

PrEP Clinical Guidelines

PREPARED BY:
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BUREAU OF COMMUNICABLE DISEASES
DIVISION OF DISEASE CONTROL AND HEALTH PROTECTION
FLORIDA DEPARTMENT OF HEALTH

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*Pre-Exposure
Prophylaxis (PrEP)
Resource Materials for
Health Care Clinicians*



CHD Pre-Exposure Prophylaxis (PrEP) Clinical Guidelines for Prevention of HIV infection

Tenofovir disoproxil fumarate (TDF)/emtricitabine (FTC) fixed dose combination (Truvada®) has been approved by the U.S. 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 patients compliant in taking PrEP medication every day. The Florida Department of Health County Health Departments (CHDs) are providing a PrEP program for patients in need. The provision of PrEP medication to patients will be through the 'Issuance Program' or by pharmacists in CHDs with their own on-site pharmacy. There is no charge to the CHDs nor to the patients served, regardless of payer source, for the PrEP medication. Patients will be dispensed up to a 90-day supply of PrEP medication which allows time for staff to access ongoing medication through either insurance, the Patient Assistance Program, or Medicaid.

Each patient should be encouraged to have a primary care provider and inform their provider they are taking Truvada for PrEP, however, having a primary care provider is not a requirement for enrolling in PrEP. Health care providers are encouraged to review the Risk Evaluation and Mitigation Strategy (REMS) program for education and information regarding PrEP for individuals at high risk including on-line training. See page 9 for additional details including the link to the REMS website.

Please review the PrEP Clinical Protocol developed for use in conjunction with this PrEP Guidance.

Key Principles for Prescribing PrEP

The following information is modified from New York State Department of Health AIDS Institute: PrEP to Prevent HIV Acquisition Guideline www.hivguidelines.org/prep-for-prevention/prep-to-prevent-hiv/

Truvada works to prevent HIV from establishing permanent infection by inhibiting HIV-1 replication in the body. Truvada® is the only FDA approved medication for PrEP.

- PrEP is indicated for individuals who have a **documented negative HIV test result** and are at **ongoing high risk for HIV infection**. A negative HIV-1/2 antigen/antibody 4th generation test result needs to be confirmed as close to initiation of PrEP as possible. Include documentation of no HIV exposures within 15–21 days of PrEP initiation.
- During assessment with patient, if it's determined that a recent exposure to HIV has occurred within the last 72 hours, counsel patient on PEP medication and provide/refer for PEP services immediately. Provide patient with return visit for repeat HIV test and PrEP services; schedule accordingly so a treatment gap doesn't occur.
- PrEP helps protect the HIV seronegative partner in a serodiscordant relationship or during attempts to conceive in serodiscordant relationships. PrEP helps to protect men and women at risk for HIV through their sexual or injection drug use behaviors.
- Patients need education about the time it takes to achieve adequate protection taking daily PrEP; seven days for receptive anal sex and 20 days for all other activities, including vaginal sex, insertive anal sex, and injection drug use.

- PrEP should not be offered as a sole intervention for HIV prevention. PrEP should be prescribed as part of a comprehensive prevention plan including the use of barrier protection with condoms.
- Individualization in PrEP programs is at the choice of the clinician. Initiation of Truvada on the **same day of the initial evaluation** for PrEP can be appropriate. The assessment should include that the patient has not had a high-risk exposure in the past 15–21 days and a negative HIV 3rd or 4th generation rapid test result on the day of PrEP initiation. If the provider chooses to perform baseline labs prior to PrEP initiation, the patient's at-risk activities must be assessed and considered before dispensing Truvada at the return visit. Performing a rapid HIV test on the day of providing PrEP medication is recommended.
- Patients receiving PrEP require regular visits, at least every three months, to monitor HIV status, screen for sexually transmitted infections (STIs), assess adherence and evaluate for side effects. Follow-up and monitoring of patients receiving PrEP also includes prevention services such as risk-reduction counseling, access to condoms, STI preventive education, and mental health and substance use screening, when indicated.
- 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.

