question 2) and would like emergency contraception, it should be offered and documented in the visit record (as given, declined, referred).

OFFICE USE ONLY – INTERPRETER/ASSISTIVE SERVICES

If the patient requires a professional translator due to limited English proficiency (LEP), or requires other assistive services, use this section to document the translator's name, title, and number as applicable.

SECTION 3. HEALTH SCREENING QUESTIONS

Questions 1-12: Clients identify the gender of their sexual partners. These answers should guide the interview process. If uninsured, men and transwomen who have had sex with men in the past year are eligible for ***Hepatitis B & C testing*** through the Office of Epidemiology.

Question 13: Clients who have had anonymous sex may be at increased risk for STI acquisition and should be encouraged to regularly test for syphilis, HIV, and gonorrhea and chlamydia at all appropriate sites.

Question 14: Identifies clients who may be at increased risk for STI acquisition and should be encouraged to regularly test for syphilis, HIV, and gonorrhea and chlamydia at all appropriate sites. Education should be provided on risk reduction, HIV window periods and retesting dates, and HIV Pre- and Post-Exposure Prophylaxis (PrEP and nPEP).

Question 15: Clients who report that they have had sex with an MSM in the past year are at an increased risk for STIs and should be encouraged to be tested for syphilis, HIV, and gonorrhea and chlamydia at all appropriate anatomical sites.

Questions 16-17: These questions help identify clients who may be at increased risk for STI acquisition and should be encouraged to regularly test for syphilis, HIV, and gonorrhea and chlamydia at all appropriate sites. If uninsured, they are also eligible for both ***Hepatitis B & C testing*** through the Office of Epidemiology. Risk reduction education should be provided and referrals made per patient request (document referrals on the visit record).

Question 18: Helps identify clients who may be at increased risk for ***Hepatitis B & C*** and, if uninsured, are eligible for testing through the Office of Epidemiology.

Questions 19-21: These questions help identify clients who may be at increased risk for STI acquisition and should be encouraged to regularly test for syphilis, HIV, and gonorrhea and chlamydia at all appropriate sites. If uninsured, they are also eligible for both ***Hepatitis B & C testing*** through the Office of Epidemiology. Risk reduction education should be provided and referrals made per patient request (document referrals on the visit record).

Question 22-23: Helps identify clients who may be at increased risk for ***Hepatitis C*** and, if uninsured, are eligible for ***Hepatitis C testing*** through the Office of Epidemiology.

Question 24: Helps identify clients who may be at increased risk for ***Hepatitis B*** and, if uninsured, are eligible for ***Hepatitis B testing*** through the Office of Epidemiology. Education about the hepatitis B vaccine should be provided. If available, the client should be offered the opportunity to receive a dose of the ***Hep B vaccine*** during the clinic visit.

Questions 25-26: Helps identify clients who may be at increased risk for STI acquisition and should be encouraged to regularly test for syphilis, HIV, and gonorrhea and chlamydia at all appropriate sites. Referrals should be made to intimate partner violence (IPV), domestic violence, and/or sexual assault services as necessary. Document all referrals on the visit record. Follow existing policies for providing services to minors and mandatory reporting if applicable.

Question 27: Helps identify clients who may be at increased risk for STI acquisition and should be encouraged to regularly test for syphilis, HIV, and gonorrhea and chlamydia at all appropriate sites. Identifying the most

common internet sites and apps will help to guide DIS investigations and possible future public health interventions.

Question 28: If a client's partner has other partners, it increases the likelihood of STI acquisition. The client should be encouraged to test for syphilis, HIV, gonorrhea and chlamydia at all appropriate anatomical sites.

Question 29: Allows clients to indicate whether they are interested in learning more about PrEP or PEP. Clients indicating interest should be offered PrEP or PEP, or referred to appropriate services (document all referrals in the visit record).

Question 30-31: Information on the date of the client's last (i.e. most recent) HIV and syphilis tests should be used to inform current testing recommendations.

