HIV MANAGEMENT

Federal Bureau of Prisons

Clinical Guidance

April 2021

WHAT'S NEW IN THIS DOCUMENT

This document updates the September 2018 version of the BOP Clinical Guidance on Management of HIV Infection. Treatment information has been updated to be in line with the Department of Health and Human Services (DHHS) Guidelines for the Use of Antiretroviral (ARV) Agents in HIV-1-Infected Adults and Adolescents, issued in **December 2019**.

Document Content Improvements

- **Title:** The title has been changed to *HIV Management* (from *Management of HIV Infection).*
- **Abbreviations:** A new section now lists *abbreviations* for ARV drugs and drug classes.
- **Standard Precautions for Infection Control:** Now covered in a new *Section 16.*
- **Resources and References:** *Appendix 1* has been updated and expanded.

HIV Testing: Updates were made to *HIV testing and interpretation of results* (*Section 2),* including an expanded overview of the 4th generation process and interpretation of inconclusive and false-positive lab tests.

ICD-10 Diagnostic Codes: These codes, used in documenting HIV testing and infection status, have been added to the *Reporting* section, *Section 2*.

HIV Co-Morbidities: These recommendations regarding periodic medical evaluations in *Section 4* now include *evaluation for cardiovascular disease*.

Recommended Immunizations for HIV-Positive Adults: *Vaccination information* is now in a new *Table 1*, including updated vaccines available for herpes zoster and hepatitis B.

Primary Prophylaxis Revisions

- **Primary Pneumocystis Pneumonia (PCP) and Toxoplasmosis:** Primary prophylaxis for *PCP and toxoplasmosis* may not be required in patients with CD4 > 100 and suppressed HIV viral load.
- **Mycobacterium Avium Complex (MAC):** Primary prophylaxis for *MAC* is not recommended for patients who are immediately initiated on ART, regardless of CD4 cell count.

Initial Antiviral Therapy (ART) *(Section 7)*

- **An INSTI + NRTI** backbone is now the *preferred initial therapy*.
- **PI-Based, NNRTI-Based alternative and INSTI-Based regimens** should be considered for *initial therapy in special circumstances*.

Medications: *Biktarvy®* (BIC/TAF/FTC)**,** *Symtuza®* (DRV/c plus TAF/FTC), and *doravirine* (DOR) have been added to the ARV medication lists.

Special Considerations: A new *Section 8* covers considerations for *special populations* with HIV—elderly, pregnant, and transgender patients.

Cervical Cancer Screening: New and revised appendices cover *Pap Test Results* (*Appendix 5b*) and *Cervical Cancer Screening Recommendations for HIV-infected Women* (*Appendix 5c*).

Pre-Exposure Prophylaxis (PrEP): New information has been added, including a new subsection on *Individuals at Risk for Acquiring HIV* in *Section 15* and a new *PrEP Fact Sheet* in *Appendix 8*.

TABLE OF CONTENTS

1. PURPOSE AND OVERVIEW

The *BOP Clinical Guidance for HIV Management* provides guidance on the screening, evaluation, and treatment of federal inmates with HIV infection, with a focus on primary care.

The BOP clinical guidance is not intended to replace the more extensive guidelines published by the Department of Health and Human Services (DHHS), the Centers for Disease Control and Prevention (CDC), the Infectious Disease Society of America (IDSA), and the International AIDS Society (IAS).

➔ *See Appendix 1 for a list of guidelines and resources for the medical care of HIV-positive persons.*

➔ *The DHHS Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents are updated regularly and should be consulted at: https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/whats-new-guidelines. Providers can sign up to receive email update notifications.*

2. DIAGNOSIS AND REPORTING

➢ Testing for HIV in the BOP

Testing of inmates for HIV infection must be a **priority** for the BOP.

- Almost one in seven persons living with HIV infection in the U.S. has not yet been diagnosed.
- Only 55% of HIV-infected individuals in the U.S. have suppressed viral loads—a result commonly linked to undiagnosed HIV infection or failure to retain diagnosed patients in care.

