HIV Essentials and Quick Clinical Guides

Updated May 2023

The Pacific AETC (AIDS Education and Training Center) *HIV Essentials and Quick HIV Clinical Guides* compilation consists of seven of our most popular clinical reference guides used in primary care, urgent care, and emergency room clinical settings. The recommendations are based on HRSA, CDC, IDSA, IAS-USA, and WHO guidelines, along with current practices used by our expert clinicians.

This compilation starts with two "Essentials" documents which can be printed on single letter-sized pieces of paper and folded into a pocket for quick reference during a busy clinic. The protocols and quick clinical guides provide more details for implementation, and each document can be printed separately and used on their own.

Seven of our most popular clinical reference guides used in primary care, urgent care, and emergency room clinical settings.

Contents

Have questions? Need clinical help?

In the Pacific Region (Arizona, California, Hawaii, Nevada and the 6 US Affiliated Pacific Islands: American Samoa, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Guam, Republic of the Marshall Islands, and Republic of Palau) request free training and technical assistance from the **Pacific AETC: paetc.org, 415 476 6153, paetcmail@ucsf.edu.**

Outside the Pacific Region contact the AETC National Coordinating Resource Center: **aidsetc.org, 973 972 5141, info@aidsetc.org.**

National Clinician Consultation Center (NCCC) for HIV testing and care/treatment questions: 800 933 3413 or nccc.ucsf.edu

You can reach a live consultant (voicemail available after hours) or **submit consultation requests online at nccc.ucsf.edu**. Please check website for live hours.

Post Exposure Prophylaxis (**PEP**) questions: **888 448 4911**

Perinatal HIV testing & reproductive care questions: **888 448 8765**

Pre Exposure Prophylaxis **(PrEP)** questions: **855 448 7737**

Hepatitis C Consultation Line **844-437-4636**

Substance Use Consultation Line **855 300 3595**

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Funding for this presentation was made possible by 5 U1OHA29292-08-00 from the Human Resources and Services Administration HIV/AIDS Bureau. The views expressed do not necessarily reflect the official policies of the Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government. Any trade/brand names for products mentioned in this document are for training and identification purposes only.

Pill and injectables photos: US DHHS National Institutes of Health (NIH), Test Positive Aware Network (TPAN) and ViiV Healthcare.
Design: Queridomundo Creative

AETC AIDS Education & Training Center Pacific

Clinical Essentials: HIV testing, Rapid ART, PEP, PrEP

Updated May 2023

▶HIV testing

■ How should I test for HIV?

Test everyone ages 13+!

CDC guidelines: test everyone ages 13-64 at least once. Retest after initial test based on risk assessment. Use ICD-10 code Z11.4.

- Order this lab for most people:
  HIV 4th gen antigen+antibody test (lab-based)
  For possible exposure in the past month, add HIV viral load (HIV RNA PCR or NAAT) to the Ag/Ab test.
- Offer as a normal part of labs:
  "We test everyone's cholesterol, sugars, liver, kidneys, and screen for HIV and hepatitis." Or: *"We need to check your cholesterol and sugars again, and since we haven't checked for HIV yet, let's do that. The HIV test is a normal part of health screening for everyone. Sound OK?"*
  (*Be sure to mention you are ordering an HIV test so the patient is informed and has the chance to opt out.)

■ How do I interpret 4th gen HIV test results?

HIV Ag/Ab non-reactive:	HIV Ag/Ab reactive & HIV1/2 diff reactive:	HIV Ag only reactive & HIV1/2 neg + RNA detected:	HIV Ag/Ab reactive & HIV1/2 neg & RNA neg:
negative for HIV (2-3 week window period from exposure)	**chronic infection** call linkage coordinator, offer rapid ART	**acute infection** call linkage coordinator, offer rapid ART!	**negative** likely false pos Ab result; if high risk, check HIV2 DNA or RNA

■ How do I disclose a positive result?

1. Call your HIV provider, linkage coordinator or other team member as soon as you see the result to coordinate a warm-handoff to HIV care.
2. Call the patient for an in-person visit to discuss lab results. Disclose in-person ideally the same day as the confirmed result, and when not possible, aim to disclose and provide ART within 5 working days.
3. When the patient is sitting, calmly and neutrally let them know.
   "Your lab results show that you have HIV." Give them a few moments and listen.
   "Would you be willing to share your thoughts, feelings or questions about this?"
   Listen, address concerns: *"We have really good treatment to help you live as long and healthy as possible. May I introduce you to (your HIV linkage coordinator)? They will help answer questions and connect you with HIV care."*

▶Rapid ART: immediate HIV treatment

Rapid ART increases retention in care and viral load suppression. Disclosure and an ART Rx the same day as confirmed diagnosis is ideal; otherwise aim for within 5 working days. Use ICD-10 code B20 or Z21.

1. **New diagnosis with confirmed labs: contact HIV linkage coordinator ASAP** to schedule disclosure and same-day warm hand-off to HIV intake, readiness counseling, med visit.
2. **Obtain baseline labs as soon as possible:** If not done before first HIV visit, can be done the same day the ART Rx is written.
   Baseline labs *(higher priority)*: HIV 4th gen if only rapid test result; HIV viral load (RNA/NAAT), HIV genotype, CD4 (lymphocyte panel 4), CBC, CMP, hep B sAg/sAb/cAb, UA, GC/CT (exposed sites), RPR.
   Lower priority: hep A tAb, hep C Ab w/ reflex, non-fasting lipids, HgA1C, TB QFT/IGRA, toxo IgG.
3. **Perform a brief, targeted medical history and exam:** check for previous ART, PrEP, PEP use, sexual and drug exposures, comorbidities, meds, allergies, TB & opportunistic illness symptoms.
4. **Offer an ART prescription:** choose one of preferred regimens:
   Biktarvy® ***(bictegravir/tenofovir AF/emtrcitabine)*** *1 pill PO daily*
   For most people, including those with high pregnancy potential: **Tivicay®** ***(dolutegravir 50mg)*** **+ (Truvada®** ***(TDF 300mg/emtricitabine 200mg)*** **or Descovy®** ***(TAF 200mg/emtricitabine 25mg)*****)**, *1 pill each PO daily*
   For people who used CAB-LA as PrEP and INSTI resistance testing results are not yet available: **Symtuza®:** ***darunavir/cobicistat/emtricitabine/ tenofovir alafenamide,*** *1 pill PO daily*
   See guidelines for certain clinical situations.
5. **Follow-up labs and meds in 5-7 days.**

▶PEP: HIV Post-Exposure Prophylaxis

PEP should be started within 72 hours of exposure; the sooner, the better. Use ICD-10 billing code Z20.6.

1. **Assess risk for HIV.** High risk—offer PEP: condomless receptive anal or vaginal sex, sharing needles. Consider PEP for: condomless insertive anal or vaginal sex. Obtain time for last possible exposure.
2. **Screen for acute HIV infection:** Symptoms include flu-like or mono-like symptoms such as high fever, myalgias, lymphadenopathy, arthralgias, rash, sore throat. Order HIV viral load.
3. **Order labs:** rapid HIV test if available, 4th gen HIV test, HIV viral load, hep C Ab w/reflex, hep BsAg, CMP, STI tests, upreg if applicable.
4. **If appropriate, prescribe 28-days of PEP.**
   No need to wait for lab results. Preferred regimens include:
   Tivicay® ***(dolutegravir 50mg)*** **+ (Truvada®** ***(TDF 300mg/ emtricitabine 200mg)*** **or Descovy®** ***(TAF 200mg/ emtricitabine 25mg)*****)**, *1 pill each PO daily*
   Or **Biktarvy®** ***(bictegravir/tenofovir AF/emtrcitabine)*** *1 pill PO daily*
   Or for those with high pregnancy potential, use the Tivicay® + (Truvada® OR Descovy®) regimen listed above
   (click on med name for drug assistance programs)
5. **Repeat HIV 4th gen Ag/Ab test in 6 and 12 weeks.**
6. **Assess need and offer PrEP after 28-day course of PEP is complete.**

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▶PrEP: HIV Pre-Exposure Prophylaxis

For help: PrEPline 855 448 7737
For resources: PleasePrEPMe.org

■ **Candidates for PrEP:** anyone requesting PrEP, has condomless anal or vaginal sex, inject drugs, has recent STIs, or partners with positive or unknown HIV status. **Use ICD-10 billing code Z20.6.**

■ **Preferred PrEP regimen for all at-risk adolescents and adults ≥35 kg:**
Truvada®: Tenofovir DF 300 mg + Emtricitabine 200 mg: 1 pill PO daily
- For guidance around "on-demand" 2-1-1 dosing with Truvada,® see the PrEP Quick Guide.

■ **Alternative PrEP regimen for people with or at risk of kidney or bone dysfunction, excluding people at risk only from vaginal/front hole sex or injection drug use:**
Descovy®: Tenofovir AF 25 mg + Emtricitabine 200 mg: 1 pill PO daily

■ **Injectable PrEP regimen for all at-risk adolescents and adults >35 kg, current or at-risk kidney dysfunction: Cabotegravir (CAB-LA): 600mg (3ml) IM gluteal muscle, 2 initial injections 4 weeks apart, maintenance injection every 8 weeks**
- (optional oral lead in)

■Side effects and drug interactions

- Short-term side effects: headache, nausea, diarrhea and abdominal discomfort usually resolve in a few weeks. CAB-LA: injection site reactions, fatigue, joint/muscle aches.
- Truvada and Descovy are active against chronic hepatitis B, so beware of hepatitis B flare when stopping.
- Use with caution in chronic kidney disease, risk of CKD and/or regular use of nephrotoxic medication. Renal dysfunction is seen in 1-2% of patients taking Truvada. For further information about drug interactions, see: **hiv-druginteractions.org**

■Contraindications:

- **Absolute:** acute, early, or chronic HIV infection (treat for HIV using a 3-drug regimen), eGFR<60 for Truvada or eGFR<30 for Descovy. For CAB-LA: Unknown or positive HIV-1 status, coadministration with CYP3A4 inducers
- **Caution:** Hepatitis B with cirrhosis/transaminitis, osteoporosis or history of fragility fracture for Truvada.

■Time to achieve protection:

- **Time to optimal protection with daily F/TDF is 7 days** for all people/types of exposure. Time to maximal protection for F/TAF and CAB have not yet been established.
- **Oral PrEP should be continued for at least 2 days after last rectal exposure and 7 days after last vaginal/front hole or blood exposure.**

■First visit:

- **Evaluate for exposures in the last 72 or so hours and need for PEP** (post-exposure prophylaxis)
- **Evaluate readiness for PrEP:** ask about interest and readiness, build rapport; discuss efficacy, side effects, support for and importance of adherence, insurance coverage and support for continuity, plan for refills and follow-up.
- **Labs:** CMP, 4th gen HIV test, GC/CT (throat, rectal, urine), RPR, UPT, hepBsAg, sAb, cAb, hep C Ab w/reflex. If using injectable PrEP, also get an HIV RNA.
- **If symptoms of acute HIV infection in past month** (fever, flu- or mono-like symptoms, rash, sore throat), get HIV viral load (will be positive ~10 days after exposure). **Consider treating for acute HIV and do not start PrEP unless virual load is negative.**
- **If HIV test neg and no symptoms of acute HIV infection,** write Rx for 1-month supply, no refill.

■ **1-month follow-up visit: Evaluate adherence and side effects.** Rx for 2-month supply, no refill.