Question 32: Allows clients to identify any further topics or issues that they would like to discuss. Appropriate education and referrals should be provided and documented on the visit record.

OFFICE USE ONLY

History reviewed by: The interviewer and reviewer (if applicable) should initial and date the interview record at the bottom of the second page after reviewing it with the client. If the client will see a clinician during their visit, then a clinician must review and initial this form. For nurse-only (non-clinician) visits, then a nurse must review and initial this form. Any changes to the client's medical or sexually transmitted infection history should be recorded on the "General Health History" form.

Appendix N: Virginia Pre-Exposure (PrEP) Program Confidential Application

Virginia Pre-Exposure Prophylaxis (PrEP) Program (PrEP Program) CONFIDENTIAL APPLICATION

☐ **APPROVED**

SECTION 1: APPLICANT INFORMATION

Must Provide Proof of Legal Name

Legal Last Name: _____ **Legal First Name:**_____ **MI:**_____

Preferred name (if different than legal name):_____

Date of Birth: ____/____/_____ **Email:** _____
MM DD YYYY

Assigned Sex at Birth: ☐ male ☐ female

Current Gender Identity: ☐ male ☐ female ☐ transgender(male to female) ☐ transgender (female to male)
☐ transgender-unspecified: _____

Pronoun (optional): ☐ he/him ☐ she/her ☐they/they

Home Address If you have a home address, complete the address field below. **Must Provide Proof of Virginia Residency**
If you do not have a home address, complete the **No Home Address Declaration.** **PO Boxes cannot be accepted**

Address:_____ **Apartment/Unit #:** _____

City:_____ **State:** ___ **ZIP:** _____

No Home Address Declaration If you do not have a home address complete the following statement:
I do not have a home address. Last night I stayed (circle):
☐at a park ☐in a car ☐ at a shelter ☐on the street ☐with family/friends ☐somewhere else

In the city of:_____

Mailing Address Same as my home address above: ☐ Yes ☐ No **If no**, please provide a physical address below.
PO Boxes cannot be accepted

Address:_____ **Apartment/Unit #:** _____

City:_____ **State:** VA **ZIP:** _____

Primary Phone: (___)_____-_____ **May we leave a voicemail?** ☐ Yes ☐ No

¿Quisiera usted recibir documentos de nosotros en español?
Would you like to receive documents from us in Spanish? ☐ Sí ☐ No

Race (Check all that apply)
☐ Asian
☐ Black/African American
☐ White/Caucasian
☐ Alaska Native/American Indian
☐ Native Hawaiian/Pacific Islander
☐ Other, specify:_____

Ethnicity (Check One):
☐ Hispanic/Latino(a)
☐ Non-Hispanic/Latino(a)

Virginia Pre-Exposure Prophylaxis (PrEP) Program
(PrEP Program) CONFIDENTIAL APPLICATION

Health Insurance

Do you currently have any type of health insurance? □ Yes □ No
If yes, does your insurance provide prescription drug coverage? □ Yes □ No

Do you have Medicaid coverage? □ Yes □ No
If no, does the client meet the eligibility standards? □ Yes □ No
(between the ages of 18 to 64 & income under 138% of FPL)
If eligible, has the client applied for Medicaid? □ Yes □ No **Date of application:**_____

Medical History

Please list all allergies: _____

Prior to today, have you ever been diagnosed with (check all that apply):
□ Syphilis □ Gonorrhea □ Chlamydia
If you checked any of the boxes above, were you diagnosed with these in the last year? □ Yes □ No

Have you ever used any of the following substances (check all that apply):
- □ Alcohol (ex. beer, wine, liquor)
- □Amphetamines (ex. meth, speed, non- prescription use of Adderall)
- □ Cocaine or crack-cocaine
- □ MDMA (ex. molly, ecstasy)
- □ Hallucinogens (ex. LSD, acid, mushrooms)
- □ GHB
- □ Marijuana (ex. joints, blunts, edibles)
- □ Opiates (ex. heroin, Fentanyl, OxyContin or Morphine)

