HIV Pre-Exposure Prophylaxis (PrEP) Clinical Guidelines

PREPARED BY:
THE HIV/AIDS SECTION – MEDICAL TEAM
BUREAU OF COMMUNICABLE DISEASES
DIVISION OF DISEASE CONTROL AND HEALTH PROTECTION
FLORIDA DEPARTMENT OF HEALTH

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One goal of the Florida Department of Health (Department) is to reduce the number of new diagnoses of HIV in the state of Florida. Biomedical interventions are now available which allow an individual to take a medication daily which will significantly reduce the risk of acquiring HIV. This biomedical intervention is called pre-exposure prophylaxis or PrEP.

This guidance presents an overview of relevant information for clinicians, including physicians, physician assistants, nurse practitioners and registered nurses, who are providing PrEP in clinical settings. Important considerations for starting and monitoring a patient on PrEP are presented below.

Prior to starting an individual on PrEP, the HIV status of the individual must be ascertained. This can be done using a confirmatory HIV test result received within the past seven days, or with a negative rapid HIV test at time of PrEP initiation, with a blood based confirmatory test drawn at the same time.

Prep is indicated for the following hiv negative individuals:

- Persons with a sexual partner living with HIV who is not consistently virally suppressed, or
- Persons who inject drugs, or
- Sexually active persons not in a monogamous relationship with someone known HIV negative AND with any of the following:
 - Vaginal or anal sexual intercourse without condoms, or
 - A sexual partner with one or more HIV risk factors, or
 - A history of a sexually transmitted infection (STI) by lab testing or self-report or syndromic STI treatment, or
 - A person deemed at risk of HIV acquisition at the end of non-occupational postexposure prophylaxis (nPEP) therapy, or
 - sharing needles or works, or
 - A patient requesting PrEP

CONTRAINDICATIONS:

- HIV-positive status
- Estimated creatinine clearance less than 60 mL/min for Truvada®
- Estimated creatinine clearance less than 30 mL/min or women using vagina for sex for Descovy[®]
- Signs/symptoms of acute HIV infection with history of recent at-risk exposure
- Allergy or contraindication to any medicine in the PrEP regimen
- Individuals that are unwilling to take a pill every day or follow-up every three months for lab work

KEY EFFECTIVENESS MESSAGES:

- PrEP is highly effective for preventing HIV infection when taken every day as prescribed
- PrEP does not prevent pregnancy or STIs

SIDE-EFFECTS:

- PrEP users may have side-effects such as nausea, abdominal cramps, headache; these
 are usually mild and resolve over the first few weeks of taking PrEP.
- New onset or worsening renal function is possible with Truvada® for PrEP use.
- One percent average loss of bone mineral density; recovers after discontinuing Truvada® for PrEP use.

CODING FOR PrEP VISITS:

- PrEP Initial/Counseling 5701
- PrEP Initiation/Prep Rx 5702
- PrEP Follow-Up/Rx Refill 5703
- For further coding information: HMS Service and Time

REQUIRED LABORATORY TESTS FOR INITIAL PrEP SERVICES:

- Point of care HIV test and HIV-1/2 antigen/antibody blood-based test.
- Comprehensive Metabolic Panel or serum creatinine to calculate creatinine clearance. See link to calculate creatinine clearance: Creatinine Clearance Calculator
- Hepatitis panel (chronic) or, at a minimum, hepatitis B surface antigen (HBsAg), hepatitis B surface antibody (HBsAb).
- Chlamydia/N. gonorrhea Nucleic-Acid Amplification Testing (NAAT)- perform site specific swabs as indicated (oral, anal, vaginal) plus urine NAAT for men (not needed for women if vaginal swab obtained; if urine testing in women, vaginal swab not needed).
- Rapid Plasma Reagin (RPR titer) for syphilis.
- Urinalysis or urine dipstick to check for protein.
- Pregnancy test (if indicated).
- Optional: vaginal swab for T. Vaginalis NAAT

LABORATORY TESTS FOR CONTINUED PrEP SERVICES:

Please see pages 12 and 13 for full PrEP initiation and follow-up testing information.