■Follow-up visit every 3 months (or 2 months for CAB-LA):

- **HIV Ag/Ab, RPR/VDRL, GC/CT** (exposed sites), UPT (if pregnancy potential) q3-4 months. If age ≥50 or eCrCl<90, check a serum creatinine q6 months. If on injectable PrEP, get both HIV Ag/Ab and HIV RNA tests q2 months.
- **Refill** for 3-month supply only if HIV test negative; refer to immediate linkage to care if HIV test positive.
- **At every visit assess** for adherence, side effects, exposures (number of partners, anal/vaginal insertive/receptive exposures, condom use, drug use), desires around sexual wellness and continued PrEP use.
- **Counsel to return for HIV test if off of PrEP for > 1 week and had possible exposure.**

■ **Every 12 months: Hepatits C antibody or RNA; evaluate continued desire/need for PrEP.**

Preexposure Prophylaxis for the Prevention of HIV Infection in the United States (2021 Update) fi Clinical Practice Guideline. Available at **cdc.gov/hiv/guidelines/preventing.html**.

QUESTIONS? NEED HELP?

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Outside the Pacific Region, contact the AETC National Coordinating Resource Center: aidsetc.org, call **973 972 5141**, or email **info@aidsetc.org.**

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Submit consultation requests online at nccc.ucsf.edu.

AETC AIDS Education & Training Center Pacific

Clinical Essentials: HIV New Diagnosis and Health Care Maintenance

Updated May 2023

▶New HIV Diagnosis

■ At diagnosis, screen for:

- CD4 and HIV viral load
- HIV genotype including RT, PI, integrase resistance if prior CAB-LA or other concern
- HAV IgG, HBV cAb, sAg, sAb, HCV Ab - for evidence of coinfection and immunity
- IGRA or PPD/TST to rule out latent TB
- HLA–B*5701 for hypersensitivity if considering abacavir
- CBC w/ diff, complete metabolic panel, lipids, fasting glucose or HbA1c
- STI screens: RPR, GC/CT (incl. extra-genital), trichomonas.
- Toxo IgG for evidence of prior exposure (counsel to avoid exposure if negative).
- Consider checking G6PD levels. Assess need for PCP/PJP prophylaxis
- Consider CMV IgG for lower-risk patients (i.e. non-MSM and non-PWID): if negative, avoid CMV+ blood products.
- Consider VZV antibody and vaccinate if non-immune and CD4>200 cells/mm^3.
- Perform full physical and mental health assessment at diagnosis and at each follow-up visit as clinically indicated.

■ Recommended follow-up visits:

- 1 week after antiretrovial therapy (ART) initiation
- Every 4-8 weeks until viral suppression, then Q3-6 months
- Consider more frequent screen if pregnant, chestfeeding, or sexually active with partner who is pregnant/chestfeeding.

▶Chronic HIV

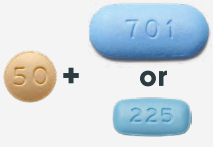
■ Treatment: antiretroviral therapy (ART) should be started as soon as possible.

- **DHHS Recommended initial regimens** for most people living with HIV (2 NRTIs + 1 INSTI):

Biktarvy®: Bictegravir/emtricitabine/TAF

Triumeq®: Dolutegravir*/abacavir/lamivudine (only if HLA-B5701 negative)

Tivicay® + either Truvada® or Descovy®: Dolutegravir* 50 mg+ tenofovir/emtricitabine (TDF 300/200 mg or TAF 25/200 mg)



Dovato®: Dolutegravir/lamivudine (only if HLA-B570 negative. Do not use if HBV coinfection, or HIV RNA >500,000 copies/mL)

Cabenuva®: Cabotegravir/rilpivirine – long acting injectable ART (Patient should first achieve viral suppression on another regimen before switching to CAB-RPV)

■ Check the following labs:

- **CD4:** Q3-6 months in first 2 years after initiation of ART. After 2 years of ART with consistently suppressed viral load: CD4>300-500 cells/mm^3 monitor annually. CD4>500 cells/mm3: monitoring is optional.
- **Viral load:** 2-8 weeks after ART initiation, then every 4-8 weeks until suppressed. First 2 years of ART: Every 3-4 months. After 2 years of ART with consistently suppressed viral load: Q6 months. Consider more frequent screen if pregnant, chestfeeding, or sexually active with partner who is pregnant/chestfeeding.
- **Cr, LFTs:** At 4-8 weeks after ART initiation, then Q6 months.
- **CBC w/ diff:** Q3-6 months (w/ CD4), then annually
- **Fasting lipid panel:** Annually, if abnormal, Q6 months.
- **Fasting glucose or HgA1c:** Annually, if abnormal, Q3-6 months.
- **TB screen:** Annual IGRA.
- **Repeat resistance testing:** In setting of treatment failure on ARVs—ensure that INSTI resistance testing is included if patient has been exposed to integrase inhibitors.

**For people who are pregnant or have childbearing potential, we recommend counseling patients through informed decision-making regarding the use of dolutegravir and other ARV drugs for people who are pregnant or have childbearing potential. Discuss future reproductive plans and timing with all patients as well as the risks and benefits of conceiving on specific ARV medications and contraceptive options.*

STI screening

- Screen for STIs annually at minimum (unless sexually abstinent), more frequently (Q3-6 months) as clinically indicated with ongoing exposures
- GC/CT vaginal/cervical/urine for sexually active patients
- GC/CT oropharyngeal swab for patients reporting receptive oral sex. Refer to CDC STD treatment guidelines.
- GC/CT rectal swab for patients reporting receptive anal sex
- Syphilis (RPR)
- Hepatitis C and hepatitis B serologies (if not previously infected or immune)
- Trichomonas at baseline and yearly in people with vaginas

Opportunistic Infection Prophylaxis:

- P. Jiroveci (PCP) if CD4 <200 cells/mm^3 or CD% <14%
- Toxoplasmosis if CD4 <100 cells/mm^3 and Toxo IgG positive
- Mycobacterium avium complex (MAC) if not on HIV ART, VL>200 copies/mL and CD4 <50 cells/mm^3
- CMV retinitis screen if CD4 <50 cells/mm^3 (quarterly)
- Consider discontinuing prophylaxis if CD4 100-200 and patient has an undetectable viral load on ART (see guidelines)

Immunizations:

- HBV if HBVsAg, sAb and cAb negative: Give series at regular dose. Check HBsAb 2-3 months after series and if not immune, repeat series at double dose (40 mcg). Consider immunization for isolated HBcAb + patients as well.
- HAV if HAV IgG negative
- Meningococcal vaccine (MenACWY) 2 initial dose series at least 8 weeks apart, then every 5 years
- Flu shot annually (inactivated; not live)
- Pneumococcal vaccine: Either PCV20 alone or PCV15 + PPSV23 (at least 8 weeks later) for adults aged 19-64 years with HIV and for 65 and older if vaccine history is absent or unknown
- Tdap (if not received as an adult; tetanus recommended every 10 years)
- HPV vaccine: all men and women up to 45 years old
- Zoster (RZV): Two-dose series of Shingrix recommended for all adults 19 y/o and older
- COVID-19: see CDC guidelines
- MMR: Two-dose series at least 1 month apart (Contraindicated if CD4 <200)
- Varicella: Two-dose series 3 months apart (Contraindicated if CD4 <200)

Age-Appropriate cancer screening:

- Cervical cytology at baseline and repeat 6-12 months later, then annual thereafter if neg (refer for colposcopy if abnormal). If 3 consecutive pap smears are negative, may spread out pap smears to Q3 years. Avoid HPV co-testing for patients <30 years old. See OI guidelines for screening frequency if HPV co-testing is available.
- Consider anal cytology for patients reporting receptive anal sex, patients with anal warts, patients with cervical dysplasia present (there is no clear consensus in DHHS guidelines currently; discuss risk/benefit of screening).
- All other cancer screenings follow routine primary care healthcare maintenance guidelines for general population (i.e. mammography, colorectal screening).

Screen for co-morbidities and address psychosocial well-being, including:

- Ask about current priorities: "What is most important to you right now?"
- Screen and offer support/treatment for:
- Mental health and psychiatric conditions including depression, anxiety, PTSD
- Substance, tobacco,and alcohol use disorder
- Unstable housing and food insecurity
- History of or current trauma
- Identify and troubleshoot strengths and barriers to medication adherence
- Assess family planning desires and sexual health and well-being for all patients
- Conduct comprehensive transmission risk reduction counseling (i.e. Treatment as Prevention, "Undetectable=Untransmittable"). Offer PEP or PrEP if indicated/appropriate for HIV-negative partners.
- Offer support for disclosure of diagnosis to partners, family and friends

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Sources:

Panel on Antiretroviral Guidelines for Adults and Adolescents. *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV.* Department of Health and Human Services. aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/0.

Primary Care Guidelines for the Management of Persons Infected with Human Immunodeficiency Virus: 2013 Update by the HIV Medicine Association of the Infectious Diseases Society of America. Clinical Infectious Diseases 58; 2013; 58 : 1 -34

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Pill photos: US DHHS National Institutes of Health (NIH) and Test Positive Aware Network (TPAN).

Feedback/questions: **paetcmail@ucsf.edu**.

AETC AIDS Education & Training Center Pacific

HIV Testing and Disclosure FAQs

Updated May 2023

Whom should I test for HIV?

Test everyone ages 13+!

- CDC guidelines: test everyone ages 13-64.
- **Repeat testing every 6 months for people at high risk:** HIV+ partners with viral loads >200, MSM, STIs, multiple sexual partners, injection drug use.

Also test any patients coming in for/as/with:

- STI testing or treatment
- Tuberculosis
- Pregnancy, including people without a documented HIV test result presenting for delivery
- Hepatitis B and C
- History of handling blood, receiving, donating or selling blood in areas without a securely screened blood supply
- Consider **diagnostic HIV testing** for flu-like symptoms 2-8 weeks after a risky exposure (get HIV RNA viral load and 4th gen test), oral thrush, herpes zoster, unexplained anemia, thrombocytopenia, WBC abnormalities, recurrent infections

Which HIV test do I use? Billing code?

- **HIV 4th generation antigen+antibody lab test**
- For exposure in the last month: HIV RNA PCR viral load test
- Use **ICD-10 code Z11.4**: screening for HIV

How do I interpret 4th gen HIV test results?

HIV Ag/Ab non-reactive:	HIV Ag/Ab reactive & HIV1/2 diff reactive:	HIV Ag only reactive & HIV1/2 neg + RNA detected:	HIV Ag/Ab reactive & HIV1/2 neg & RNA neg:
negative for HIV (2-3 week window period from exposure)	**chronic infection** call linkage coordinator, offer rapid ART	**acute infection** call linkage coordinator, offer rapid ART!	**negative** likely false pos Ab result; if high risk, check HIV2 DNA or RNA

What if a patient refuses to get an HIV test?

- Ask about it and address concerns and fears.
- Be sensitive; they may be scared to disclose a risk.
- Try asking again later; they may be eventually willing to test.

How do I provide opt-out HIV testing?

Let them know that it's a normal part of baseline labs.

"We test everyone's cholesterol, sugars, liver, kidneys, and screen for HIV and hepatitis, so I'll order these tests for you."

How provide opt-out HIV testing for a follow-up patient?

Let them know it will part of their next lab draw.

"We need to check your cholesterol and sugars again, and since we haven't checked for HIV yet, let's do that. The HIV test is a normal part of health screening for everyone. Sound OK?"