Have you ever injected any of the following substances (check all that apply):
- □Amphetamines (ex. meth, speed, non-prescription use of Adderall)
- □ Cocaine or crack-cocaine
- □ Opiates (ex. heroin, Fentanyl, OxyContin or Morphine)
- □ Injected other substance, specify: _____

Please check ALL risk categories that apply to you:
- □ Man who has sex with men and engages in unprotected anal intercourse
- □ Diagnosed with a Sexually Transmitted Infection (example: syphilis, gonorrhea, chlamydia)
- □ Exposure to an STI through a sexual network
- □ Ten or more sexual partners
- □ Injection drug user who has shared injection drug equipment and/ or injected one or more times a day and/or injected methamphetamines and/or engaged in high risk sexual behavior
- □ Have had unprotected anal intercourse with a partner of unknown HIV-1 status with any of the factors listed above
- □ Engaged in transactional sex (sex for money, drugs, gifts, etc.)
- □ Engage in high risk sexual behaviors with known HIV-infected partner

What is your annual income from all sources? $_____

In order to process your application in a timely manner it is important that the application is complete. If your application is not complete, we will not be able to process your application and there may be a delay in obtaining your medication.

Virginia Pre-Exposure Prophylaxis (PrEP) Program
(PrEP Program) CONFIDENTIAL APPLICATION

Authorized Representative

Please provide the following information for any family/friends you would like us to be able to talk to about your participation in the PrEP Program

First and Last Name:_____

Primary Phone Number: _____ **Email:**_____

Date of Birth: _____/_____/_____
MM DD YYYY

Eligibility, Agreement, Release of Information, & Assignment of Benefits

CONSENT and Signature

In accordance with the Health Insurance Portability and Accountability Act (HIPAA) regulation at §164.508, it is VDH's policy that uses and disclosures of your protected health information (PHI) must be made with your written authorization. By signature of this Authorization Form, you authorize VDH to release records necessary to support your application for payment by Medicare, Medicaid, and/or other health care benefits. Your signature on this Authorization Form requests third party payers to pay any authorized benefits to VDH on your behalf, and you hereby give your authorization to VDH to obtain, verify, and/or release your demographic, medical, prescription, and/or insurance coverage information with other entities, as necessary, to effectively manage your medication access. You understand that your information may be shared with, but is not limited to the following: physicians, health department personnel, other Division of Disease Prevention programs (including Surveillance, Care and Prevention), treatment center personnel, pharmacy services provider, referral source, clinic, insurance broker and/or insurance carrier. It is VDH's policy to safeguard your PHI disclosures. VDH agrees to treat any and all PHI as confidential as required by HIPAA at §164.530(c). At your request, VDH will provide you with an accounting of the uses and disclosures made with your PHI, in accordance with the HIPAA Privacy Rule at §164.528 and §164.514(d)(3). VDH will also accommodate your right to inspect and obtain a copy of your PHI for as long as VDH maintains the information. This authorization will remain in effect for as long as you and your dependent remain a participant in the PrEP Program or until you revoke it. You have the right to revoke this authorization at any time, provided that your request for revocation is submitted in writing, as required by HIPAA at §164.508(b)(5).

By signature of this Client Responsibilities and Release of Authorization, you certify that all information is correct to the best of your knowledge, and that if any of your eligibility information changes you agree to update the program with any changes in your income or eligibility.