SPECIAL SITUATIONS:

- High-risk potential exposure to HIV in the past 72 hours: use non-occupational postexposure prophylaxis (nPEP) for 28 days, then if clinically indicated start PrEP.
- High risk potential exposure in the past 15 days, monitor more closely at PrEP onset for signs and symptoms of acute HIV infection.
- Acute viral syndrome at presentation with history of high-risk exposure, draw HIV-1
 Polymerase Chain Reaction (PCR) viral load and consider delay in PrEP start until result
 known.
- Pregnancy: PrEP should be offered and/or continued but breast feeding is not recommended.
- If hepatitis B Surface Antibody negative offer vaccination; if HBsAg positive educate on risk of severe flares of hepatitis if PrEP stopped and refer to Primary Care Provider for ongoing evaluations of chronic hepatitis B infection.

 Adolescents (younger than 18 years of age) may not be provided PrEP in our County Health Department (CHD) program unless parental consent obtained. Refer adolescents to community provider for PrEP initiation.

MEDICATIONS FOR PREP:

Tenofovir disoproxil fumarate (TDF)/emtricitabine (FTC)(F/TDF) fixed dose combination (Truvada®) and tenofovir alafenamide (TAF)/emtricitabine (FTC)(F/TAF) fixed dose combination (Descovy®) have been approved by the United States Food and Drug Administration (FDA) for use as PrEP in combination with safer sexual practices to reduce the risk of individuals acquiring HIV.

Clinical trial data shows Truvada® for PrEP to be an effective HIV prevention strategy for **ALL** patients compliant in taking PrEP medication every day.

Clinical trial data shows Descovy[®] for PrEP to be an effective HIV prevention strategy for men who have sex with men and transgender women during anal receptive and insertive sex. Descovy[®] is **NOT** indicated for use as PrEP in persons having receptive vaginal sex.

SAMPLES FOR PrEP:

As a potential cost-savings measure for the Department, we ask that CHD practitioners consider the use of manufacturer samples and vouchers for PrEP clients, as appropriate, and in accordance with the Bureau of Public Health Pharmacy's Policy <u>DOHP 395-1</u>, which states CHD practitioners are allowed to obtain manufacturer samples.

Ready, Set, PrEP is a nationwide program lead by Health and Human Services (HHS) that provides access to PrEP medication for patients who lack prescription drug coverage. Information is available at Get your PrEP, or call toll-free 855-447-8410.

Gilead's Advancing Access program provides various coverage options for both insured and uninsured patients. Information is available at <u>Advancing Access</u>, or call toll-free 1-800-226-2056.

FREQUENTLY ASKED QUESTIONS

Basic prescribing information and side effects

Q: Is the patient at risk for being in the window period for HIV seroconversion at the time you are considering starting PrEP?

A: Obtain a detailed sexual/Intravenous Drug Use (IDU) risk assessment. If the patient's history of last at-risk exposure was greater than 15–21 days ago, an HIV 1/2 antigen/antibody bloodbased HIV test should be adequate in ruling out recent HIV infection in most cases. If there is a high-risk exposure within the past 72 hours the patient should be evaluated for nPEP. If there has been a high-risk exposure greater than 72 hours but less than 15–21 days ago, the clinician may want the patient to return for HIV testing appropriate to his/her risk history and the clinician's professional assessment. Starting PrEP and monitoring closely for signs and symptoms of HIV seroconversion is an acceptable option in some patients.

Q: What are signs and symptoms of acute HIV infection?

A: Within two to four weeks after infection with HIV, approximately 70 percent of people will have a flu-like illness. This is the body's natural response to HIV infection. These symptoms can include fever, chills, night sweats, sore throat, muscle aches, fatigue, lymphadenopathy and oral ulcers. The symptoms may last for a few days and up to several weeks. Around 30 percent with acute HIV infection will **NOT** have any symptoms during the acute phase of HIV infection.

Q: What if my patient experiences HIV seroconversion while on PrEP?

A: During PrEP treatment, anytime a patient has a positive HIV test result, it is urgent to notify and move the patient into HIV medical care. Less experienced clinicians are urged to seek consultation with an experienced HIV clinician. Consider consultation with the HIV Section Telehealth Team to assist with rapid access to HIV assessment, care and treatment.

Q: PrEP patients are tested for HIV every quarterly visit. Do we need to perform Pre and Post-test counseling at initial and follow-up visits?