Clinicians should discuss the option of PrEP with each of the following at-risk individuals who are HIV negative:

- Individuals who may be at-risk for HIV exposure.
- Men who have sex with men (MSM) who engage in unprotected anal intercourse.
- Individuals who are in a serodiscordant sexual relationship with a known HIV-infected partner.
- Individuals who engage in unprotected anal, oral, or vaginal intercourse (without a condom).
- Individuals who exchange sex for money, drugs, or housing.
- Injection drug user (IDU) including persons injecting hormones, who report any of the following behaviors: sharing injection equipment (works), or share drug paraphernalia.
- Individuals diagnosed with at least one bacterial STI in the last year.
- Individuals who have been prescribed non-occupational post-exposure prophylaxis (nPEP) who anticipate continued high-risk behavior or have had multiple courses of nPEP.
- Partner(s) of unknown HIV status or with any of the factors listed above.

Medical Contraindications

- Documented HIV infection.
- Clinical symptoms consistent with acute HIV viral infection such as: fever, headaches, fatigue, arthralgia, vomiting, myalgia, diarrhea, pharyngitis, rash, night sweats and adenopathy (cervical and inguinal) may occur within 2–4 weeks of infection.
- Truvada drug-resistance has occurred in patients prescribed Truvada who are in the window period before testing can diagnose the acute phase of HIV infection.
- Inability to adhere to a daily PrEP regimen, as adherence ensures plasma and tissue drug levels reach and maintain a protective level.
- Creatinine clearance <60 mL/min.
- Chronic active hepatitis B virus (CAHB) without ongoing monitoring of hepatitis B virus (HBV) infection by their primary care provider or liver specialist.

Important Considerations when Prescribing PrEP

Is the patient an adolescent?

The FDA has approved the use of Truvada® in HIV-1 uninfected adults and adolescents weighing at least 35 kg. Studies in this population are underway. Consider PrEP for adolescents at high risk for HIV.

- Adolescents under the age of 18 in Florida who are treated in CHDs for PrEP services must have parental consent.

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

Obtain detailed sexual/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 4th generation HIV test should be adequate for the majority of cases. If there is high risk exposure, the patient should return for HIV testing appropriate to his/her risk history and the clinician's professional assessment.

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

Discuss possibility of kidney disease for all PrEP patients. With individuals who have pre-existing risk factors, consider closer monitoring during long term therapy.

What if the patient has a history of renal insufficiency?

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: www.globalrph.com/crcl.htm.

Is the patient taking concomitant nephrotoxic drugs or drugs that have interactions with Truvada?

Obtain a thorough medication history including over the counter medications such as nonsteroidal anti-inflammatory drugs or other drugs that have interactions with TDF/FTC.

- Use hiv-druginteractions.org/ to check for possible interactions.

Does the patient have chronic active HBV infection?

Truvada is active against HBV infection.

- Although not FDA-approved for the treatment of HBV, Truvada® may be used as treatment for HBV infection and for prevention of HIV infection.
- In patients with chronic hepatitis B infection, discontinuation of Truvada® requires close monitoring because of the concern for rebound viremia. Severe acute exacerbations of hepatitis B have been reported in patients infected with HBV who have discontinued Truvada.
- 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.

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

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 www.nof.org/preventing-fractures/general-facts/bone-basics/are-you-at-risk/
- Discuss risk of bone loss with all PrEP patients. For individuals with pre-existing risk factors or demonstrated osteoporosis/osteomalacia/osteopenia, consider closer monitoring.

Pregnancy or planning pregnancy?

PrEP may be one option to help protect the HIV seronegative partner from acquiring HIV infection in serodiscordant couples during attempts to conceive.

- If a woman is pregnant when starting PrEP or becomes pregnant while on PrEP, discuss the known risks and benefits of taking Truvada during pregnancy.
- 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; assess the risk/benefit of continuing PrEP therapy for a woman breastfeeding her infant. See information at: www.cdc.gov/hiv/pdf/prep_gl_clinician_factsheet_pregnancy_english.pdf.
- Consultation is available at the National Clinician Consultation Center on Perinatal HIV/AIDS at nccc.ucsf.edu/clinician-consultation/perinatal-hiv-aids/ or call (888) 448-8765, 24 hours, seven days a week.
- Providers should report information regarding use of PrEP during pregnancy to the Antiretroviral Pregnancy Registry at www.apregistry.com.