I have read, understand and agree to the above ***Client Responsibilities and Release of Authorization****. I have verified that the information provided in this application is complete and accurate to the best of my knowledge.*

_____ _____
Signature of Client, Parent/Legal Guardian or Person acting in Loco Parentis Date Signed

_____
Relationship (If signature is not of Client)

_____ _____
Signature of Person Obtaining Consent Date Signed

Please provide the information below if a friend, family member or advocate helped to complete this application:

First Name	MI	Last Name
Address		
City	State	Zip
Phone Number		

Checklist for Submitting a Complete PrEP Program Application:

☐ Proof of Legal Name (New PrEP Program Applicants Only)

Please provide us a copy of one of the following to verify your full legal name:

- Any state driver's license or identification card
- Passport

☐ Proof of VA Residency

Please provide us a copy of one of the following to verify your VA residency:

- Current Virginia State driver's license or identification card
- Virginia voter registration card
- Utility bill or recent cell phone bill
- Lease/rental/mortgage agreement

☐ Proof of Income

Please provide us a copy of one of the following to verify your proof of income:

- Copies of three most recent, consecutive pay stubs that show group income and payroll deductions complete copy of most recent Federal Income tax return
- Veteran's or other retirement benefits (a copy of award letter or any other official documentation showing the amount received on a regular basis)
- Government benefits and/or award (such as Social Security and unemployment benefits)

☐ Proof of No Income

Please provide us a copy of one of the following to verify no income proof:

- Termination or layoff notice from most recent employer on company letterhead
- A "proof of no income" letter that identifies the source of the applicant's food and shelter (letter signed by agency, shelter, relative, friend, or some other non-agency source of support)

☐ Medicaid Enrollment

Please remember to answer these questions, when completing a PrEP Program application:

- Does the client has Medicaid?
- Is the client Medicaid eligible?
- Has the Medicaid application process been initiated?

☐ Insurance Card

If you have insurance, please provide us a copy of your insurance card.

☐ Application completed in pen

☐ Application filled out completely (both Section 1 & Section 2) with all required documentation, dates and signatures

Virginia Pre-Exposure Prophylaxis (PrEP) Program
(PrEP Program) CONFIDENTIAL APPLICATION

SECTION 2: HIV & HEALTH STATUS INFORMATION

We must confirm your HIV and health status in order to process your application. This section must be completed by you **and** your health care provider. Please submit this form to us with this application or ask your health care provider to send it directly by mail or fax. You can call us at 804-864-7938 if you have questions about this form.

Client Section – To Be Completed By The Client

I authorize my health care provider to release the information on this form to the Virginia State Department of Health.

Full Legal Name _____ Date of Birth _____
(MM/DD/YYYY)

_____ _____
Applicant or Legal Guardian Signature **(Do Not Leave Blank)** Today's Date (MM/DD/YYYY) **(Do Not Leave Blank)**

Health Care Provider Section – To Be Completed By The Health Care Provider □ 340b

Is this patient HIV negative? □ Yes □ No **Date of last negative HIV test:** ____/_____/_____
MM DD YYYY

Name of health department or clinic for medication pick-up:_____

Address:_____

City: _____ **State:** VA **ZIP:** _____

By signing below, you:

- Confirm that you have evidence of the patient's HIV status and risk.
- Certify the information on this form is accurate and complete to the best of your knowledge.

_____ _____
Health Care Provider Signature **(Do Not Leave Blank)** Today's Date (mm/dd/yyyy) **(Do Not Leave Blank)**

_____
Health Care Provider – Print First & Last Name

Send to: ATTN: DDP at PO Box 2448, Richmond, VA, 23218-2448 or Fax #: 804-864-8053

For persons with disabilities, this document is available on request in other formats. To submit a request, please call 1-800-864-VDH (TDD/TTY call 711).