A: While it is not required to perform pre and post-test counseling at initial and follow-up visits, the opportunity for pre and post-test counseling must be made available to all clients at all visits where an HIV test is performed. Per Section 381.004(4), Florida Statutes, CHDs must provide the opportunity for pre and post-test counseling which includes the meaning of the test and test results, the potential need for confirmatory testing and the availability of partner notification services.

Q: What if my PrEP patient has clinical complaints or lab abnormalities that are unrelated to their PrEP therapy?

A: Every PrEP patient needs to be informed we are providing PrEP clinical services for the prevention of HIV infection. Each patient should be informed repeatedly of the need to obtain a primary care provider and should be assisted with options for care in your region.

Adolescents and special populations (pregnancy, transgender)

Q: Can an adolescent take PrEP?

A: The FDA has approved the use of Truvada[®] in at risk adults and adolescents weighing at least 35 kilograms (kg.) not currently diagnosed with HIV. Descovy[®] is indicated in at-risk adults and adolescents weighing at least 35 kg to reduce the sexual risk of HIV-1 acquisition, **excluding** individuals at risk from receptive vaginal sex. Consider PrEP for adolescents at high risk for HIV and refer to a local provider for PrEP assessment unless parental consent can be obtained.

Q: Pregnancy or planning pregnancy?

A: PrEP may be one option to help protect the HIV seronegative woman from acquiring HIV infection in serodifferent couples or for women at-risk of HIV acquisition during attempts to conceive or during pregnancy.

- Consultation is available at the National Clinician Consultation Center on Perinatal HIV/AIDS at <u>National Clinician Consultation Center</u>, or call (888) 448-8765, 24 hours, seven days a week.
- If a woman is pregnant when starting PrEP or becomes pregnant while on PrEP, discuss the known risks and benefits of taking Truvada® during pregnancy. PrEP in pregnancy: safe, but many unanswered questions | aidsmap
- After discussing the potential risks of Truvada[®], consideration can be given to continue PrEP during and after pregnancy for those with ongoing risk for HIV. Truvada[®] is excreted in breast milk and breastfeeding is not recommended; assess the risk/benefit of continuing PrEP therapy for a woman breastfeeding her infant.
- Providers should report information regarding use of PrEP during pregnancy to the Antiretroviral Pregnancy Registry at <u>The ARV Pregnancy Registry.</u>

Q: Is Descovy® (F/TAF) being tested for use for PrEP in women?

A: The safety of F/TAF for PrEP in women will be evaluated with at least two studies, CONRAD 137 (active controlled study evaluating the safety and efficacy of F/TAF and F/TDF in 525 ciswomen) and PrEP VACC (two-stage HIV vaccine trial, in the first stage, women will be randomized 1:1 to receive either F/TAF or F/TDF for 26 weeks). Results are not available currently.

Q: Does estrogen therapy on transgender women (TGW) have any effect on Tenofovir (TDV) and emtricitabine (FTC) levels?

A: Yes, there is a decrease in rectal tissue concentration of these drugs, but levels are consistent with at least four doses/week. Data suggest that TGW might need higher levels of adherence than cismen when on feminizing therapy.

Bone density

Q: Does the patient have osteopenia/osteomalacia/osteoporosis?

A: There may be a risk of bone loss associated with Truvada®. Risk factors include: over age 50; female; menopausal; family history of osteopenia; low body weight; history of broken bones; loss of height; inadequate dietary intake of calcium and vitamin D; low intake of fruits and vegetables; too much dietary protein, sodium and caffeine; inactive lifestyle; smoking; excessive alcohol intake; losing weight.

• Review Are You At Risk? - National Osteoporosis Foundation (nof.org)

Discuss risk of bone loss with all PrEP patients. For individuals with pre-existing risk factors or demonstrated osteoporosis/osteomalacia/osteopenia, consider closer monitoring.

Hepatitis B Virus (HBV)

Q: Does the patient have chronic active HBV infection?