These HIV testing policies apply in the BOP:

- **An opt-out strategy** of voluntary testing for HIV infection is recommended for **all inmates**,
- regardless of sentencing status. Many people with HIV infection are asymptomatic and unaware of their infection. Therefore, all inmates should be offered HIV testing, consistent with CDC guidelines and BOP medical director. An "opt out" approach involves an **informed refusal** of testing, rather than **informed consent** (or "opt in") for testing.
- **Voluntary testing** is done when the inmate requests testing through an Inmate Request to Staff Member. This voluntary testing is available to **all inmates**—regardless of sentencing or duration of stay.
- **Mandatory testing** is performed when there are indications and risk factors, and the test is clinically indicated and/or surveillance testing is required. Inmates must participate in mandatory HIV testing programs, in accordance with Program Statement 6190.04.
- **Involuntary testing** is performed following an exposure incident**.** Written consent of the inmate is not required. If an inmate refuses testing, testing will be conducted in accordance with Program Statement 6190.04 regarding Use of Force.

➔ *Criteria for HIV testing are described more specifically in Appendix 2.*

➢ Counseling of Inmates Prior to HIV Testing

All inmates to be tested for HIV infection should receive pre-test counseling from qualified health care personnel, in accordance with current BOP policy. Counseling should use plain language, and be conducted in a language that the inmate understands.

Per Program Statement 6190.04 (*https://www.bop.gov/policy/progstat/6190_004.pdf*), the counseling session should provide the limitations of the test: the inability to detect early infections, the possibility of false positives and false negatives, and the possible need for additional testing. The information should also cover the complications and consequences of a negative or positive test result.

NOTE: *The institution's Admission and Orientation program meets the HIV pre-test counseling requirement if documentation, such as a sign-in roster, is obtained and kept on file. Inmates are not required to sign an informed consent form during HIV counseling sessions.*

➢ HIV Testing and Interpretation of Results

All BOP laboratory facilities test for HIV using a 4th generation HIV-1/2 antigen/antibody combination immunoassay test, as follows:

STEP 1. The first step of 4th generation testing is a screening test that includes HIV-1 and HIV-2 antibodies and the HIV-1 p24 antigen.

- Testing for the HIV-1 p24 antigen allows for detection of early infections (within 2–6 weeks after infection), before the HIV-1 antibody is produced.
- A **positive** screening test indicates the presence of either HIV-1 or HIV-2 antibodies, or both, or the HIV-1 p24 antigen. It could also be a false positive.
- A **negative** screening test indicates no evidence of HIV infection.

  NOTE: *If the patient has had recent contact with an HIV-positive person and/or has signs of acute HIV infection, order an HIV type 1 RNA viral load. If the HIV viral load is negative, repeat the screening test and HIV viral load in 1-2 weeks. See Section on Early HIV Infection.*

STEP 2. If the screening test is positive, 4th generation testing automatically reflexes to the HIV-1/2 antibody differentiation assay (confirmation test).

- A **positive** result on the differentiation assay will indicate either chronic HIV-1 infection, chronic HIV-2 infection, or HIV-1/HIV-2 coinfection.
- A **negative or indeterminate** result on the differentiation assay requires further testing.

STEP 3. If the screening test is positive and the HIV-1/2antibody differentiation assay is negative or indeterminate, the provider should then order an HIV Viral Load (Quantitative RNA) Test.

- If the HIV viral load test is positive, this indicates acute/early HIV infection.
- If the HIV-1/2 antibody differentiation assay is negative or indeterminate and the HIV viral load are negative, the initial screening test is a false positive (see below).

➢ Causes of "False Positive" HIV Testing

When trying to determine whether a patient's HIV screening test is a false positive, the pretest probability, i.e., the likelihood before the test that the patient has HIV infection, can help with the interpretation. For example, a person who is MSM (men who have sex with men) or who injects drugs and shares needles has a higher pretest probability of having HIV than someone who does not.

Reported causes of a false positive, **4th generation screening test include:**

- Infections such as mycobacterium tuberculosis, viral hepatitis, rickettsia, HTLV-1, HTLV-2, toxoplasmosis, Schistosoma, malignancies; a history of multiple pregnancies (due to polyclonal cross-reactivity); recent influenza vaccination, autoimmune disorders, participation in and receiving an investigational HIV-1 vaccine; collagen vascular diseases, and lab error.
- Often, no cause can be found for the false positive result. If the cause of the false positive is due to an intrinsic factor unique to the patient, the patient will always test positive to that assay.