Appendix O: Virginia Pre-Exposure (PrEP) Program Confidential Application (Fillable Version)

Virginia Pre-Exposure Prophylaxis (PrEP) Program (PrEP Program) CONFIDENTIAL APPLICATION

☐ **APPROVED**

SECTION 1: APPLICANT INFORMATION

Must Provide Proof of Legal Name

Legal Last Name: _____ **Legal First Name:** _____ **MI:** _____

Preferred name (if different than legal name): _____

Date of Birth: _____ (MM DD YYYY) **Email:** _____

Assigned Sex at Birth: ☐ male ☐ female

Current Gender Identity ☐ male ☐ female ☐ transgender(male to female) ☐ transgender (female to male)
☐ transgender-unspecified: _____

Pronoun (optional): ☐ he/him ☐ she/her ☐ they/they

Home Address If you have a home address, complete the address field below. **Must Provide Proof of Virginia Residency**
If you do not have a home address, complete the **No Home Address Declaration.** **PO Boxes cannot be accepted**

Address: _____ **Apartment/Unit #:** _____

City: _____ **State:** ☐ **ZIP:** _____

No Home Address Declaration If you do not have a home address complete the following statement:
I do not have a home address. Last night I stayed (circle):
☐ at a park ☐ in a car ☐ at a shelter ☐ on the street ☐ with family/friends ☐ somewhere else

In the city of: _____

Mailing Address Same as my home address above: ☐ Yes ☐ No **If no**, please provide a physical address below.
PO Boxes cannot be accepted

Address: _____ **Apartment/Unit #:** _____

City: _____ **State:** VA **ZIP:** _____

Primary Phone: _____ **May we leave a voicemail?** ☐ Yes ☐ No

¿Quisiera usted recibir documentos de nosotros en español?
Would you like to receive documents from us in Spanish? ☐ Sí ☐ No

Race (Check all that apply)
☐ Asian
☐ Black/African American
☐ White/Caucasian
☐ Alaska Native/American Indian
☐ Native Hawaiian/Pacific Islander
☐ Other, specify: _____

Ethnicity (Check One):
☐ Hispanic/Latino(a)
☐ Non-Hispanic/Latino(a)

Virginia Pre-Exposure Prophylaxis (PrEP) Program
(PrEP Program) CONFIDENTIAL APPLICATION

Health Insurance

Do you currently have any type of health insurance? ☐ Yes ☐ No
If yes, does your insurance provide prescription drug coverage? ☐ Yes ☐ No

Do you have Medicaid coverage? ☐ Yes ☐ No
If no, does the client meet the eligibility standards? ☐ Yes ☐ No
(between the ages of 18 to 64 & income under 138% of FPL)
If eligible, has the client applied for Medicaid? ☐ Yes ☐ No **Date of application:** _____

Medical History

Please list all allergies: _____

Prior to today, have you ever been diagnosed with (check all that apply):
☐ Syphilis ☐ Gonorrhea ☐ Chlamydia
If you checked any of the boxes above, were you diagnosed with these in the last year? ☐ Yes ☐ No

Have you ever used any of the following substances (check all that apply):
- ☐ Alcohol (ex. beer, wine, liquor)
- ☐ Amphetamines (ex. meth, speed, non- prescription use of Adderall)
- ☐ Cocaine or crack-cocaine
- ☐ MDMA (ex. molly, ecstasy)
- ☐ Hallucinogens (ex. LSD, acid, mushrooms)
- ☐ GHB
- ☐ Marijuana (ex. joints, blunts, edibles)
- ☐ Opiates (ex. heroin, Fentanyl, OxyContin or Morphine)

Have you ever injected any of the following substances (check all that apply):
- ☐ Amphetamines (ex. meth, speed, non-prescription use of Adderall)
- ☐ Cocaine or crack-cocaine
- ☐ Opiates (ex. heroin, Fentanyl, OxyContin or Morphine)
- ☐ Injected other substance, specify: _____

Please check ALL risk categories that apply to you:
- ☐ Man who has sex with men and engages in unprotected anal intercourse
- ☐ Diagnosed with a Sexually Transmitted Infection (example: syphilis, gonorrhea, chlamydia)
- ☐ Exposure to an STI through a sexual network
- ☐ Ten or more sexual partners
- ☐ Injection drug user who has shared injection drug equipment and/ or injected one or more times a day and/or injected methamphetamines and/or engaged in high risk sexual behavior
- ☐ Have had unprotected anal intercourse with a partner of unknown HIV-1 status with any of the factors listed above
- ☐ Engaged in transactional sex (sex for money, drugs, gifts, etc)
- ☐ Engage in high risk sexual behaviors with known HIV-infected partner

What is your annual income from all sources? $ _____

In order to process your application in a timely manner it is important that the application is complete. If your application is not complete, we will not be able to process your application and there may be a delay in obtaining your medication.