A: **Truvada**[®] and **Descovy**[®] are active against HBV infection. <u>Hepatitis B Virus/HIV Coinfection</u> I NIH

- Truvada[®] and Descovy[®] may be used as treatment for HBV infection and for prevention of HIV infection.
- Chronic active HBV infection is diagnosed when hepatitis B surface antigen (HBsAg) is
 positive and there is presence of hepatitis B DNA quantitative viral load. When HBsAg is
 resulted as positive, call the patient and obtain hepatitis B bDNA viral load, hepatitis BeAntigen and Be-Antibody and FIB-4 and refer to primary care for management.
- In patients with chronic active HBV infection, discontinuation of Truvada® and Descovy® requires close monitoring because of the concern for rebound viremia and a flare in hepatitis. Severe acute exacerbations of HBV have been reported in patients infected with HBV who have discontinued Truvada® and may occur with discontinuation of Descovy®.
- Patients need to be in the care of a primary care provider or liver specialist for ongoing
 monitoring of their HBV infection while receiving PrEP services. For those underinsured
 please assist with access to a local federally qualified health center for HBV treatment.

Labs

Q: How do I code for PrEP labs?

A: Using the recently developed program component, '02H', CHDs using the State Public Health Laboratories are now able to charge PrEP-related lab costs for HIV, hepatitis and STI testing to the HIV/AIDS Section for those unable to afford lab-related charges, as long as funding is available. Potential resources for local funding of PrEP labs include general revenue, 4BAPS and or program generated income. Please contact the Prevention Program Manager at mara.michniewicz@flhealth.gov for further instruction.

Medication adherence

Q: Can PrEP fail despite good adherence?

A: Yes, although cases of HIV seroconversion in persons known to be fully adherent to PrEP are rare, there have been reports of HIV seroconversion amongst persons infected with multidrug resistant HIV and as well in persons with wild-type HIV (HIV that does not have resistance to Truvada®). Truvada® and Descovy® are one component of an HIV prevention program and rare cases such as these support the importance of condom use and continued motivational interviewing for behavior change.

Q: Is 2-1-1 PrEP an option for men who have sex with men (MSM)?

A: This is a decision individually made between the practitioner and patient. Non-daily 2-1-1 PrEP is a dosing approach for emtricitabine/tenofovir disoproxil fumarate (F/TDF, Truvada®) that has been studied in MSM in France and Canada. This approach is being used in some clinics in Europe, Canada and now in the United States. This non-daily dosing may be appropriate for MSM. Currently, the only FDA-approved dosing strategy for PrEP in the United States is the once daily dosing of F/TAF. CDC continues to recommend **only** daily use of PrEP, as approved by the FDA.

In the IPERGAY and Prevenir studies, 2-1-1 PrEP was found to be protective for the insertive and receptive partner during anal sex. Non-daily PrEP ("2-1-1" PrEP) has not been studied in cis women, cis men who have sex with women, trans men, trans women, or IDUs. Current research suggests that non-daily F/TDF is not likely to reach or remain at high enough levels in the cervix or vagina to provide effective protection against HIV infection. Non-daily PrEP ("2-1-1" PrEP) for HIV prevention is **NOT** recommended for cis women who have vaginal sex, trans men who use their front-hole, or vagina, for sex, trans women using their neo-vagina for sex, or IDUs

The 2-1-1 PrEP dosing strategy was studied in MSM as an alternative to daily dosing for persons who:

- Are at ongoing risk of HIV infection through anal sex, and
- Prefer not to take daily PrEP despite counseling about safety and tolerability of daily PrEP, and
- Anticipate being able to plan their sexual intercourse, and
- Will take their pre-sex dose of two Truvada[®] tablets at least two hours (and preferably closer to 24 hours) before sexual activity, or delay sexual activity for at least two hours (and preferably 24 hours) after taking their "pre-sex" dose of two Truvada[®] tablets, and
- Can take daily doses of Truvada® for 48 hours after their last sexual intercourse.
- Do NOT have chronic active hepatitis B infection.
- Have a calculated creatinine clearance greater than 50 mL/min.

Study participants took:

- Two Truvada[®] tablets 2-24 hours before sex (closer to 24 hours before sex was preferred), and
- One Truvada[®] pill 24 hours after the first two pills, and
- One Truvada® pill 24 hours after the second dose

Hence the name "2-1-1." If they continued to have sex on multiple consecutive days, they continued taking one Truvada® per day until 48 hours (and two doses) after their last sexual contact.