➢ Early HIV Infection (Acute and Recent)

The diagnosis of acute or recent HIV infection requires a high level of clinical suspicion. **Acute Retroviral Syndrome (ARS)**, the first stage of HIV infection, should be suspected in patients who have had high-risk exposure to HIV-1 within the past 2 to 6 weeks. People who have signs, symptoms, or laboratory findings that may include—but are not limited to—fever, lymphadenopathy, skin rash, myalgia/arthralgia, headache, diarrhea, oral ulcers, leukopenia, thrombocytopenia, and transaminase elevation.

When the possibility of early HIV infection is considered, providers should perform a 4th generation HIV test, as well as quantitative HIV viral load test, as described above under described above under *HIV Testing and Interpretation of Results*. Viral loads in this setting are generally very high (> 100,000 cps/mL).

- Acute HIV-1 infection, the phase of HIV-1 disease that occurs 2 to 4 weeks after infection, is characterized by an initial burst of viremia. While anti-HIV-1 antibodies may be undetectable during acute HIV infection, HIV-1 RNA or p24 antigens are nonetheless present.
- Recent HIV infection generally is considered the phase up to 6 months after initial infection, during which anti-HIV-1 antibodies are detectable.

NOTE: *These patients should be counseled concerning the substantial risk of transmission during the acute phase of infection and managed in accordance with the rest of this guidance.*

➢ HIV-2 Infection

HIV-2 infections are rarely observed in the United States. The CDC reports that between 1988 and June 2010, 166 cases had met the CDC case definition of HIV-2 infection. The majority of cases are endemic to West Africa or persons with cultural or socioeconomic ties to West Africa. Globally, it has been estimated that 1 to 2 million individuals have HIV-2, a number that includes people with HIV-1/HIV-2 dual infection.

(this section continues on the next page)

The **possibility of HIV-2 infection** should be considered in the appropriate epidemiologic settings:

- In patients with serologically confirmed HIV infection, but low or undetectable HIV-1 RNA levels **or**
- In patients with declining CD4 T lymphocyte (CD4) cell counts, despite apparent virologic suppression on antiretroviral therapy (ART).

  NOTE: *Treatment of HIV-2 infections should be conducted in consultation with experts in the management of HIV disease.*

➢ Counseling of Inmates Testing Positive for HIV

Inmates who are newly diagnosed with HIV infection should be provided post-test counseling utilizing BP-A0492 Form – HIV Post-Test Counseling (positive). The form will be signed by the inmate and retained in the electronic medical record.

- Counseling includes information about the meaning of the test results, the natural history of HIV disease, the benefits of antiretroviral treatment, and risk behaviors to avoid in order to prevent transmission.
- Pregnant inmates who test positive for HIV will be advised that the virus may be transmitted to the fetus and provided information on current treatment options to prevent perinatal transmission.
- All inmates testing positive will be referred to the Psychology Department for follow-up counseling.

➢ Reporting HIV Diagnosed Inmates

All inmates newly diagnosed with HIV should be reported to state health authorities, in accordance with state laws and regulations.

ICD-10-CM diagnostic codes should be used, as follows:

Z21	HIV Asymptomatic (never had an HIV-related illness)
B20	HIV Symptomatic (never had an HIV-related illness)
Z53.20	HIVtst HIV Test Refused
Z53.20	HIVref HIV Treatment Refused
B97.35	Human immunodeficiency virus, type 2 [HIV 2] **Do not use for HIV Type 1.**
R75	Inconclusive HIV Laboratory Results
Z114	Encounter for HIV Screening
Z206	Contact with and (suspected) Exposure to HIV
Z717	Negative Test (HIV counseling)

3. BASELINE MEDICAL EVALUATION

The baseline medical evaluation is indicated for inmates arriving with a history of HIV infection or who are diagnosed with HIV infection while incarcerated. This evaluation ordinarily includes a *history and physical examination*, *baseline laboratory testing*, a review of the inmate's *immunization status*, and a *treatment plan and subspecialty referrals*, as needed—all discussed below in sub-sections A–D.