Virginia Pre-Exposure Prophylaxis (PrEP) Program
(PrEP Program) CONFIDENTIAL APPLICATION

Authorized Representative

Please provide the following information for any family/friends you would like us to be able to talk to about your participation in the PrEP Program

First and Last Name:

Primary Phone Number: **Email:**

Date of Birth:
MM DD YYYY

Eligibility, Agreement, Release of Information, & Assignment of Benefits

CONSENT and Signature

In accordance with the Health Insurance Portability and Accountability Act (HIPAA) regulation at §164.508, it is VDH's policy that uses and disclosures of your protected health information (PHI) must be made with your written authorization. By signature of this Authorization Form, you authorize VDH to release records necessary to support your application for payment by Medicare, Medicaid, and/or other health care benefits. Your signature on this Authorization Form requests third party payers to pay any authorized benefits to VDH on your behalf, and you hereby give your authorization to VDH to obtain, verify, and/or release your demographic, medical, prescription, and/or insurance coverage information with other entities, as necessary, to effectively manage your medication access. You understand that your information may be shared with, but is not limited to the following: physicians, health department personnel, other Division of Disease Prevention programs (including Surveillance, Care and Prevention), treatment center personnel, pharmacy services provider, referral source, clinic, insurance broker and/or insurance carrier. It is VDH's policy to safeguard your PHI disclosures. VDH agrees to treat any and all PHI as confidential as required by HIPAA at §164.530(c). At your request, VDH will provide you with an accounting of the uses and disclosures made with your PHI, in accordance with the HIPAA Privacy Rule at §164.528 and §164.514(d)(3). VDH will also accommodate your right to inspect and obtain a copy of your PHI for as long as VDH maintains the information. This authorization will remain in effect for as long as you and your dependent remain a participant in the PrEP Program or until you revoke it. You have the right to revoke this authorization at any time, provided that your request for revocation is submitted in writing, as required by HIPAA at §164.508(b)(5).

By signature of this Client Responsibilities and Release of Authorization, you certify that all information is correct to the best of your knowledge, and that if any of your eligibility information changes you agree to update the program with any changes in your income or eligibility.

*I have read, understand and agree to the above **Client Responsibilities and Release of Authorization**. I have verified that the information provided in this application is complete and accurate to the best of my knowledge.*

Signature of Client, Parent/Legal Guardian or Person acting in Loco Parentis

Date Signed

Relationship (If signature is not of Client)

Signature of Person Obtaining Consent

Date Signed

Please provide the information below if a friend, family member or advocate helped to complete this application:

First Name MI Last Name

Address

City State Zip

Phone Number

Checklist for Submitting a Complete PrEP Program Application:

☐ **Proof of Legal Name (New PrEP Program Applicants Only)**

Please provide us a copy of one of the following to verify your full legal name:

- Any state driver's license or identification card
- Passport

☐ **Proof of VA Residency**

Please provide us a copy of one of the following to verify your VA residency:

- Current Virginia State driver's license or identification card
- Virginia voter registration card
- Utility bill or recent cell phone bill
- Lease/rental/mortgage agreement

☐ **Proof of Income**

Please provide us a copy of one of the following to verify your proof of income:

- Copies of three most recent, consecutive pay stubs that show group income and payroll deductions complete copy of most recent Federal Income tax return
- Veteran's or other retirement benefits (a copy of award letter or any other official documentation showing the amount received on a regular basis)
- Government benefits and/or award (such as Social Security and unemployment benefits)