How do I disclose a positive result?

1. Call the patient in for an in-person visit to discuss lab results.
2. Disclose in-person within one week of the result.
3. Coordinate with the HIV team to be available so you can do an immediate warm-handoff to HIV services.
4. When the patient is sitting, calmly, clearly and neutrally let them know.

   "Your lab results show that you have HIV."

   Give them a few moments to let the information sink in.

   "Would you be willing to share your thoughts, feelings or questions about this?"

   Listen and address what comes up.

   "We have really good treatment and services to help you live as long and healthy as possible. May I introduce you to _____, who will help answer your questions and connect you with care with a specialist here?"

How do I link the patient to HIV care, PEP or PrEP?

Call your HIV linkage navigator:

_____

at _____ to coordinate linkage to HIV specialty care, PEP or PrEP. Treatment reduces transmission by 96%!

Questions?

Call the **National Clinician Consultation Center (NCCC)** for HIV clinical questions: **800-933-3413**

Author: Sophy S. Wong, MD; with many thanks to the HIV ACCESS care teams for their feedback.

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Feedback/questions: **paetcmail@ucsf.edu**.

Protocol: HIV Testing and Disclosure

Updated May 2023

▸HIV testing and linkage protocol

■ **POLICY:** In accordance with the CDC guidelines, we recommend opt-out HIV antibody testing for:

- All asymptomatic patients ages 13-64 at least once in their lifetime.
- All pregnant patients at least once during their pregnancy.
- Every 3 months for patients with ongoing exposures, including people engaging in condomless anal sex, particularly receptive anal sex, and those who inject drugs—also offer them HIV Pre-Exposure Prophylaxis (PrEP) if HIV-negative.
- Patients with STIs with each new or recurrent diagnosis — also offer them PrEP if HIV-negative.
- Patients with certain comorbid conditions, which would alter or require therapy: hepatitis B, hepatitis C, tuberculosis, varicella zoster in adults, and any other opportunistic illness that suggests an immunocompromised state.

Our community-based HIV programs also provide free confidential or anonymous rapid HIV testing for any member of the community.

▸PROCEDURE: Clinic testing

■ Opt-out HIV testing

1. Include the 4th gen HIV antigen/antibody lab-based test with other screening tests:
   a. "4th gen: HIV Ag/Ab" (window period is 14 days)
   b. ICD-10: use Z11.4 as the billing code
2. Notify the patient what you will be testing them for. For example: *"We test everyone's cholesterol, sugars, liver, kidneys, and screen for HIV and hepatitis, so I'll order these tests for you."* Or *"Looks like you haven't been tested for HIV or hepatitis B/C, so let's add those tests to your next labs."*
3. No documentation is necessary unless the patient refuses the test. If the patient refuses, then document "HIV test refused" and the reason (if known) in the chart.
4. Test counseling is optional, but we strongly recommend asking patients about their sexual and drug use history, especially during intake and physical exams.

HIV Ag/Ab non reactive:
Negative results

- Let patients know at the time of testing: *"We'll let you know if we need follow-up. If you don't hear from us, the result is negative."*
- Repeat testing every 3 months for MSM, PWID & others with ongoing exposures. Repeat test with others who have potential exposures since last test. False negative can occur if exposure is recent, and testing is done during the window period.

HIV Ag/Ab reactive & HIV1/2 neg & RNA neg
Discordant/negative results

- HIV infection is unlikely. There is a very small chance that this may be an acute (within 14-day) infection or recent HIV-2 infection.
- Consider testing for HIV-2 viral load and seek expert consultation.
- Inquire about PrEP and PEP use.
- Call your HIV linkage contact or the National Clinician Consultation Center (NCCC) for help: 800-933-3413.

HIV Ag/Ab reactive & HIV1/2 or RNA detected:
Positive for acute or chronic HIV

- The patient has confirmed HIV infection
- Use ICD-10 dx code: B20 (sx) or Z21 (asx)
- Immediate follow up is critical!
- Notify patient to come in for result disclosure within 5 days.
- Notify your HIV linkage contact for help with disclosure and immediate linkage
- Counsel on risk reduction (condoms, abstinence, treatment, needle exchange)
- For people with pregnancy potential, evaluate and counsel on birth control and prevention of parent to child transmission.
- **Please see the rapid ART protocol.**

Clinical Protocol: Rapid ART

Updated May 2023

Purpose: To provide people-centered service and promote community health by reducing barriers to medical care and supporting people with HIV to access treatment immediately. Clinical trials have shown that starting antiretroviral therapy (ART) as soon as possible after diagnosis increases ART uptake, engagement in care and virologic suppression. Using ART to suppress HIV viral loads to <200 copies/mL prevents HIV sexual and vertical transmission, also known as U=U:

Undetectable = Untransmittable.

Rationale: National DHHS guidelines and international WHO guidelines recommend initiating HIV antiretroviral therapy (ART) "immediately or as soon as possible" for all people with HIV, regardless of CD4 count. Initiating ART early and rapidly, especially in acute or recent infection, may reduce the viral reservoir for that individual patient (Jain 2013), preserve CD4 function (Saez-Cirion 2013), increase retention in care (Pilcher 2017, Rosen 2016, Koenig 2016) as well as reduce viral load during a time when the patient may be at highest risk for transmission to others (Coffey 2019, Bacon 2018, Pilcher 2017, Cohen 2011).

The SF General RAPID pilot program, including 86 patients who did not have private health insurance (100%), were non-white (66%), homeless (28%), had mental health disorders (42%), substance abuse disorders (42%) demonstrated shorter time to virologic control (65 vs. 170 days), higher retention at 6 months after diagnosis (90% vs. 85%), and higher rates of ART acceptance (100% vs. 85%) among the 39 patients randomized to rapid ART compared to usual care (Pilcher, JAIDS 2017). Of the 225 patients referred to the SF RAPID program from 2013-17, 96% achieved viral load suppression within 1 year and 92% had durable viral load suppression (Coffey, AIDS 2019). In the international randomized START trial, researchers found that immediate ART had significant improvements in self-assessed quality of life scores (Lifson, AIDS 2017). In the South African RapIT trial (Rosen 2016), people randomized to receive same-day ART had 36% increased uptake of ART and 26% higher rates of viral suppression. A same-day ART randomized study with 762 patients in Haiti showed significantly better 12-month retention in care (54% vs. 42%) and likelihood of being alive (80% vs. 72%) compared to patients in standard care (Koenig, AIDS 2016).

For patients who are not newly diagnosed with HIV but are re-engaging in care, we aim for the intake/orientation appointment and an initial HIV medical visit within 5 days of presenting for care. Data from Project CONNECT (Mugavero, 2008) demonstrated significantly increased linkage to HIV medical care at 6-months when intake/orientation visits were within 5 days of the initial referral call or patient request.

▶Rapid ART and warm handoff for patients newly diagnosed with HIV

1. **New diagnosis with confirmation and same-day rapid ART linkage:** The clinician confirms diagnosis with documentation of a positive HIV viral load, HIV antibody test or 4th generation HIV Ag/Ab test with an HIV 1/2 differentiation, viral load (RNA or NAAT) confirmation. For point-of-care rapid HIV tests, you may wait until the test is confirmed positive to initiate rapid ART, or if there is high probability for HIV infection or suspected acute HIV infection (symptoms, recent exposure), send a viral load (RNA or NAAT). Consider same-day ART before you receive the result.

   a. If there are any questions, the clinician may call the **National Clinician Consultation Center: 800-933-3413**.

   b. **Immediately call the HIV linkage coordinator and/or HIV provider at your care site to coordinate the HIV disclosure, warm handoff and rapid ART linkage process.**

   c. The goal is for the rapid ART intake and clinic orientation appointment to be on the same day as the diagnosis is disclosed to the patient. The testing clinician is responsible for in-person disclosure of the positive test result to the patient, and the linkage coordinator and/or HIV provider can provide support. If the testing clinician is not available in a timely way, the linkage coordinator and intake nurse/provider may also disclose.

2. **Obtain baseline labs as soon as the diagnosis is confirmed or if patients are referred without baseline labs:** Please refer to the list of baseline labs on the third page of this protocol. For patients without contraindications to rapid ART, do not wait for lab results to prescribe ART. If ART is prescribed before baseline labs were drawn, we recommend that baseline labs be drawn as soon as possible. The starred labs (★) on page 11 are of highest priority.

3. Same-day disclosure, warm handoff and intake/orientation appointments:

a. Ideally the HIV linkage coordinator will be available by work cell to meet the patient the same day as disclosure and facilitate a same-day warm handoff to a rapid ART nurse/provider appointment, labs, medication and health insurance coverage assistance.

b. For patients without insurance, these benefits can often be activated the same-day: Ryan White AIDS Drugs Assistance Program (ADAP).

c. HIV providers at each site will have at minimum one drop-in slot available each day to accommodate same-day immediate rapid ART linkage appointments. When these drop-in slots are not filled, the same-day appointment can be made available to other patients.

d. When HIV providers are not available, please schedule same-day appointments for providers willing to prescribe rapid ART. HIV team members are encouraged to support non-HIV providers with this protocol.

4. Clinical handoff: The diagnosing clinician, if not the same as the HIV care nurse/provider, provides a care handoff to the HIV nurse/provider in-person, via phone, EHR or HIPAA-secure encrypted email.

5. Linkage facilitation: The clinician calls the HIV linkage coordinator who will:

a. Arrange for a same-day intake appointment with a nurse or provider who can conduct a brief evaluation and provide a prescription for HIV ART.

b. Keep track of the patient to ensure a **warm handoff** and successful linkage to care.

c. HIV education counseling and eligibility evaluation: on the same day as diagnosis, the HIV linkage coordinator provides the patient with an intake, including HIV health education counseling and enrollment for insurance coverage if needed.

d. ADAP and/or other medication assistance programs: If the patient is uninsured or has inadequate insurance to pay for medication, assess eligibility for ADAP (AIDS Drug Assistance Program) and/or other assistance programs and support them in the enrollment process..

e. Facilitate the patient to receive partner counseling as well as food, housing, transport and other services as needed.

6. During the rapid ART nurse/provider appointment:

a. The patient's information is entered into the EHR HIV template (if applicable).

b. The nurse/provider conducts a brief, targeted medical history and exam.

i. Ask about current priorities: "What is most important to you right now? How do you want to feel?"

ii. HIV history and readiness for treatment: "How do you feel about taking medications for HIV?"

1. Date of last negative HIV test and prior HIV tests
2. PrEP and PEP use history
3. Any other HIV medication use (e.g. ART sold on the street or given by friends or family)
4. Sexual/drug exposures and serostatus of partners. If known to have a partner with HIV, ask if the partner has history of medication resistance

iii. Medical history:

1. Co-morbidities, especially renal and liver conditions
2. Medications
3. Drug allergies
4. Review of systems to assess for acute HIV symptoms and opportunistic illnesses
5. If not already obtained, the nurse/provider orders baseline labs (see next page).

c. Screen for TB and cryptococcal meningitis and if positive, start OI treatment first, then start ART within 2 weeks for TB and within 2-4 weeks for cryptococcal meningitis with close monitoring for immune reconstitution inflammatory syndrome (IRIS).

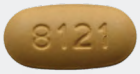
■ Recommended Rapid ART regimens: use ICD10 code B20 or Z21.