PrEP Initiation

Required Laboratory Tests for Initial PrEP Services:

- HIV 1/2 Antigen/Antibody 4th generation blood-based test plus/minus 3rd/4th generation Rapid HIV test .
- Comprehensive Metabolic Panel (CMP) or serum creatinine to calculate creatinine clearance.
 - Link to calculate creatinine: www.globalrph.com/multiple_crcl.htm
- Hepatitis panel or, at a minimum, hepatitis B surface antigen (HBsAg) ± hepatitis B surface antibody (HBsAb).
- STI screening:
 - Chlamydia/N. gonorrhoea – Nucleic-Acid Amplification Testing (NAAT)- perform site specific swabs as indicated (oral, anal, vaginal) + urine NAAT for men (not needed for women if vaginal swab obtained).
 - Rapid Plasma Reagin (RPR) for syphilis.
- Urinalysis or urine dipstick to check for protein.
- Pregnancy test (if indicated).

Baseline HIV Test

- Clinicians providing **same-day** PrEP should also obtain an initial 3rd or 4th generation rapid HIV test while waiting on the HIV 1/2 antigen 4th generation HIV blood-based test results.

The Hepatitis Screening Panel [Hepatitis A Antibody (anti-HAV), Total or IgG; HBsAb, Qualitative; HBsAg with Reflex Confirmation; hepatitis B core antibody (HBcAb), Total; hepatitis

C antibody (anti-HCV) with Reflex to HCV, Ribonucleic Acid (RNA), Quantitative, Real-Time PCR] is available at most of the CHDs through the hepatitis 09 program.

- If immunization status for hepatitis B is not known; assess Florida SHOTS.
- Immunize against hepatitis B in non-immune patients.
- If hepatitis B surface antigen is positive, educate patient to never discontinue Truvada without medical supervision. Arrange for evaluation and monitoring of ongoing hepatitis B infection. Hepatitis B infection is not a contraindication for taking PrEP.

Screening for STIs

Clinicians should test for STIs every three to six months as part of PrEP monitoring and ongoing laboratory testing.

- Gonorrhea and Chlamydia (Amplified GC/CT) (urine; oral, anal, vaginal swab as indicated)
- RPR for syphilis
- Link to self-collection instructions:
www.vdh.virginia.gov/content/uploads/sites/10/2016/01/CT.GC-QA-Manual-LHD-extragenital-3.pdf

Prescribing Recommendations

Regimen: Truvada® one tablet taken orally with or without food once daily (TDF 300 mg + FTC 200 mg).

First Prescription: 30 to 90-day supply with no refill. CHDs can order Truvada in advance through the Issuance Program from Central Pharmacy or provide through their on-site CHD pharmacy. Truvada may also be acquired through a retail pharmacy or Medication Assistance Program (MAP).

At the first Truvada prescription, it is advised to follow-up with the patient, in person or by phone, within the first two weeks to assess for side effects and compliance.

Subsequent Prescriptions: no more than a 90-day supply should be provided. The visit should include counseling, confirmed negative HIV test result, STI assessment, mental health and substance use evaluation, risk/harm reduction assessment and education required for refill.

There is insufficient evidence at present to suggest tenofovir alafenamide (TAF)/FTC fixed-dose combination Descovy® can be substituted for Truvada. Therefore, Descovy should not be prescribed for PrEP until human clinical trial data are available to support its use.

PrEP Follow-Up Encounters

At each visit (every 90 days):

- Assess adherence.
- Provide risk-reduction counseling.
- Offer condoms.
- Assess/manage patient side effects.
- Review signs and symptoms of acute HIV infection with instructions to seek medical attention urgently should they occur.

STI screening – Frequency:

- Ask about STI and HIV symptoms every visit.
- Document at-risk event summary since last visit; assess change negotiated from prior visit; motivational interviewing with documentation of patient's planned interval change in the next three months.

Laboratory Follow-up Testing:

- STD screening in standard guidelines is recommended every six months. Studies have shown quarterly screening to be superior in identifying STD infections, many of which are asymptomatic.