☐ **Proof of No Income**

Please provide us a copy of one of the following to verify no income proof:

- Termination or layoff notice from most recent employer on company letterhead
- A "proof of no income" letter that identifies the source of the applicant's food and shelter (letter signed by agency, shelter, relative, friend, or some other non-agency source of support)

☐ **Medicaid Enrollment**

Please remember to answer these questions, when completing a PrEP Program application:

- Does the client has Medicaid?
- Is the client Medicaid eligible?
- Has the Medicaid application process been initiated?

☐ **Insurance Card**

If you have insurance, please provide us a copy of your insurance card.

☐ **Application completed in pen**

☐ **Application filled out completely (both Section 1 & Section 2) with all required documentation, dates and signatures**

Virginia Pre-Exposure Prophylaxis (PrEP) Program
(PrEP Program) CONFIDENTIAL APPLICATION

SECTION 2: HIV & HEALTH STATUS INFORMATION

We must confirm your HIV and health status in order to process your application. This section must be completed by you **and** your health care provider. Please submit this form to us with this application or ask your health care provider to send it directly by mail or fax. You can call us at 804-864-7938 if you have questions about this form.

Client Section – To Be Completed By The Client

I authorize my health care provider to release the information on this form to the Virginia State Department of Health.

Full Legal Name _____ Date of Birth _____ (MM/DD/YYYY)

_____ _____

Applicant or Legal Guardian Signature **(Do Not Leave Blank)** Today's Date (MM/DD/YYYY) **(Do Not Leave Blank)**

Health Care Provider Section – To Be Completed By The Health Care Provider ☐ 340b

Is this patient HIV negative? ☐ Yes ☐ No **Date of last negative HIV test:** _____ MM DD YYYY

Name of health department or clinic for medication pick-up: _____

Address: _____

City: _____ **State:** VA **ZIP:** _____

By signing below, you:

- Confirm that you have evidence of the patient's HIV status and risk.
- Certify the information on this form is accurate and complete to the best of your knowledge.

_____ _____

Health Care Provider Signature **(Do Not Leave Blank)** Today's Date (mm/dd/yyyy) **(Do Not Leave Blank)**

_____

Health Care Provider – Print First & Last Name

Send to: ATTN: DDP at PO Box 2448, Richmond, VA, 23218-2448 or Fax #: 804-864-8053

For persons with disabilities, this document is available on request in other formats. To submit a request, please call 1-800-864-VDH (TDD/TTY call 711).

Appendix P: Virginia PrEP Drug Assistance Program

No Income Verification Letter

Virginia PrEP Drug Assistance Program
No Income Verification Letter

I understand that *(insert name):*_____ is receiving assistance from the Virginia Department of Health (VDH). To the best of my knowledge, the applicant has no income and I certify this to be true. I am either providing the applicant with food and shelter or providing the applicant with financial support.

I am providing (check one):

- ☐ Food and Shelter
- ☐ Financial Support $_____ approximate amount per month

_____

(My relationship to the applicant-for example: friend, cousin)

_____ _____

Signature of person providing support Printed name of person providing support

_____

Address

_____ _____

Telephone number Date

If you have any questions, please contact VDH at **804-763-9506**. Please fax back to **804-864-8053** or mail to **P.O. Box 2448, Room 338, Richmond, Virginia 23218, Attn: Eric Mayes.**

Appendix Q: PrEP Medication Order Form

PrEP Medication Order Form

Refills will not be processed until 21 days after the last fill date.

BEFORE requesting a refill from the Division of Pharmacy Services, complete the following checklist:

- Has the client picked up their last medication order? Yes or No (circle one). If yes, request medication refill.
- If yes, write in the date here: _____
- If no, why? _____ **Do not request more medication.**
- Does the client need a new HIV test? Yes or No (circle one) If yes, do not request medication refill.