Biktarvy®: Bictegravir/emtricitabine/TAF, *1 tab once daily*

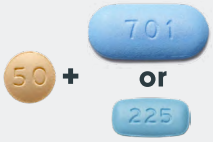
Triumeq®: Dolutegravir*/abacavir/lamivudine
(only if HLA-B5701 negative and without chronic HBV), *1 tab once daily*

Dovato®: Dolutegravir/lamivudine (only if HLA-B570 negative. Do not use if HBV coinfection, or HIV RNA >500,000 copies/mL), *1 tab once daily*

Symtuza®: darunavir/cobicistat/emtricitabine/tenofovir alafenamide (For people who used CAB-LA as PrEP and INSTI resistance testing results are not yet available), *1 tab once daily*



Tivicay® + either Truvada® or Descovy®: Dolutegravir* 50 mg+
(TDF 300/200 mg or TAF 25/200 mg), *1 tab each once daily*



Cabenuva®:
Cabotegravir/rilpivirine – long acting injectable ART (injection every 1-2 months)
(Patient should first achieve viral suppression on another regimen before switching to CAB-RPV)

**For people who are pregnant or have childbearing potential, we recommend counseling patients through informed decision-making regarding the use of dolutegravir and other ARV drugs for people who are pregnant or have childbearing potential. Discuss future reproductive plans and timing with all patients as well as the risks and benefits of conceiving on specific ARV medications and contraceptive options.*

d. If the patient accepts rapid ART, the provider, or the nurse with precepting provider:

- **i.** prescribes a 30-day supply of medication.
- **ii.** notifies the pharmacy that the prescription is for immediate fill.
- **iii.** notifies the linkage coordinator to follow-up on medication coverage, pick-up and initiation within 1-3 days.
- **iv.** schedules a follow-up appointment within 5-7 working days to discuss lab results, assess medication and treatment plan.

e. If the patient declines rapid ART, use Motivational Interviewing techniques to discuss their reasons and preferences, and schedule a follow-up appointment within 5-7 working days to discuss laboratory results and reassess treatment plan.

▶Baseline labs

When possible, please order these baseline labs as soon as diagnosis and disclosure is made. The starred labs (★) are of highest priority for safely starting ART, in case the patient would like to split up the lab draws.

Highest priority labs

- ★ If only point-of-care rapid test has been done, order a 4th gen HIV Ag/Ab test
- ★ HIV viral load (RNA or NAAT); CPT code 87536
- ★ CD4 count and %; CPT code 86360
- ★ HIV genotype; CPT codes 87900, 87901, 87906
- ★ CBC with differentiation
- ★ Complete metabolic panel, including renal and liver function
- ★ Hepatitis B sAg
- ★ RPR or VDRL
- ★ Urinalysis with microscopy; you may consider checking microalbumin
- ★ GC/CT NAAT (urethral, vaginal/front hole, rectal, pharyngeal, depending on exposures)

Additional baseline labs

- Hepatitis A total Ab
- Hepatitis B sAb, cAb
- Hepatitis C Ab or RNA if prior treatment
- Lipid profile (non-fasting is fine)
- HgA1C
- VZV IgG
- IGRA
- Toxoplasmosis IgG
- If considering Abacavir: HLA B*5701; CPT 81381
- For some patients: consider urine pregnancy, G6PD levels, CMV IgG, and trichomonas screens.

▶Rapid ART for patients re-engaging in care or transferring care

1. If the patient was previously diagnosed but does not have documentation of the test result or past history: if available, conduct a rapid HIV test and draw blood to send an HIV 4th gen Ag/Ab test along with other baseline labs. You may consider a positive rapid test as sufficient proof to start the rapid ART process.

2. **If the rapid test is positive or they have documentation of their HIV diagnosis,**

   a. **and they HAVE NOT been on ART before** and are willing to start, conduct the intake, baseline labs, brief visit and provide an ART prescription on the same day when possible, following the same steps for newly-diagnosed patients.

   b. **and they HAVE been on ART before** and can provide the names of their medication and adherence history with some degree of confidence, conduct intake, get baseline labs, sign a release for medical and pharmacy history, contact the pharmacy to verify their most recent ART regimen, facilitate a brief visit and ART prescription on the same day when possible, or as soon as possible within 5 working days. Do not wait for documentation before starting ART. Get INSTI resistance testing with the genotype if the patient has prior INSTI exposure. You can start ART the same day or a few days before you get resistance testing.

▶Rapid ART eligibility and medication coverage as of May 2023

1. If the patient is:
   - Insured with affordable co-pay: they are covered; ensure referral to accepting provider.
   - Insured with high co-pay: see co-pay assistance programs below.
   - Use ICD10 codes B20: "Human immunodeficiency virus [HIV] disease" or Z21: "asymptomatic HIV."

2. **Co-pay assistance programs**

   i. If patient has a high co-pay, Gilead (maker of Biktarvy,® Truvada® and Descovy®) has a co-pay assistance program: gileadadvancingaccess.com, **877-505-6986**

   ii. Updated co-pay assistance resources can be found on the **NASTAD website**.

4. **Uninsured patients: Patient Assistance Programs for medications:**

■ **Biktarvy,® Truvada® and Descovy®:** The Gilead Advancing Access Program can provide a 30-day supply at no cost for those without coverage, up to 500% FPL: gileadadvancingaccess.com.

1. Go to the website to download the most current enrollment form.
2. Follow the directions to complete & submit the form. If you have a Gilead designated agent, call them after 20 minutes.
3. Gilead can provide a same-day voucher: Fax a letter stating why same-day ART is necessary to the fax number on the form. The letter needs the patient's name, DOB, social security number, date of exposure, any kind of income, household size, and state that it is necessary for new or acute infection.
4. Call **800-226-2056** (Monday - Friday, 6 am-5pm PST) to get a voucher and bin number to take to pharmacy, and patient should be able to get the medication.

■ **Biktarvy® starter kits**

1. A Gilead Therapeutic Specialist may be able to provide start kits including 7 pills of Biktarvy® to each facility.
2. The starter kits are designed to help with each facility's current rapid ART protocol and in situations where the provider has decided a regimen switch is appropriate.
3. The starter kits can be replenished by calling the Gilead Therapeutic Specialist. There may be limited amount so please discuss with your representatives as to what is an appropriate amount for your facility.
4. The starter kits must be signed by an HCP-program designated prescribing provider aligned to each clinic at the time of drop off.
5. Your representative can give you more information as to which HCP provider can sign for the starter kits. If other providers are interested in signing for the starter kits, your Gilead Therapeutic Specialist can submit the appropriate paperwork. The process for adding a new HCP provider can take up to 3 months.

■ Symtuza® starter kits and same-day starter vouchers:

A Janssen represenative may be able to provide Symtuza® starter kits for your facility. Contact them to find out.

The Janssen CarePath portal provides online and phone support to obtain same-day pharmacy vouchers for Symtuza® for patients meeting their eligibility requirements: janssencarepath.com/hcp/symtuza

■ Dolutegravir (Tivicay®):

The Viiv Healthcare Patient Assistance Program will provide a same-day voucher for a 30-day supply of dolutegravir at a local pharmacy.

1. Fill out the enrollment form: viivconnect.com/get-started
2. An advocate must call. Any healthcare staff can become an advocate on the same day by calling: **844-588-3288**, 5am–8pm PST, best to call by 4 pm. You will get an advocate number and patient ID to complete the voucher.
3. The patient brings the voucher and the prescription to a local pharmacy.
4. Do not fax the form before the patient picks up the medications. Faxing the form initiates the mail-order refill service and invalidates the initial voucher number. After the patient picks up the first 30-day supply, you can determine if mail order services is needed. If no other medication coverage will be in place for the next fill, then consider faxing the form.

▶ Rapid ART tracking and Quality Management

1. Track the following dates for each newly diagnosed patient and previously diagnosed patient who is re-engaging in care.

- **Diagnosis/lab result date:** date that HIV confirmatory lab results were available for review.
- **Referral date:** date when the patient confirmed they want to establish care with your site.
- **Intake date:** date the patient came in with a confirmed diagnosis to see a member of your team to establish care (e.g. received orientation and eligibility, Ryan White enrollment).
- **First medical visit date:** date the patient came in to see a clinical provider and received any care related to HIV (does not have to be with an HIV specialist or provider).
- **ART date:** date the patient received the first ART prescription from your site.
- **Viral load suppression date:** the first date the patient had an HIV RNA viral load <200 copies/ml.

2. Set the rapid ART metrics and goals for the patient population you want to track, for example:

a. San Francisco's RAPID ART definition = diagnosis to visit in 5 days + visit to Rx in 1 day

- **Diagnosis to visit within 5 days** = number of patients whose date of confirmed HIV lab result to the date of first HIV-related medical visit was within 5 days.
- **And visit to Rx (prescription) within 1 day** = number of patients whose date of first HIV-related medical visit to the date of first ART prescription was within 1 day.

b. HIV ACCESS Rapid ART definition = intake to Rx in 1 day

- **Intake to Rx (prescription) within 1 day** = number of patients whose date of intake to date of first ART prescription was within 1 day.

c. New diagnosis rapid ART metric = % of newly diagnosed patients in the last 12 months who meet the rapid ART definition you've chosen (SF's or HIV ACCESS definition above).

d. Re-engagement rapid ART metric = % of patients re-engaging in care and not on ART in the last 12 months whose date of referral to date of ART prescription was within 5 days.

3. Set your goals, time-frame and action plan. Some examples:

   a. From January 2020 to June 2020, we aim to increase % meeting the SF RAPID new diagnosis definition from 60% to 80% using the steps outlined in this protocol.

   b. From January 2020 to June 2020, we aim to increase the % for people re-engaging in HIV care with an ART Rx within 5 days of referral using the steps outlined in this protocol.

■ Case example for a newly diagnosed patient with HIV

On 1/9/2020 Berkeley Free Clinic called your team's linkage contact person about a patient who received confirmation for an HIV positive test result on 1/6/2020 and spent the weekend deciding on which clinic to get care. The patient came in to see the linkage coordinator at your clinic on 1/9/2020 and saw a medical provider for an ART prescription on the same day.

Diagnosis date: 1/6/2020 Referral date: 1/9/2020

Intake date: 1/9/2020 **First medical visit date:** 1/9/2020 **ART date:** 1/9/2020

If the newly diagnosed patient rapid ART metric is defined as time from referral to ART, then this patient meets both the SF RAPID and the HIV ACCESS definition for same-day rapid ART. Her time from diagnosis to medical visit was 3 working days, and the time from medical visit to ART is 0 days (same day). Her time from intake to ART is 0 days (same day).

■ Case example for a patient re-engaging in care

On 1/9/2020 Berkeley Free Clinic called your team's linkage contact person about a patient who's been out of care, re-tested HIV positive and wants to come to your clinic. The patient is not totally sure when he was first diagnosed but is guessing it was 5 years ago at Highland Hospital. He gets on the phone and confirms he wants to be seen at your clinic and provides his contact information to the linkage coordinator over the phone. The patient came in to see the linkage coordinator on 1/10/2020 and saw a medical provider for an ART prescription on the same day.

Diagnosis date: 2013 (estimated) **Referral date:** 1/9/2020

Intake date: 1/10/2020 **First medical visit date:** 1/10/2020 **ART date:** 1/10/2020

If the re-engaging rapid ART metric is defined as date of referral to date of ART prescription within 5 days, then this patient meets the criteria for re-engaging patients and rapid ART. His time from referral to ART is 1 day.