Things to Note

- 2-1-1 PrEP has a similar toxicity and side effect profile to daily PrEP. Individuals should not choose 2-1-1 PrEP to decrease side effects or toxicity. You should not expect to have fewer side effects on 2-1-1 PrEP.
- Individuals opting to use 2-1-1 PrEP should ensure that **every** sexual episode is covered by condoms, PrEP, or both. Using condoms in addition to these strategies reduces risk for other sexually transmitted diseases (STDs) (e.g. syphilis, gonorrhea and chlamydia).
- 2-1-1 dosing makes the most sense for people who have, on average, no more than one sexual encounter per week.
- People using the 2-1-1 PrEP may find that they want to switch to daily PrEP when their frequency of sexual intercourse changes. Patients should not choose 2-1-1 PrEP simply due to cost without exploring how they can access daily PrEP.
- 2-1-1 PrEP should be prescribed by a Practitioner. Acquiring PrEP for 2-1-1 from friends or sex partners puts them at risk of acquiring HIV as they are not taking PrEP as prescribed for them.
- Patients taking either daily PrEP or 2-1-1 PrEP should be tested for HIV and STDs at least every three months.

Daily PrEP and 2-1-1 PrEP

	Daily PrEP	2-1-1 PrEP
Effective HIV prevention for?	Anyone	Only studied in cis men who have sex with cis men
What kind of sexual contact?	Anal and vaginal (front hole) sex and oral sex	Anal sex only (Insertive and/or receptive)
Side effects?	As listed by your provider	Same as daily PrEP
How it is taken it?	One pill every day – EASY!	A pre-sex dose of two tablets 2-24 hours before you first have sex, then one pill every 24 hours after the pre-sex dose until you have had two post-sex doses
When are doses taken?	Anytime once a day	Must be timed at least two hours before sex and continued for multiple timed doses after sex – consider setting an alarm for a reminder
Requires planning sex in advance?	No	Yes, by at least two hours and preferably by 24 hours
What if a dose is missed?	Take it as soon as you remember, unless it is the next day, do not double up on doses.	You may need PEP instead – please contact your provider

Q: How long until the PrEP medication is protective?

A: For MSM it is recommended to initiate PrEP with a double dose (2 pills) on day one followed by one pill daily thereafter. With the double dose protection is achieved in 24 hours. For receptive vaginal sex and injection drug use, maximum protection occurs in about 21 days of daily dosing.

Other STIs

Q: Is PrEP usage associated with an increased incidence of STIs?

A: Clinical studies have shown PrEP usage is associated in some patients with an increased incidence of STIs. In PrEP programs within our CHDs, we recommend routine STI screening at each visit regardless of symptoms. Finding and treating asymptomatic STIs reduces the risk of HIV acquisition and as well the risk of transmitting infections to others. Finding STIs is an opportunity for counseling, and consideration of more frequent STI screening may be indicated.

Q: Should female patients be screened for trichomoniasis even if asymptomatic?

A: Although not a current recommendation in PrEP guidelines, *T. Vaginalis* infection increases the risk for HIV acquisition two- to -threefold. Testing should be done in women reporting vaginal discharge. Screening should be considered in women reporting multiple sex partners, exchanging sex for payment or illicit drug use.

Renal

Q: What if the patient has a history of known renal insufficiency?

A: Assess estimated or calculated creatinine clearance at or before initiating treatment. In patients at risk for renal dysfunction, assess estimated creatinine clearance, serum phosphorus, urine glucose and urine protein before starting treatment and periodically during treatment. Creatinine Clearance Calculator: Creatinine Clearance Adult - GlobalRPH CrCl calculator Practitioners must weigh the risk of HIV infection versus potential for worsening renal function. Contact the Clinician Consultation Center National Clinician Consultation Center (ucsf.edu).

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

A: Discuss possibility of kidney disease for all PrEP patients starting Truvada[®]. With individuals who have pre-existing risk factors, consider closer monitoring of creatinine and protein during long term therapy. Preferentially, practitioners treating men or transgender women can initiate Truvada[®] for PrEP through the Issuance Program and obtain Descovy[®] for ongoing PrEP through the Patient Assistance Program.

Q: What if the estimated Glomerular Filtration Rate (eGFR) is under 60?

A: Seek physician approval to provide PrEP with Truvada® if the eGFR is under 60 mL per minute. Descovy® is not recommended in individuals with eGFR below 30 mL per minute and is not to be used in women who use their vagina for sex. Creatinine measurements vary from day to day and depend on hydration, exercise, diet creatine use (common among body builders) and other factors. If a single creatinine measurement is above the normal range, the measurement should be repeated.