Labs every three months:

- HIV 1/2 Ag/Ab 4th generation blood- based test
- Pregnancy test (if indicated)
- STI screening (recommended)

Labs every six months:

- RPR for syphilis
- Chlamydia trachomatis/Neisseria gonorrhoea (CT/NG) RNA, Transcription-mediated Amplification (TMA) (urine; oral, anal, vaginal swab(s) as indicated)
- CMP or serum creatinine (≥ 60 ml/min to continue Truvada)
- Urinalysis or urine dipstick to check for protein

Labs every twelve months:

- HCV screen (MSM and/or IDU)

Discontinuation of PrEP Regimen**Discontinue PrEP if patient receives a positive HIV test result:**

- Recommend immediate Antiretroviral Therapy (ART) in consultation with a provider experienced in HIV treatment; consider referral to nearest Test and Treat program or link to HIV primary care services. Refer to Disease Intervention Specialist for assessment.
- Obtain HIV-1 Polymerase Chain Reaction (PCR) RNA viral load with reflex to HIV-1 genotypic resistance testing; adjustments may be made to the ART regimen once resistance test results are available.

Discontinuation of Truvada in patients with CAHB can cause severe flare-ups of hepatitis B infection. Discontinuation of Truvada in these patients should only be done by the clinician providing follow-up and monitoring of their chronic hepatitis B infection.

Symptoms of Acute HIV: An estimated 40%–90% of patients who become infected with HIV-1 will have symptoms such as fever, myalgia, night sweats, arthralgia, lymphadenopathy, skin rashes, loss of appetite and possible other flu-like symptoms. Some individuals may

have no symptoms at all. Evaluate for these symptoms at each visit and educate patients to seek medical attention urgently should any of these symptoms develop while on Truvada.

Discontinue PrEP in patients without CAHB infection who:

- Develop renal disease (creatinine clearance less than 60 mL/min).
- Are non-adherent to medication or appointments after attempts to improve adherence.
- Are using medication for purposes other than intended.
- Reduce risk behaviors to the extent that PrEP is no longer needed.

New HIV Health Management System (HMS) Codes effective July 2018

HIV PrEP Service Codes:

5701 –PrEP Initial/Counseling

5702 – PrEP Initiation/PrEP RX

5703 – PrEP Follow-up/RX Refill

Patient is receiving services through STD - PC 02 and is a candidate for PrEP services.

- Code 02/5701 thru 02/5703

Patient is receiving services through Family Planning - PC 23 and is a candidate for PrEP services.

- Code 23/5701 thru 23/5703

Patient receiving services through Primary Care, Child Health (29) and Adult Health (37) and is a candidate for PrEP services.

- Code 29 or 37 5701 through 29 or 37 5703

For CHD specialty designated PrEP clinics:

- May code PrEP services to 03/A1/5701 through 03/A1/5703

The revised HIV Health Management Component (HMC) service codes can be viewed in the 2018 HMS Manual. Attached is a one-page coding resource form for clinic staff to reference when providing PrEP services.



Coding Resource
4-2018.docx

Note: The Bureau of Clinic Management and Informatics Electronic Health Record will be rolling out the HIV-PrEP template in 2019. In the interim, you may use existing templates that are already available in the Medical History, Sexual Health and STD sections of the Electronic Health Record (EHR).

In addition, attached are two local CHD PrEP forms that can be used for documenting the initial visit and follow-up visits.



Prep Initial.docx



Prep Follow
up.docx

Please see additional information including the link to the Bureau of Clinical Informatics Share Point page with instructions for adding the local PrEP forms. The information and link are at the top of the *PrEP Resources and References* page.