Author: Sophy S. Wong, MD; with many thanks to the HIV ACCESS care teams for their feedback.

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Feedback/questions: **paetcmail@ucsf.edu**.

AETC AIDS Education & Training Center Pacific

Quick Clinical Guide: HIV Non-occupational Post-Exposure Prophylaxis (PEP)

Updated May 2023

1. Assess risk for HIV based on exposure.

***PEP should be started within 72 hours of exposure; the sooner, the better. PEP is indicated for the following high-risk exposures with someone living with HIV and a viral load > 200 copies/mL or someone at risk for HIV with unknown status.**

Level of risk	Types of exposures
High risk ▶ offer PEP	• Condomless receptive anal sex • Condomless receptive vaginal sex • Sharing needles
Moderate risk ▶ consider PEP, discuss with patient	• Condomless insertive anal sex • Condomless insertive vaginal sex
Low risk ▶ would not offer PEP	• Insertive or receptive oral sex (consider for receptive if significant bleeding, ulcerations or trauma in mouth and ejaculation) • Sharing cookers, cotton or other drug paraphernalia • Zero/no risk: Blood or semen splash on intact skin • Zero/no risk: Exposure to urine, saliva or bites

2. Screen for symptoms of acute HIV Infection.

- Fever, fatigue, myalgias, lymphadenopathy rash, and/or sore throat (flu-like symptoms) are the most commont acute HIV symptoms.
- If symptoms are present, order an HIV RNA viral load, consider providing rapid ART and ensure close follow-up.

3. Order labs. You do not need to wait until labs are drawn or resulted before starting PEP.

- **4th generation HIV Ag/Ab test or rapid HIV test**
- **HIV viral load (RNA PCR or NAAT)**
- STI testing, serum creatinine, hep C Ab w/reflex, hep B surface antigen (HBsAg), urine pregnancy test (if applicable)

4. Choose a 3-drug PEP regimen: Duration for all regimens is 28 days.

- **Use ICD-10 code Z20.6 (exposure to HIV) for billing.**
- **Write out "for post-exposure prophylaxis" in notes to the pharmacy to help with coverage.**
- **Discuss choices with the patient; consider coverage/cost and adherence to the regimen.**

■ Preferred regimens*

Biktarvy® ***(bictegravir/tenofovir/emtrcitabine)*** *1 pill PO daily*

Or **Tenofovir DF/emtricitabine** ***300/200 mg (Truvada® or generic**)*** **+ Tivicay®** ***(dolutegravir 50 mg)****, each 1 pill PO daily*
(This regimen recommended in people with high pregnancy potential)

**The use of Biktarvy® or Descovy® for PEP is based on expert opinion and limited clinical data. They are not currently included in CDC PEP guidelines.*
***Avoid using tenofovir DF (Truvada® or generic) in patients with known kidney disease (eGFR/eCrCL <60 mL/min). In patients with eGFR>30 mL/min, Descovy® (Tenofovir alafenamide (TAF) 25mg/emtricitabine 200mg) may be considered in the place of Truvada® or generic tenofovir DF/emtricitabine.*

5. Counsel patient on possible side effects and importance of taking meds daily for full 28 days.

a. Common side effects of tenofovir (Truvada® and Descovy®): nausea, abdominal discomfort or headache

b. Adherence tips: Use a pill box, electronic/phone reminder, link dosing to a daily habit or routine.

6. Arrange for a repeat 4th generation HIV test in 6 and 12 weeks.

7. Consider offering patient "PEP to PrEP."

Patients should be considered for transition to PrEP with Truvada® (tenofovir DF/ emtricitabine) or Descovy® (tenofovir AF/ emtricitabine) immediately after completing 28 days of PEP, or if future HIV exposures are likely or possible.

To transition from PEP to PrEP, check an HIV Ag/Ab test while on week 4 of PEP and prescribe PrEP so they can start PrEP as soon as they are done with PEP. Confirm that the HIV testing done during week 4 of PEP is negative to continue PrEP.

8. Advise patient on options for PEP follow-up or if HIV test is positive.

Contact your in-house PrEP navigators, HIV linkage staff or HIV providers. If you do not have in-house staff, please refer to your local health department.

Have questions?

National Clinician Consultation Center PEP Hotline (nccc.ucsf.edu): 888-448-4911

PEP medication coverage:

■ Insured patients

- Write in notes to the pharmacy: "for HIV post-exposure prophylaxis, ICD10 code Z20.6"
- Most private insurers cover PEP
- If patient has a high co-pay, use the following co-pay assistance programs can also be used:
  - » Gilead (Truvada®): gileadadvancingaccess.com
  - » Merck (Isentress®): activatethecard.com/7574/#
  - » Viiv (Tivicay®): viivconnect.com

■ Uninsured patients

- A number of manufacturer assistance programs can help provide access to PEP medications (see next page).

PEP manufacturer patient assistance programs:

Truvada®, Descovy® and Biktarvy®:

Patient Assistance Programs will provide a same-day 30-day supply at no cost for those who are without coverage, <500% FPL, meet medical necessity and are within 72 hours of exposure:

1. Complete online enrollment form with patient: gileadadvancingaccess.com
2. Fax letter of necessity to the number on the form; The letter needs name, DOB, social security number, date of exposure, any kind of income, household size, and needs to state that this is a necessary drug due to exposure.
3. Call **800-226-2056** (M-F, 6am-5pm PST) to get voucher and bin number to take to pharmacy,
4. Call local pharmacy to ensure tht medication is available; with voucher/bin number, the patient should be able to get same-day access to medication at no cost.

Biktarvy® starter kits may be available to you

1. A Gilead Therapeutic Specialist may be able to provide starter kits with 7 pills of Biktarvy® to each facility.
2. These starter kits are patient resources and designed to help with each facility's current rapid ART protocol or in situations where the provider has decided to a regimen switch is appropriate.
3. The starter kits can be replenished by calling the Gilead Therapeutic Specialist.
4. The starter kits must be signed by an HCP-program designated prescribing provider at drop-off.
5. Your representative can give you more information as to which HCP provider can sign for the starter kits. If other providers are interested in signing for the starter kits, your Gilead Therapeutic Specialist can submit the appropriate paperwork. Adding a new HCP provider can take up to 3 months.

Dolutegravir (Tivicay®):

The Viiv Healthcare Patient Assistance Program can provide a same-day voucher for a 30-day supply of dolutegravir at a local pharmacy.

1. Fill out the enrollment form: viivconnect.com/get-started/
2. An advocate must call. Any healthcare staff can become an advocate on the same day by calling: **844-588-3288**; best to call by 4 pm. You will get an advocate number and patient ID to complete the voucher.
3. The patient brings the voucher and the prescription to a local pharmacy.
4. Do not fax the form. Faxing the form initiates the mail-order refill service and invalidates the initial voucher number.

Authors: Stephanie Cohen, MD, MPH; Samali Lubega, MD; Philip Peters, MD; Sophy S. Wong, MD

Funding for this presentation was made possible by 5 U1OHA29292-08-00 from the Human Resources and Services Administration HIV/AIDS Bureau. The views expressed do not necessarily reflect the official policies of the Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government. Any trade/brand names for products mentioned in this document are for training and identification purposes only.

Feedback/questions: **paetcmail@ucsf.edu**.

AETC AIDS Education & Training Center Pacific

CDPH

Quick Clinical Guide: HIV PrEP Pre-Exposure Prophylaxis

Updated May 2023

Pre-exposure prophylaxis (PrEP) is safe and effective for significantly reducing the risk of HIV infection in sexually active individuals and people who inject drugs (PWID). The U.S. Preventive Services Task Force has given PrEP Grade A status. This document is a brief "how-to guide," including medication coverage options and links to patient assistance programs for low-income patients. For resources and referrals, go to **PleasePrEPMe.org**. All web links are clickable in this document.

1. Identify patients who may benefit from PrEP:

- HIV-negative individuals, including adolescents, men who have sex with men (MSM) and women, transgender individuals, who may benefit from PrEP include:
- People who ask for PrEP
- People with HIV-positive partners or partners at high risk or with unknown HIV status
- People with sexual exposures including condomless anal sex, multiple sex partners, or transactional sex (such as sex for money, drugs, food, or housing)
- People who have been or their partners have been incarcerated
- People who inject drugs (PWID) or substances and people who use stimulants, such as methamphetamine, during sex

Do NOT withhold PrEP from eligible candidates who:

- Are pregnant or planning to conceive
- Inconsistently use condoms or other risk-reduction methods
- Engage in substance use
- Have mental health disorders of any severity
- Experience intimate partner violence
- Have unstable housing or limited social support
- Have recently had an STI
- Have a partner with HIV who has an undetectable viral load

2. Discuss PrEP with your patient

Be present and listen. Ask about interest in and readiness for PrEP:

- What do you know about PrEP? Do you know anyone on PrEP?
- What makes you want to start PrEP? What do you hope PrEP will do for you?
- What barriers do you foresee? How long do you foresee being on PrEP?

Let them know what to expect and about the potential risks and benefits of PrEP. Important points include:

Adherence	Adherence is correlated with higher effectiveness. Tailor adherence strategies to patient needs and lifestyle (pillbox, phone or online reminders, cell phone alarms, etc.). Many people who inject drugs are capable of adhering to PrEP. • For rectal exposures, detectable drug blood levels equivalent to ≥4 doses/week are associated with a high level of protection. • For vaginal/front exposures, detectable drug blood levels equivalent to 6-7 doses/week are associated with a high level of protection.
Time to protection	Time to protection varies by site of exposure: • About 7 daily doses in rectal tissue. Note that there are alternatives to daily dosing that achieve protection in rectal tissue, such as "on-demand" 2-1-1 dosing (see page 3). • About 21 daily doses in cervico-vaginal tissue, but don't let this be a barrier to prescribing PrEP. • About 21 daily doses for blood exposures in people who inject drugs.
Risk of Resistance	Resistance to HIV medications can occur if acute HIV is not identified quickly while on PrEP. A negative HIV test result should be documented within 7 days of initiating PrEP and every 3 months thereafter. Please counsel the patient to report immediately to clinic if they develop symptoms compatible with acute HIV infection (such as fever with sore throat, rash, or headache).
Potential side effects	PrEP is very well-tolerated. Nausea, abdominal discomfort, or headache is experienced in about 10% of people taking PrEP and usually resolves in a few weeks. Other side effects are rare (see page 3 for details).

3. Take a medical, sexual, substance use history and review of symptoms.

Check for:

- HIV exposures in the prior 72 hours; if present, offer post-exposure prophylaxis (PEP): ebgtz.org/resource/pep-guide
- Recent symptoms of a mono-like illness (fever with sore throat, rash or headache): if present, test for acute HIV (order an HIV RNA PCR viral load and an HIV 4th generation Ag/Ab test) and consider deferring PrEP until test results are back.
- Any history of renal disease, liver disease, or osteoporosis, which impacts which PrEP agent is selected. Please see page 3.
- Willingness and ability to take a medication on a schedule and return for regular appointments and labs while taking PrEP.