***Note: a new HIV test is required if client missed a pick-up.**

- Does the client need a new prescription? Yes or No (circle one) If yes, submit new prescription with medication refill.

1. Program/Provider Site: _____

2. Program Site PrEP Navigator/Contact Name: _____

3. Program Site Contact Phone Number: _____

4. Program Site Contact Phone Fax Number: _____

5. Pick-up Site: _____

6. Medication Ordered By: _____ Date: _____

PrEP Client Name and Date of Birth **Name:**	*Pharmacy Use*

Client Signature: _____

Pick-up Date: _____

Instructions:

1. Complete checklist at top of form.
2. Complete all fields
   (Fields 1- 5 may be pre-filled. Field 6 should be signed and dated each month by the person placing the order.)
3. If this is the initial order - fax this form and the prescription to the Division of Pharmacy Services at: 804-371-0236 **and** to the Division of Disease Prevention (DDP) at 804-864-8053
4. **After form is signed by client - fax this form only to DDP**

Appendix R: Supplemental HIV Test Result Form

Supplemental HIV Test Result

HIV STATUS UPDATE:

INSTRUCTIONS: *This form must be submitted to the PrEP Program if the patient has not received their medication within the last 30 days or the Division of Pharmacy Services will not release any more medication.*

1. The provider must:
   a. Review the HIV test result, and record it by checking the appropriate box in Section 2 along with the date of the test.
   b. If the medication is being sent to a local health department or a clinical site, fill in the appropriate address,
   c. Sign and date to certify the HIV test result.
   d. Fax the completed form to the Division of Disease Prevention PrEP program at: **804-864-8053.** Do not fax this form to the Division of Pharmacy Services.

Record and Certify HIV Test Result:

Patient's name:_____ **Date of Birth:**____/_____/_____
MM DD YYYY

Is this patient HIV negative? □ Yes □ No **Date of last negative HIV test:** ____/_____/_____
MM DD YYYY

***Name of health department or clinic for medication pick-up:**_____

Address:_____

City: _____ **State:** VA **ZIP:** _____

**** Complete only if the client is picking up medication at a clinical site or local health department. For clients picking up at a local health department be sure there is a completed encounter for each medication pick-up.***

By signing below, you:

- Confirm that you have evidence of the patient's HIV status and risk.
- Certify the information on this form is accurate and complete to the best of your knowledge.

_____ _____
Health Care Provider Signature (Do Not Leave Blank) Today's Date (Do Not Leave Blank)

_____
Health Care Provider – Print First & Last Name

For DDP Use Only - Approved By: ☐ **340b**

_____ _____
Signature Date

Fax completed form to 804-864-8053. Do not fax this form to the Division of Pharmacy Services.

For persons with disabilities, this document is available on request in other formats. To submit a request, please call 1-800-864-VDH (TDD/TTY call 711).

Appendix S: Request for Alternate Delivery of Medication Form

Request for Alternate Delivery of Medication (Ship to Home)

Program: ☐TB ☐FP ☐STI ☐MCH ☐VA MAP ☐PrEP

Billing Information for Health Department: Cost Code:_____ FIPS:_____ PSD _____

If unsure of coding, consult the district business manager. Billing information not required for VA MAP or PrEP.

Health Department Site:_____

Contact Person:_____

Contact Phone:_____

Fax Number:_____

Note: For VA MAP and PrEP, health department is the medication access site, which could be non-health department clinics and pharmacies that are pick-up sites.

Client Name:_____ **Date of Birth:_____**

Shipping Address:_____

Current client address has been verified: ☐ **Date:_____**

Client Phone Number:_____

Medication(s) Requested to be Shipped to Above Address:

_____

_____

_____

_____

Information below for pharmacy staff to complete and fax back to Health Department at fax listed above:

Tracking Number:_____

Shipping Cost: _____ Date Received:_____