DOH – How to Obtain Medication

Medication Procurement and Payment Options for PrEP	
CHD	<ul style="list-style-type: none"> Supply of Truvada is available to CHDs from Central Pharmacy through the Issuance Program or by the CHD Pharmacist for the CHDs with an on-site pharmacy (no charge for PrEP medications).
Private Insurance	<ul style="list-style-type: none"> Most private insurances cover PrEP. Coverage varies based on plan. There may be deductibles and co-payments.
Medicaid	<ul style="list-style-type: none"> PrEP prescription costs, medical appointments and lab tests covered. Prior approval is required and renewed every three months. Link to Florida Medicaid Prior Authorization Form for HIV Prophylaxis – PrEP: ahca.myflorida.com/medicaid/Prescribed_Drug/pharm_thera/paforms/HIV_Diagnosis_Verification_Form.pdf
Medicare	<ul style="list-style-type: none"> Review patient's coverage, prior authorization is required.
Uninsured	<ul style="list-style-type: none"> DOH serves HIV-negative persons who are uninsured or underinsured. Fees are based on sliding fee scale determined by income. <ul style="list-style-type: none"> Fees include provider visits and lab testing, counseling, and supportive primary care services consistent with clinical guidelines of PrEP. CHD may provide PrEP medication (Truvada) from Central Pharmacy. MAP will be used for medication procurement.
Medication Assistance Programs (MAP)	
Gilead [®] Co-Pay Coupon Card	<ul style="list-style-type: none"> Gilead Advancing Access Co-Pay Coupon Card www.gileadadvancingaccess.com/hcp/financial-assistance/copay-support or www.gileadadvancingaccess.com/copay-coupon-card <ul style="list-style-type: none"> For eligible residents of the U.S., Puerto Rico, or U.S. territories. Patient must have insurance. Patient must not be enrolled in Medicare or Medicaid. Covers up to \$4,800 in co-pays per year. To speak to someone, call Advancing Access 1-800-226-2056.
Gilead [®] Medication Assistance Program	<ul style="list-style-type: none"> Gilead MAP (855) 330-5479 start.truvada.com/individual <ul style="list-style-type: none"> Covers prescription costs Patient must be uninsured or their insurance does not cover any prescription cost. <p>NOTE: Gilead requires re-enrollment and negative HIV test result every six months for medication assistance program.</p>
Patient Advocate Foundation	<ul style="list-style-type: none"> Patient Advocate Foundation's Co-Pay Relief (PAF)(CPR) <ul style="list-style-type: none"> Provides assistance to insured patients only; family income below 400% Family Poverty Level (FPL) www.copays.org/diseases/hiv-aids-and-prevention PAF launched HIV, AIDS & Prevention CareLine, at (844) 737-6674 or by web, seeks to connect patients with individualized, case management services free of charge to help with navigating system, coverage options, insurance denials, etc. Online at hivoraids.pafcareline.org/


Truvada for a PrEP Indication – Risk Evaluation and Mitigation Strategy (REMS) Program

REMS is a strategy to manage known or potential serious risks associated with a drug product and is required by the FDA to ensure that the benefits of the drug outweigh its risks. To assure Truvada for a PrEP indication is prescribed and taken safely, Gilead has worked with the FDA to develop materials for the REMS program to educate and inform health care providers and uninfected individuals at high risk for acquiring HIV-1. You may review the website at: www.truvadapreprems.com/

Two pertinent forms recommended for use are:

- 1.) Prescriber/Patient Agreement Form for Initiating Truvada for PrEP:
www.truvadapreprems.com/Content/pdf/Agreement_Form.pdf
- 2.) Checklist for Prescribers: Initiation of Truvada for Pre-exposure Prophylaxis (PrEP):
www.truvadapreprems.com/Content/pdf/Checklist_for_Prescribers.pdf

For materials on PrEP/REMS, click here [Access REMS resources](#)