4. Obtain baseline testing

HIV test: HIV antibody test (4th gen Ag/Ab recommended) +/- HIV RNA test	All patients need a negative HIV antibody test (4th generation Ag/Ab recommended) prior to initiation of PrEP. If patient is a candidate for long acting injectable PrEP, a negative HIV RNA test is needed. In patients with acute HIV symptoms or who report a possible HIV exposure in the last month, test with both an HIV RNA PCR viral load and an HIV 4th generation Ag/Ab test. If the patient has confirmed positive result, disclose and start HIV treatment or refer to an HIV provider as soon as possible; Truvada® or Descovy® alone is inadequate therapy for HIV infection.
Serum Creatinine (e.g. as part of a basic or complete metabolic panel)	Estimated GFR or CrCl by serum labs should be ≥60 ml/min (Cockcroft-Gault) to safely use Truvada® and ≥30 ml/min to safely use Descovy®. An online calculator can be found here: **tinyurl.com/CrClcalculator**
Hepatitis B surface antigen (HBsAg)	Truvada® and Descovy® are active against hepatitis B virus (HBV). Patients with chronic HBV can use either agent for PrEP but should have liver function tests monitored regularly during PrEP use and after discontinuing PrEP; hepatitis can flare if PrEP is discontinued. Patients who are HBsAg and HBsAb negative should be offered HBV vaccination if not previously infected or immunized.
Hepatitis C antibody	Determine baseline hepatitis C infection status and obtain repeat testing at least yearly among MSM, PWID and others with ongoing exposures.
STIs (based on sexual exposures)	Test patients on PrEP for syphilis and for urethral, rectal, and pharyngeal GC and CT based on reported exposure routes (not based on gender/sexuality) every 3 months. Consider using self-collected swabs for GC/CT testing. Consider offering the HPV and hepatitis A virus (HAV) vaccines if not previously vaccinated.
Pregnancy test (when appropriate)	People who can become pregnant (reproductive-age cisgender women, some transgender men and non-binary people) should receive a pregnancy test and have contraception plans reviewed. In patients trying to conceive, PrEP should be coordinated with prenatal care with attention to the patient's reproductive and breastfeeding plans. Descovy® is NOT approved for use as PrEP in this population. Perinatal HIV/AIDS consultation is available at **888-448-8765.**

5. Initiate PrEP

If there are no contraindications and the patient wants to use PrEP, PrEP can be initiated.

- **Same-day PrEP prescriptions are encouraged when possible.** The California Office of AIDS and Pacific AIDS Education and Training Center strongly encourage writing a prescription and starting PrEP on the same day a patient comes in for consultation when:
  - the patient has a negative HIV test within the last 2 weeks and no HIV exposures since this test,
  - all laboratory testing is obtained that day, and
  - the patient has no symptoms of acute HIV infection.

  If it has been more than 2 weeks since baseline labs were obtained, repeat an HIV test and start PrEP the same day while awaiting results of the repeat HIV test.

- **To transition from PEP to PrEP**, check an HIV 4th gen Ag/Ab test while on week 4 of PEP and prescribe PrEP so the patient can start PrEP the day after PEP is completed. Confirm that the HIV testing done during week 4 of PEP is negative.

6. Select PrEP medication

There are three agents FDA-approved for PrEP, Truvada, Descovy and Apretude, which are safe and highly effective in clinical trials.

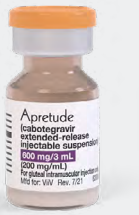
PrEP Medication	 **Truvada®** **Tenofovir disproxil 300 mg + Emtricitabine 200 mg (F/TDF)**	 **Descovy®** **Tenofovir alafenamide 25 mg + Emtricitabine 200 mg (F/TAF)**
Indications	Truvada® is approved for use for all adults and adolescents ≥35 kg with indications for PrEP.	Descovy® is approved for use for adults and adolescents ≥35 kg at risk for sexually acquired HIV, excluding individuals at risk only from receptive vaginal/front hole sex or only from injection drug use.
Dosing	1 pill once daily unless using a PrEP 2-1-1 schedule	1 pill once daily
"On Demand" PrEP: 2-1-1 dosing Note that while there is substantial published data supporting this strategy for MSM, it has not been reviewed by the FDA or recommended by the CDC. The International AIDS Society of the US (IAS USA), World Health Organization (WHO), and European AIDS Clinical Society (EACS) all endorse the option of this dosing strategy.	**2-1-1 for MSM with anal exposures only:** 2 pills 2-24 hours before anal sex (24 hours before for optimal protection) - then 1 pill 24 hours after first dose - then 1 pill 24 hours after second dose. • If there is another exposure within 7 days of the last dose, take 1 pill 2-24 hours before anal sex, then 1 pill 24 hours after first dose, then 1 pill 24 hours after second dose. • If there are continued daily sexual exposures, continue 1 pill daily until 48 hours has passed since last sexual encounter. For a detailed 2-1-1 guide, go to: tinyurl.com/HIVPrEP211.	The PrEP 2-1-1 dosing schedule is **not** recommended for use with Descovy® outside of a clinical trial.
Side Effects	Generally safe and well tolerated • Headache (7%) and abdominal discomfort (3%), which often resolve in a few weeks • Small decrease in eGFR, which improves upon discontinuation of Truvada® • Slightly decreased bone density, but no increased risk of fractures	Generally safe and well tolerated • Abdominal discomfort, nausea (5%) and headache (2%), which often resolve in a few weeks • Small increase in LDL cholesterol • Slight increase in body weight
Other Notes	Estimated GFR or CrCl by serum labs should be ≥60 ml/min (Cockcroft-Gault) to safely use Truvada®.	Estimated GFR or CrCl by serum labs should be ≥30 ml/min (Cockcroft-Gault) to safely use Descovy®.

- There were no differences in adverse clinical outcomes such as broken bones or heart disease between people taking either drug.
- Provide adherence counseling and anticipatory guidance about common side effects.
- Discuss patient strategies for daily adherence.
- Counsel patients on risk reduction using condoms with PrEP to decrease transmission of STIs.

Injectable PrEP

Cabotegravir (CAB-LA) *(Apretude)*

Long-acting form of PrEP, approved for all at-risk adolescents and adults (>35kg), that could be appropriate for increased adherence, patients with renal disease or those who prefer non-oral form of PrEP.



600mg (3ml) IM gluteal muscle

2 initiation injections 4 weeks apart, followed by maintenance injection every 8 weeks

Optional oral lead in (1 x30mg cabotegravir QD x30 days

2 initiation injections (4 weeks apart) → maintenance injection every 8 weeks. Injection to start on last day of oral lead-in or within 3 days thereafter.

Patient assistance program available through ViiV Connect https://www.viivconnect.com/for-providers/viivconnect-programs/medications/

■Contraindications:

- Unknown or positive HIV-1 status
- Coadministration with any of the following: carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, and rifapentine (↓[CAB] due to UGT1A1)

■Drug interactions:

- Concurrent therapy with rifabutin requires adjustments to CAB dose and injection schedule
- **Methadone:** clinical monitoring recommended as methadone treatment may need modifications

■Discontinuing CAB-LA

Once injections are discontinued, CAB-LA plasma concentrations decrease over many months and eventually to nonprotective levels, also known as the "tail" phase. This increases the risk of HIV acquisition and also CAB/INSTI resistance which can present serious implications when selecting an ART regimen.

- Counsel patient on the "tail" phase and potential need for continued PrEP. If indicated, prescribe daily oral PrEP, beginning within 8 weeks after last injection.
- Educate on nPEP and other possible exposures
- Quarterly follow-up visits and HIV RNA tests for 12 months

■Oral and Injectable PrEP Monitoring

Timeframe	Oral (F/TDF or F/TAF)	Injectable (CAB LA)
Initiation/Screening	• HIV Ag/Ab test (RNA if hx of PO PrEP in past 3 mo, or IM PrEP in past 12 mo) • eCrCl • Syphillis, Gonorrhea, Chlamydia • CMP, Lipid panel (F/TAF) • Hep B serology • Hep C *only MSM, TGW, PWID • Pregnancy test	• HIV Ag/Ab and HIV RNA • Syphillis, Gonorrhea, Chlamydia • CMP
@ 1 Month		• HIV Ag/Ab and HIV RNA
Every 2 months		• HIV Ag/Ab and HIV RNA
Every 3 months	• HIV test Ab/Ag test • Syphillis, Gonorrhea, Chlamydia *only MSM/TGW • Pregnancy test	
Every 4 months		• HIV Ag/Ab and HIV RNA • Syphillis, Gonorrhea, Chlamydia *only MSM/TGW

Timeframe	Oral (F/TDF or F/TAF)	Injectable (CAB LA)
Every 6 months	• eCrCl *if >50y/o or baseline eCrCl<90ml/min • Syphillis, Gonorrhea, Chlamydia • CMP	• HIV Ag/Ab and HIV RNA • Syphillis, Gonorrhea *only heterosexually active women and men • Chlamydia *only MSM/TGW
Every 12 months	• eCrCl *if >50y/o or baseline eCrCl<90ml/min • Lipid panel (F/TAF) • Hep C *only MSM, TGW, PWID	• HIV Ag/Ab and HIV RNA • Syphillis, Gonorrhea • Chlamydia *only heterosexually active women and men
If discontinuing	• HIV test (acute) • eCrCl • Pregnancy test • Syphillis, Gonorrhea, Chlamydia *only MSM/TGW	• HIV RNA test q3 months for 12 months • Syphillis, Gonorrhea, Chlamydia *only MSM/TGW

7. Monitor and provide ongoing support for patients using PrEP

Timeframe	Action
30 days after initiation • An in-person follow-up visit is highly recommended for patients 24 years old and under or those who may have difficulties with adherence • A phone call is a reasonable alternative for other patients	• Assess for: » Side effects and patient interest in continuing. » Adherence: link to regular habits, set reminders, reinforce importance of dosing schedule, and address any challenges the patient has faced. » Ongoing risk: provide risk reduction counseling. » Signs and symptoms of acute HIV infection. • Prescribe additional 60-day supply with no refills.
Every 3 months • Labs • Visit • Refills	• At visit: adherence and risk reduction counseling. • HIV test: 4th generation antigen/antibody test preferred. • STI screening for persons who have receptive anal sex: RPR test for syphilis, site specific GC/CT. • Pregnancy test for appropriate patients. • Prescribe a 90-day supply if HIV test negative at each visit • For stable patients, continue labs but consider telemedicine follow up and/or decreasing visit frequency.
Every 6 months	• Serum Creatinine: stop if eGFR declines. • Urinalysis for proteinuria screening (only if on Truvada and/or risk of kidney disease) • STI screening for all persons: RPR test for syphilis, site specific GC/CT • CMP
Every 12 months or more often based on assessed risk	• Hepatitis C antibody (w/reflex viral load if avail),particularly for MSM and PWID. • Urinalysis for proteinuria screening and lipid panel (if on Descovy)

8. What if my patient tests positive for HIV while on PrEP?

a. Discontinue Truvada® to avoid development of HIV resistance

b. Start patient on HIV antiretroviral treatment as soon as possible in accordance with **HIV Treatment Guidelines (tinyurl.com/HIVTreatmentGuidelines)**, and/or facilitate a warm hand-off referral to an HIV provider immediately.

c. For questions and support, call the **National HIV Clinicians Consultation Center: 800-933-4313**.

d. Order HIV genotype and document results

e. Report the test result to your local health department

9. PrEP coverage options

Insured patients

- Many **private insurers** cover PrEP.
  - » Adolescents covered on their parents' plan can keep their info confidential by signing up at myhealthmyinfo.org.
- **ICD-10 codes** for PrEP include:
  - » **Z20.6:** Contact with and (suspected) exposure to human immunodeficiency virus [HIV]
  - » **Z20.2** Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
  - » **Z71.7** Human Immunodeficiency Virus (HIV) counseling
- If patient needs help with co-pays, the Gilead co-pay assistance program can provide co-pay assistance for up to $7,200 annually fof either agent: gileadadvancingaccess.com or **877-505-6986**
- Other payment assistance programs are listed on the **Fair Pricing Coalition website: tinyurl.com/FPCcopays**