Calculation of eGFR is based on lean body weight.

- To estimate lean body weight (male): Medical Calculators | Medscape Reference
- To estimate lean body weight (female): Medical Calculators | Medscape Reference
- To manually calculate the eGFR: CrCl Cockroft-Gault (medscape.com)

Note: for transgender persons not on hormonal therapy, use their gender at birth. If on hormone therapy for more than three months, use their current gender.

For patients considered at increased risk of ongoing HIV infection, consider contacting the Clinical Consultation Center for PrEP (see PrEP Resources and References below)

Q: Is the patient taking concomitant nephrotoxic drugs or drugs that have interactions with Truvada® or Descovy®?

A: Obtain a thorough medication history including over-the-counter medications. Drugs that may impair renal function (such as nonsteroidal anti-inflammatory drugs) may interact with Truvada®. Drugs that induce p-glycoprotein (such as carbamazepine, oxcarbazepine, phenytoin, rifabutin, rifampin) may interact with Descovy®

Use <u>HIV Drug Interactions Checker</u> to check for possible interactions.

Additional guidance:

CDC PrEP Guidelines 2017

National Clinician Consultation Center - PrEP

CDC PrEP Guidelines Supplement 2017 Update

Clinical Guideline Program PrEP for Prevention

Pre-Exposure Prophylaxis Service (PrEP line): 855-HIV-PrEP (855-448-7737) Clinical Consultation Center at UCSF

Antiretroviral Patient Medication Information Sheets. Medication Information Sheets

Telehealth:

Telehealth services for PrEP are available. When anticipating a telehealth PrEP patient please call one of the following staff by starting with the first person in the list below and progressing downward:

Administrative Assistant - (O) 239-656-2501; (M) 239-292-3054 Telehealth APRN - (M) 239-339-3899 Telehealth PA - (M) 904-254-0258 HIV AIDS Section Medical Director - (M) 850-519-3734

One of the clinicians noted above will accept the telehealth session and will be the one with whom you establish an audiovisual connection. Before each Telehealth encounter, test the Audio-Visual (A/V) system and problem-solve any connection issues.

LABORATORY GUIDANCE

TEST NAME	Initial	TEST	TEST	TEST	1 st Follow-up	2 nd	Ongoing	Ongoing
TEOT IVAILE	PrEP	CODE	CODE	CODE	Visit (3	Follow-up	Every	Every six
	Visit	Quest	State	Lab Corp	months/90 Days)	Visit (six months)	90 Days	months
HIV 1/2 Ag/Ab Immunoassay	х	0091431	0500	083935	Х	х	х	
Point of Care (POC) rapid HIV test	х	POC Testing DOH	None	None				
Hepatitis Testing	х	498 HBsAg 499 Anti-HBs 8472 Anti-HCV with reflex	None	006510 HBsAg 006530 Anti-HBs 144065 Anti-HCV with reflex				
Comprehensive Metabolic Panel	Х	10231	Does not run Test	322000	Х	Х		х
RPR w/ reflex to titer or	Х	0092156	0250	012005	х	Х	Х	
Syphilis Antibody with cascading reflex	Х	90349		082345	X	х	Х	
Chlamydia/GC Amplification (TMA) urine CT/GC - Vaginal swab, endocervical CT/GC - Oral throat swab CT/GC - Rectal swab	X	11363 11363 70051 16506	0430 0430 0430 0430	183194 188698 188672	X	х	Х	
Urinalysis	Х	0006448	Does not run Test	003772	Х	Х		Х
Urinalysis (in-house dipstick) (POC)	х	CHD	CHD	CHD	х	Х		Х
HCG, Beta subunit, QNT, Serum (pregnancy test)		0008396			х	Х	Х	

TEST NAME	Initial PrEP Visit	TEST CODE Quest	TEST CODE State		1 st Follow-up Visit (three months/90 Days)	2 nd Follow-up Visit (six months)	Every	Ongoing Every six months
HCG pregnancy test (POC)	Х	CHD	CHD	CHD	Х	Х	Х	
APRI Test (AST and Platelets)				385875				

Lab Tests – PrEP Services

Note:

- 1. Encourage vaccination for hepatitis A and hepatitis B if not immune
- 2. Annually assess need for ongoing PrEP and repeat hepatitis C screen if indicated.