PrEP Resources and References	
HMS SharePoint site link to PrEP Local Forms	<ul style="list-style-type: none"> Here is the link to the Share Point page with both of the above local forms, PrEP initial and PrEP Follow-up, click here. If you need additional assistance, your local CHD System Administrator may request assistance from DL HMS Support at DLHMSSupport@flhealth.gov. Josh Martin or Adam Reeves, HMS Clinical Informatics, will contact the local CHD System Administrator to help with adding the local forms at your CHD.
Clinical Consultation Center for PrEP	<ul style="list-style-type: none"> You may contact the Clinical Consultation Center at (855) 448-7737 or (855) HIV-PrEP, Monday through Friday, 11:00 a.m. to 6:00 p.m. EST for expert PrEP consultation and assistance. Additional information is available at the Clinical Consultation Center website, nccc.ucsf.edu/clinician-consultation/prep-pre-exposure-prophylaxis/.
AIDS.gov	<ul style="list-style-type: none"> Managed by the US Department of Health and Human Services (DHHS), <i>Pre-exposure Prophylaxis (PrEP)</i> webpage, www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/pre-exposure-prophylaxis/
Centers for Disease Control and Prevention (CDC)	<ul style="list-style-type: none"> CDC's <i>Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2014: A Clinical Practice Guide</i>, www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf CDC PrEP 2017 Update: <div style="text-align: center;">  <p>CDC 2017 PrEP Guideline Update.d</p> </div> CDC's <i>Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2014: A Clinical Providers' Supplement</i>, www.cdc.gov/hiv/pdf/guidelines/PrEPProviderSupplement2014.pdf National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (U.S.) Division of HIV/AIDS Prevention. Published date: November 24, 2015. Patient information in English, stacks.cdc.gov/view/cdc/35760; Patient information in Spanish, stacks.cdc.gov/view/cdc/35759 <i>New York State Guidance for the Use of Pre-Exposure Prophylaxis (PrEP) to Prevent HIV Transmission—2016</i>, www.hivguidelines.org/prep-for-prevention/
NASTAD	<ul style="list-style-type: none"> A Common Patient Assistance Program Application Form for HIV Medicine: Improved and Available, www.nastad.org/blog/common-patient-assistance-program-application-form-hiv-medicine-improved-and-available Billing Coding Guide for HIV Prevention: PrEP, Screening, And Linkage Services
AHCA/Medicaid	<ul style="list-style-type: none"> Florida's Agency for Health Care Administration, www.fdhc.state.fl.us/medicaid Link to Agency for Health Care Administration Pharmacy Prior Authorization Forms, ahca.myflorida.com/medicaid/Prescribed_Drug/pharm_thera/paforms.shtml
HIV/AIDS Section DOH Prevention Program	<ul style="list-style-type: none"> Florida Department of Health Prevention Program, www.floridahealth.gov/diseases-and-conditions/aids/prevention/prEP.html

PrEP Resources and References, continued

Florida AIDS Education & Training Center (AETC)	<ul style="list-style-type: none">• For additional resources, visit North Florida AIDS Education and Training Center (AETC), www.aetc.medicine.ufl.edu or Southeast AETC, www.seaetc.com/
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Bureau of Central Pharmacy

Bureau Chief - Dr. Darren Evans

October 2017

Pre-Exposure Prophylaxis (PrEP) Ordering Procedure for CHDs with a Pharmacy

Procedures

Ordering

Pre-Exposure Prophylaxis (PrEP) medications will be ordered from the Bureau of Public Health Pharmacy (BPHP) as bulk products. The current BPHP's PFS, lists the available products.

- (1) Procurement from the BPHP
 - (a) Ordering Information from the BPHP – CHDs with pharmacies may order drugs using the on-line order forms listed on the BPHP web page.
 - (b) PrEP drugs can be ordered by following the steps below from the BULK form.
 1. The Bulk Pharmaceutical Request Form will automatically prepopulate the 'Form Details' after you select your facility.
 2. Select Bulk Form.
 3. Select [Pre-Exposure Prophylaxis \(PrEP\)](#).
 4. Select the drug you would like to order.

CHD staff must pay special attention to the product's unit of issue when ordering bulk drugs from the BPHP. Failure to order properly may result in a serious under or over shipment of product.
 - (c) Order Frequency - Orders should be submitted to the BPHP on a semimonthly or as needed basis.

Distribution by CHDs

Pharmacist (RPh) Dispensing - A Florida licensed pharmacist employed by the CHD or working under contract with a CHD may dispense pharmaceuticals pursuant to Chapter 465, Florida Statutes, Chapter 893, Florida Statutes, and Florida Administrative Code Rule 64B16-27.