Uninsured patients

- The **Gilead Advancing Access** PrEP medication assistance program will provide monthly Truvada® or Descovy® deliveries to the patient or clinic at no cost for those without prescription coverage and who meet income guidelines (≤ 500% FPL).
  - » Call **800-226-2056** for inquiries or to apply by phone, Monday-Friday, 6am-5pm PST
  - » Fax the completed application and proof of income to 855-330-5478: tinyurl.com/GileadEnrollment.
  - » If approved, one bottle (30-day supply) will be available for pickup at any non-Kaiser pharmacy. For pickup, provide an ID, bin, group, or PCN number (provided by Gilead). Refills can be coordinated with the pharmacy.
  - » Alternatively, medication bottles may also be shipped to a clinic in 3-14 days. A Gilead representative will call the provider before the 2nd bottle is sent to confirm refill if continuing to ship to clinic.
  - » Patients must re-apply (i.e. resubmit proof of eligibility) every 12 months.
  - » U.S. and undocumented residents are eligible. Social security numbers are not required. Proofs of income include: W2, 1040 tax return, 2 pay stubs from the last 90 days or letter stating monthly income. The letter stating monthly income should include the residence address and must be signed and dated but does not need to be notarized.
- The **Ending the HIV Epidemic: Ready, Set, PrEP (getyourprep.com)** will provide monthly Truvada® or Descovy® deliveries to the patient or clinic at no cost for those without prescription coverage regardless of income for up to 200,000 patients per year. Patients must provide proof of lack of prescription coverage, a recent negative HIV test result, and a current prescription for PrEP.

10. Have questions?

The National HIV PrEPLine for clinicians provides guidance on PrEP:
855-448-7737

Go to **PleasePrEPMe** for a location-responsive PrEP provider directory, online chat navigation in English and Spanish, and many resource pages including for patients, providers, youth, trans and non-trans women: **pleaseprepme.org**

Further information about PrEP can be found at:

- **Please PrEPME PrEP Navigator Manual: pleaseprepme.org/prepnavigatormanual**
- **CDC website: cdc.gov/hiv/risk/prep/index.html**

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Funding for this presentation was made possible by 5 U1OHA29292-08-00 from the Human Resources and Services Administration HIV/AIDS Bureau. The views expressed do not necessarily reflect the official policies of the Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government. Any trade/brand names for products mentioned in this document are for training and identification purposes only.

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AETC AIDS Education & Training Center Pacific

Quick Clinical Guide: HIV Health Care Maintenance

Updated May 2023. This information is based on the following guidelines: DHHS, September 2022 (https://clinicalinfo.hiv.gov); IAS-USA

Be present, listen and triage needs on the first visit; deal with life-threatening issues and provide rapid access to ART (antiretroviral therapy). Let them know what to expect and about U=U (Undetectable = Untransmittable), that treatment prevents transmission. Fill in the history as you build rapport. Remember to use open-ended questions. Higher priority topics are highlighted with a star ★ and in red font; aim to discuss these topics in the first few visits.

Current needs and history

- ★ **What is most important to you right now?**
- ★ How do you want to feel?
- ★ **HIV:** beliefs around HIV, U=U, first known positive test, seroconversion, HIV exposures, prior HIV meds, PEP, CD4, viral loads, genotypes and ART or partner ART history.
- ★ **OIs:** derm symptoms (zoster hx), PCP, toxo, MAC, CMV (GI or retinitis), crypto, histo, cocci, thrush, TB, bacillary angiomatosis (Bartonella), recurrent bacterial infections
- ★ **Concurrent medical conditions:** diabetes, CAD, htn, lipids, renal insufficiency, neuropathy, hepatitis, etc.
- ★ **TB:** PPD/TST or IGRA hx, LTBI treatment, CXR hx, prior TB tx
- ★ **STI:** hx and tx, particularly GC/CT, syphilis, HPV, HSV
- ★ **Mental health** hx: ask about mood instability, psychosis, trauma, any history of psychiatric treatment
- **Reproductive health** hx: pregnancy hx (if relevant), family planning desires, plans for future pregnancies
- Use of **complementary medicine**
- Most recent **dental and eye exams**
- **Vaccination history**

Medication History

- ★ **ART history**, such as PEP, PrEP or treatment of HIV
- ★ **Drug allergies**
- **Complementary & OTC medicine:** herbs, pills, procedures, etc.
- Steroids, body-building supplements, other hormones

Health Related Behaviors

- ★ **Partner notification and testing:** ask, "Please tell me about your partners (sexual and IDU). Would you like our help to let them know and offer HIV testing and services?"; offer help with testing
- ★ **Sexual health:** ask, "How is your sex life? How do you enjoy sex? How do you prefer we refer to your genitals?"
- ★ **STI harm reduction:** serodifferent partner(s); barrier methods; use this as a chance to discuss condoms/PrEP
- ★ **Sexual orientation, gender identity:** ask about how they identify and what name they use
- ★ **Drug use:** methamphetamines (what form? Intravenous, muscled, smoked, snorted, ingested?), cocaine/crack, heroin and other opioids, GHB, ecstasy, ketamine (Special K), alcohol, tobacco, marijuana
- **Substance use disorder treatment/rehab** and quit history; current interest in rehabilitation and harm reduction services
- ★ **Substance use harm reduction:** needle exchange
- **Exercise**
- **Diet:** consider taking a 3-day diet history

Family History

- **Premature CAD**
- **Malignancies**
- ★ **G6PD**, sickle cell
- **Psychiatric disorder**

Social History

- **HIV beliefs:** How do they feel about HIV? How do they feel about taking HIV medications? What do they know already about HIV transmission, U=U, natural history, prognosis, CD4, viral loads, treatments, OIs, prevention, PrEP? Have they known others living with HIV? What are those relationships like?
- **Health beliefs:** What have their experiences with health care been like? How do they want to interact with the clinic?
- **Current priorities:** What is most important to you right now? What do you care about most right now?
- **Future beliefs:** What are your hopes for your future?
- **Partner hx:** health of relationships, disclosure status, partner(s) tested? Need help with disclosure/testing? Children in need of HIV testing?
- **Social supports:** friends, family, community
- **Spiritual support:** spiritual practice and/or community
- **Intimate partner violence (IPV):** past and current
- **Incarceration** history
- **Homelessness/housing instability:** current and historical
- **Food:** sources, reliability
- **Water source:** ensure clean drinking water supply
- **Travel:** birthplace, travel (check for histo, cocci, TB exp)
- **Pet status:** cats (bartonella, toxo), reptiles (salmonella)
- **Gardening and soil exposure:** Toxo, crypto, MAC
- **Income:** employment, public benefits and stability of these sources
- **Insurance:** uninsured, ADAP, Medicaid, Medicare, private insurance; check on visit, labs and prescription drug coverage and copays
- **Legal issues:**
  - Issues related to **jail/prison and probation**?
  - Issues related to **immigration**?
  - **Benefits, social security, disability?**
  - **Housing?**
  - Ask about a **DPOA and Living Will**; make sure you revisit this if they don't have them.
  - Do they need documentation or services related to **children and/or dependents**?
- ★ **Emergency contacts**

Symptoms & Physical Exam

Ask about symptoms, perform exam and pay special attention to:

- **Consitutional:** fevers, night sweats, weight loss
- **Skin:** dermatitis, folliculitis, fungus, molluscum, Kaposi's sarcoma
- **HEENT:** ask about floaters and perform retinal exam if CD4 <200, look in mouth for leukoplakia and thrush, check dentition
- **Lymph Nodes:** cervical, axillary, inguinal
- **Abdomen:** liver and spleen
- **Neurologic:** mental status, cognition, sensation
- **Anogenital:** discharge, rash, ulcers, warts, fissures, abscesses

Baseline Labs

Strength of Recommendation: **A:** strong **B:** moderate **C:** optional **D:** should usually not be offered **E:** should never be offered

Quality of Evidence for Recommendation: **I:** at least one RCT with clinical results **II:** clinical trials with lab results **III:** expert opinion

Labs highlighted in light blue are repeated for most patients.

Test	Repeat Frequency	DHHS	IDSA	Evidence	Reasons & Notes
HIV Ag/Ab	None if confirmed	Y	Y	AI	Confirm & document diagnosis; helps benefits eligibility
CD4 absolute and %	-Baseline and repeat 4 weeks later -Q3-6 months until VL UD for 1-2yrs (see notes)	Y	Y	-AI for baseline -AIII for confirmation -CIII for CD4/CD8	-If CD4=300-500 & VL UD x2yrs: check CD4 Qyear (BII, IDSA AII) -If CD4>500 & VL UD x2yrs: CD4 is optional (CIII)
Viral Load	-Baseline, Q4-8wks till UD, then Q3-6 mo (see notes) -also at initiation, tx failure, 4 wks after start/blip/switch	Y	Y	-AIII for baseline; -AIII to monitor ART efficacy	-Q3mo for monitoring treatment response -If VL UD x1 year, can check Q6 months (AIII; IDSA AII for VL UD x2yr) -If VL>200, recheck in 4-8 wks (AII)
Genotype: RT and PI +/- INSTI	Baseline for all patients with HIV; can start ART while waiting for results; repeat with virologic failure while on ART	Y	Y	-AII for baseline -AI for virologic failure -AIII for preg	-In early infection: more likely to pick up transmitted resistant strains -later on, check to guide ART regimen choice/change -Add INSTI genotype if concern for INSTI resistance
Metabolic panel & LFTs	4-8 wks after starting ART, then Q6 mo	Y	Y	AIII	Monitor toxicity, liver and renal function
CBC	Q3-6 mos w/ CD4, then every yr	Y	Y	AIII	Monitor toxicity, check cytopenias
Hep A IgG Ab	Verify once after vax	Y	Y	AIII	If negative IgG, vaccinate (AI)
Hep B sAg, sAb, cAb	Baseline and verify once after vax, may repeat if sAg neg at baseline and sAb neg	Y	Y	AIII	-If neg, vaccinate, check sAb in 2mo -If cAb+ and sAb-, check DNA and consider vax if DNA neg (AIII)
Hep C Ab	Baseline and repeat Qyear if has exposures (MSM, PWID)	Y	Y	AIII	-Check RNA if Ab pos to check for chronic infection; consider tx (AI)
VZV Ab	Baseline & verify after vax	Y	Y	-AII for VZVIG -BIII for adult vax -AII for peds vax	-Give VZVIG if Ab neg and exposed to active VZV (AII) -Give 2-dose series of RZV for all others regardless of CD4 count (AIII)
Toxo IgG	Baseline only	Y	Y	-BIII -Repeat CIII	-If negative, counsel prevention (pork, lamb, cat litter) -If positive, prophylaxis when CD4<100
TB IGRA or TST (PPD)	Baseline and repeat Qyear if neg and has exposures	Y	Y	AII	-Test at baseline and treat if positive for LTBI -If neg, repeat Qyear if ongoing exposures -If CD4<200, repeat when CD4>200
RPR or VDRL syphillis screen	Q3-6 months, based on risk	Y	Y	-AIII, BIII for repeat -AII for LP in neuro or ocular sxs	-If new infection, treat! -check LP/CSF w/neuro sxs (AI), active tertiary, tx failure (<4-fold↑)
Lipids	-HRSA req Qyr total chol -baseline, then 6wks after starting PIs; Qyr if normal	Y	Y	AIII	-Assess need to tx -following PI/NNRTI side effects -HRSA requirement
Glucose/AIC	Check fasting glucose with lipids, Qyr	Y	Y	AIII, A/B (USPSTF)	See lipid notes above
UA, creatinine clearance	-Baseline -Definitely before starting TDF or IDV	Y	Y	AIII	-HIV confers an increased risk of nephropathy -TDF and IDV are nephrotoxic
GC/CT (3-sites PRN), **trich***	Baseline for all, trich for women; Q3-6mo if pos/risk	Y	Y	-AIII for baseline -AI/III for repeat	-Patients with exposures: at least annual retest (AI) -Retesting for all patients by expert opinion (AIII)
HLA-B*5701 for ABC use	If considering abacavir as part of ART regimen	Y	Y	-AI for before starting ABC	-If positive, avoid abacavir use (AI) -document result in medical chart (AII)
Tropism for MVC use	If considering or on maraviroc (CCR5 inhibitor)	Y	Y	-AI for CCR5 tx -BIII for failure	-Get phenotypic test (AI) -predicts if CCR5 antagonist (maraviroc) will work