Lab Tests – PrEP Services

Lab Tests related to PrEP Services - 2018

TEST NAME	TEST CODE
HIV 1/2 Ag/Ab, 4 th gen (preferred)	Quest 0091431
HIV 1/2 Ag/Ab, 4 th generation test and/or 3 rd generation rapid HIV test (in house)	State 0500
Comprehensive Metabolic Panel (CMP) (14) (includes Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), creatinine with eGFR)	Quest 10231
Basic Metabolic Panel (BMP) (includes creatinine with eGFR)	Quest 10165
Creatinine	Quest 375
Hepatitis Panel	Quest 0006462
Hepatitis B Surface Antigen (HBsAg) w/reflex to confirmatory	Quest 0000498
Hepatitis B Surface Antibody (HBsAb)	Quest 26526
Hepatitis Screen – Panel	State 0380
Hepatitis Surface Antigen (HBsAg)	State 0300
Hepatitis B Surface Antibody (HBsAb)	State 0310
Hepatitis C antibody (HCV Ab) (if +, reflex to HCV)	Quest 8472
RPR w/ reflex to titer	Quest 0092156
RPR	State 0250
Chlamydia/GC Amplification (TMA) urine	Quest 11363
CT/GC - Vaginal swab, endocervical or urethral	Quest 11363
CT/GC - Oral throat swab	Quest 70051
CT/GC - Rectal swab	Quest 16506
GC/Chlamydia (Amplified GC/CT) urine	State 0430
GC/CT - Vaginal swab	State 0430
GC/CT - Oral throat swab	State 0430
GC/CT - Rectal swab	State 0430
Urinalysis	Quest 0006448
Urinalysis (in-house dipstick)	CHD
HCG, Beta subunit, QNT, Serum (pregnancy test)	Quest 0008396
HCG pregnancy test (in-house)	CHD

*Hepatitis B Surface Antigen (HBsAg) – if result is reactive, automatically reflexes to confirmatory for an additional charge.

*Hepatitis C antibody (HCV Ab) – if result is positive, automatically reflexes to a viral load for an additional charge.

CMP includes Albumin, Albumin/Globulin Ratio (calculated), Alkaline Phosphatase, ALT, AST, BUN/Creatinine Ratio (calculated), Calcium, Carbon Dioxide, Chloride, Creatinine with Glomerular Filtration Rate (GFR) Estimated, Globulin (calculated), Glucose, Potassium, Sodium, Total Bilirubin, Total Protein, Urea Nitrogen

BMP includes BUN/Creatinine Ratio (calculated), Calcium, Carbon Dioxide, Chloride, Creatinine with GFR Estimated, Glucose, Potassium, Sodium, Urea Nitrogen (BUN)

Recommended ICD 10 - CM Codes for PrEP and PEP

The International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) coding system does not designate specific billing codes for PrEP or PEP related services. The New York State Department of Health and the New York City Department of Health and Mental Hygiene recommend the use of the following ICD-10-CM codes for PrEP and PEP related outpatient services.

VISITS: All office visits must include a “principal diagnosis/first-listed condition” to be billable. Z20.6, bolded below, is classified as an “acceptable principal diagnosis” in the ICD-10-CM system. Always include Z20.6 when coding PrEP or PEP visits. If an insurer requires additional coding clarifying a patient’s risk, Z20.2 (sexual exposure risk) and F19.20 (injection drug use exposure risk) can be added. These codes avoid the use of the Z72.x codes that are considered stigmatizing because they indicate “problems related to lifestyle.”

TESTS: HIV, STD, HCV and other tests associated with PrEP and PEP are related to the patient’s ongoing risk of infection, even if the patient is asymptomatic. Screening tests are ordered at initial visit. Subsequent visits use ‘contact with’ codes. Tests which are ordered to evaluate the patient for conditions potentially associated with long-term use of PrEP medication should include the code Z79.899.

PrEP-related Codes – Initial Visit		
Coding for:	ICD-10 Code	Description
Visit	Z20.6	Contact with and (suspected) exposure to HIV
	Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
Initial Tests	Z01.812	Encounter for pre-procedural laboratory examination (Applicable to blood and urine tests prior to treatment or procedure)
	Z11.3	Encounter for screening for infections with a predominantly sexual mode of transmission
	Z11.4	Encounter for screening for human immunodeficiency virus
	Z11.59	Encounter for screening for other viral diseases*
PrEP-related Codes – 2nd and Subsequent Visits		
Coding for:	ICD-10 Code	Description
Visit and Tests	Z20.6	Contact with and (suspected) exposure to HIV
	Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
	Z79.899	Other long-term drug therapy
	Z20.5	Contact with and (suspected) exposure to viral hepatitis*
	Z51.81	Encounter for therapeutic drug monitoring
PEP-related Codes – Initial and Subsequent Visits		
Coding for:	ICD-10 Code	Description
Visit and Tests	Z20.6	Contact with and (suspected) exposure to HIV
	Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
	Z77.21	Contact with and (suspected) exposure to potentially hazardous body fluids
	Z20.5	Contact with and (suspected) exposure to viral hepatitis

Modified from New York State Department of Health, NYC Health

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