Consider the following tests in certain patients:

- **Urine pregnancy:** Screen in people with pregnancy potential of reproductive age.
- **G6PD:** Screen in patients with family history, African or Mediterranean descent; G6PD deficiency leads to a higher risk of hemolysis to the use of dapsone, primaquine and less to sulfas. (IDSA AII, note that it can be an expensive test, ~$200).
- **CMV IgG:** In low-risk patients (not in history of anal intercourse who are very likely to be CMV+); if negative, use CMV-neg blood prod ucts; if positive and CD4<50, patients need a dilated eye exam (IDSA, score AII).
- ***STI screening details:** Trichomonas and GC/CT NAAT swabs for vaginal/front hole receptive sex, GC/CT rectal swab for anal receptive sex, GC pharyngeal culture for oral receptive sex, GC/CT NAAT first-void specimen for urinary symptoms; repeat annually for sexually-active patients and Q3-6 months for patients at higher risk (IDSA, AI). See CDC STD guidelines.
- **Testosterone:** Consider checking morning total testosterone level in adult cisgender men at risk for hypogonadism with fatigue, weight loss, libido loss, erectile dysfunction, depression, or evidence of bone mineral density loss; repeat once to confirm; treat hypogonadism if <300 (IDSA AII).

Not recommended: Baseline CrAg or MAC blood culture not recommended for asymptomatic screening (IDSA AII).

Studies and screenings

Test	Frequency, comments	Evidence, who recommends
Anal Pap and DRE for anal cancer screen, in people reporting anal receptive sex, w/anal warts and/or cervical dysplasia	-Annual if ongoing exposures and baseline is normal -Use polyester swab in Thin Prep, go in 2-3" thru int. sphincter, rotate and apply lateral pressure 15-30sec -Refer ASCUS, LSIL, HSIL to high-resolution anoscopy	At this time, no national guidelines exist for routine screening for anal cancer. MSM have 20-fold increased risk of anal cancer. DRE: BIII for annual; anal pap IDSA score CII
Cervical Pap for women: pap testing alone (any age) or pap with HPV co-testing (for 30+ yo)	-Baseline and repeat 6 or 12 months later, then annual -If 3 consecutive paps are negative, then every 3 years -Avoid co-testing with HPV for women <30 yo -If at all abnormal, get colposcopy	AI for baseline CIII for 6-month repeat after baseline BII for annual pap BII for pap every 3 years
GC/CT urethral, rectal, pharyngeal tests/swabs for exposed sites	-Repeat Q3-6 months with ongoing exposures	BII
GC/CT cervical and trich for vaginal/front hole exposures	-Do baseline for GC/CT/trich for all -Repeat trich yearly; repeat GC/CT w/sxs & exposures	AI for baseline and symptoms
Dental exam and cleaning	-Q6 months; also ask about flossing, gum-stimulation	US HIV/AIDS Bureau checks for Q12 exam
Dilated eye exam for CD4<50	-CMV retinitis screen for CD4<50	*Don't let the eye exam delay ART!
Colorectal cancer screening for pts ≥45 yo	-Annual FOBT x 3 -or sigmoid Q5 years -or colonoscopy Q10 years	USPSTF score B for 45-49yo, A for 50-75yo, C for 76-85yo
Mammogram for women > 40 or 50 yo	-Ages 40-49 Q1-2 years optional, discuss risks and benefits of screening with patient -Ages 50-74 Q2 years	USPSTF score B for ages 50-74; score C for ages 40-49 IDSA score A1
DXA bone densitometry for at-risk, post-menopausal women and men ≥50 yo	-Baseline for pts at risk, post-meno women, men 50+ -Risks: ages 40-50 with FRAX>10%, thin female smokers >40 yo, history of excessive alcohol, long term steroids -After 2+ years on bisphosphonates (afterward, no data)	USPSTF score B for >65 and postmenopausal women <65 + increased risk of osteoporosis. USPSTF score I for men >50. IDSA BIII
BMI	-Annual, counsel on results	USPSTF score B

Other routine health care maintenance practices:

- Annual blood pressure check, annual depression screen, Q2-3 year eye exam with tonometry for patients aged ≥50
- Annual low-dose CT for lung cancer screen: 50-80 yo with >20-pack year smoking history, current smoker or quit <15 yrs ago
- In men who have ever smoked, aged 65-75, abdominal ultrasound to screen for abdominal aortic aneurysm
- **CXR:** Definitely in positive PPD or QFT; consider in patients with underlying lung disease for a baseline (IDSA, AII)

Prophylactic Medications (Please see the Rapid ART Guide for recommended HIV antiretroviral regimens)

Pathogen	CD4	Agent	Evidence
Pneumocystis jiroveci (PCP)	CD4 <200 [DC when CD4 >200 x 12 wks on ART]	TMP-SMX DS 160/800 mg daily; alt: dapsone 100 mg Qday (+pyrimethamine 50mg + leucovorin 25mg Qwk) or atovaquone 1500 mg Qday	AI BI
Toxoplasma gondii	CD4 <100 In +toxo IgG [DC when CD4>200 x 12 wks on ART]	TMP-SMX DS 160/800 mg daily -Alt: dapsone 50 mg Qday + pyrimethamine 50 mg Qwk+ leucovorin 25 mg Qwk	AI, BI
Mycobacterium avium complex (MAC)	Consider if not on ART, with VL>200 copies/mL & CD4 <50	Azithromycin 1200mg Qwk or clarithromycin 500 mg Q12' -Alt: rifabutin dose adj based on ART, but watch for interactions	AI BI
Mycobacterium tuberculosis (MTB)	Any CD4; look out for history of PPD≥ 5mm, QFT+	If LTBI (neg CXR, no e/o active dz), INH 300 mg Qday + Vit B-6 50mg Qday x 9mo or Rifampin 600mg qday x4 mos, but check first for ART drug interactions!	AII, BI

Vaccines

Test	Repeat Frequency	DHHS	IDSA	Evidence	Reasons
Pneumococcal PCV13/ PPV23	PCV20 alone or PCV15 + PPSV23(at least 8 weeks later)	Y	Y	AII	Prevent bacteremia
Influenza	Annually	Y	Y	AI	Higher incidence in HIV+
Hep A	At 0, 6 months; test total Ab	Y	Y	AII	Prevent fulminant hepatitis
Hep B	At 0, 1, 6 mo; test sAb & repeat @double-dose if neg	Y	Y	AI if at risk	40 µg → increased response
Tetanus (Td)	Q10 yr boost; Tdap once	n/m	Y	Tetanus Evidence: AII	Higher incidence in IVDU
Varicella	Peds at 0, 3 mo; test Ab	Y	Y	AI for kids	In CD4 >200 with neg Ab
Zoster (RZV)	-At 0 and 2-6 mos		Y	Zoster evidence: AIII	To prevent shingles and complications
HPV	At 0, 2, 6 mo for up to age 45		Y	AI	To prevent HPV-related cancers
MenACWY	At 0, 2 mo; then Q3 yrs if <7yo, Q5y if >7yo			ACIP, 9/2020	5-24x risk in HIV
MMR	At 0, 1 month	Y	Y	AIII	In CD4 >200 and no immunity
COVID-19	See CDC guidelines	Y		AIII	As of May 2023

- **Do not give live vaccines** (yellow fever, OPV, BCG, live typhoid) to HIV+ patients except for the measles vaccine.
- **Consider:** IPV Polio (don't use OPV) catch-up; MMR catch-up in CD4%>15; meningococcal for 11-12 yo +2nd dose 8 wks later
- **With travel:** Meningococcal in epidemic areas; IPV catch-up; rabies; inactivated typhoid (AAHIVM)

Follow-up Frequency for Medical Visits

- 1 week after ART initiation
- every month until viral suppression
- then every 3-6 months
- Q3 months if early asymptomatic HIV
- Q1 months if late-stage HIV, symptomatic, or initiating ART till stabilized

■ At each visit:

- Monitor adherence (AIII)
- Screen for risk behaviors (AII): sexual risk, STI exposure, IVDU
- STI symptoms (AI)
- At least yearly (and ideally at each visit), substance abuse and mental health screening, HIV partner counseling (safer sex–condoms, PrEP for HIV-negative partners, needle exchange, etc.) (AI).

Screening in Transgender Patients (from The Center of Excellence for Transgender Health **http://transhealth.ucsf.edu/**)

■ Trans men:

- Assess masculinization, total testosterone, hgb/hct 3, 6, 12 mo after initiation, then yearly and PRN.
- Other labs: SHBG, albumin at 3, 6, 12 mo months after initiation; HgA1C and lipids as per USPSTF guidelines.
- Cervical cancer screening and (if has not had double mastectomy) breast cancer screening following guidelines for non-transgender women; cervical cancer screening should not be a requirement for testosterone therapy.

■ Trans women:

- Assess feminization and CMP 3, 6, 12 mo after initiation, then yearly and PRN.
- Other labs: estradiol, total testosterone, SHBG and albumin at 3, 6, 12 months after initiation, then PRN. Prolactin levels only if symptoms of prolactinemia, and A1C and lipids as per USPSTF guidelines.
- Breast cancer screening: "As with the age of onset, given the likely lower incidence in transgender women, it is recommended that screening mammography be performed every 2 years, once the age of 50 and 5-10 years of feminizing hormone use criteria have been met. Providers and patients should engage in discussions that include the risks of over-screening and an assessment of individual risk factors (Grading: T O W)."

References:

General Guideline Resources: HIV Primary Care: DHHS, IDSA, IAS-USA, US PHS Resistance: DHHS, IDSA, IAS-USA | Vaccinations: ACIP, CDC | OI Prophylaxis and Treatment: CDC, NIH, HIVMA, IDSA Pregnant Women with HIV: DHHS | Metabolic Complications: IAS-USA, ACTG

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Saag MS, Benson CA, Gandhi RT, et al. Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults: 2018 Recommendations of the International Antiviral SocietyfiUSA Panel. *JAMA.* 2018;320(4):379fi396. doi:10.1001/jama.2018.8431. Accessed May 2023.

U.S. Preventive Services Task Force Guidelines: uspreventiveservicestaskforce.org. Accessed May 2023.