➔ *See also Section 4, Periodic Medical Evaluations for HIV-Infected Inmates for guidance on periodic follow-up assessments.*

➢ Medical History and Physical Examination

Obtain a comprehensive medical history, along with an assessment and documentation of HIV risk factors, including the following:

- When possible, estimate date of infection (based on history of prior negative results, history of symptoms of acute retroviral infection, or patient's recollection of high-risk activities).
- Record the date when HIV infection was diagnosed.
- Pre-ART (antiretroviral therapy) CD4 count (CD4 nadir), highest viral load (typically pre-ART), and most recent viral load/CD4 count.
- History of prior HIV-related complications, including opportunistic infections, malignancies, and HIV-related symptoms.
- Comorbidities that may affect choice of therapy including peripheral neuropathy, gastrointestinal disease, chronic viral hepatitis, hyperlipidemia, diabetes mellitus, mental illness, cardiovascular disease (CVD) or risk, and kidney disease.
- The baseline evaluation should include an evaluation of the patient's readiness to initiate or continue ART, including an assessment of high-risk behaviors, substance abuse, social support, mental illness, comorbidities, and other factors that are known to impair adherence to ART and increase the risk of HIV transmission.

➢ Medication History

A thorough medication history is critical for safe and effective ART (antiretroviral therapy). The medication history—preferably based on previous medical records—should include the ARV regimens prescribed, duration of treatment, response to each regimen, drug toxicities, reason for treatment changes, barriers to adherence, and prior resistance test results. Newly diagnosed patients should also be asked about any prior use of ARV agents for prevention of HIV infection.

NOTE: *If possible, prior medical records should be obtained. Consider obtaining a signed release to request outside medical records when additional information is required.*

➢ Complete Physical Examination

➔ *For a more detailed checklist, see Appendix 3, HIV-Infected Inmates – Initial Assessment.*

The examination should include the following:

- **Exam** for signs of wasting, obesity, evidence of ART-related lipohypertrophy (e.g., dorsocervical fat pad, gynecomastia, or visceral abdominal fat accumulation) and/or lipoatrophy (e.g., loss of subcutaneous fat in the face, extremities, or buttocks).
- **Funduscopic examination** for retinopathy.
- **Oropharyngeal exam** for candida and other significant oral manifestations.
- **Skin exam** for dermatologic conditions.
- **Abdominal exam** for hepatosplenomegaly.

(continued on next page)

- **Rectal exam** for men and women—including visual inspection and digital rectal examination—to evaluate for anal warts, anal cancer, evidence for other sexually transmitted diseases (STDs), as well as screening for prostate abnormalities in men.
- **Pelvic exam and Pap test** for women. The incidence of cervical pathology is 10- to 11-fold greater in HIV-infected women than in HIV-uninfected women.

  ➔ *See Appendices 5a–5c for information on cervical cancer testing and interpretation of results.*
- **Comprehensive cardiopulmonary exam**, including for evidence of CVD and diabetes; family history for these disorders should also be documented.
- **Neurology and/or neuropsychiatry assessment exam** of neurocognitive disorders, dementia, and focal neuropathies may be indicated.
- **Lymph nodes exam** for focal or rapidly progressive lymphadenopathy.

➢ Baseline Laboratory Testing

The following laboratory tests, performed during the initial patient visit, are used to identify the stage of HIV disease and to assist in the selection of ARV drug regimens.

➔ *See Appendix 4a and 4b, HIV-Infected Inmates – Baseline Screening and Evaluation and Laboratory Monitoring for a more complete list, including additional tests that may be performed under certain circumstances.*

***NOTE:** A HIV lab order set is available in the electronic chart to assist.*

- **HIV serology**
- **CD4 cell count**
- **Plasma HIV RNA** levels (viral load)
- **Complete blood count** (CBC) with differential white blood cell count
- **Complete metabolic panel (CMP)**
- **Fasting lipid profile**
- **Fasting glucose or hemoglobin A1C**
- **HLA B *5701**, if considering use of abacavir. A negative result suggests minimal risk of hypersensitivity reaction.

  ***NOTE:** Positive status should be recorded as an abacavir allergy in the patient's medical record.*
- **Genotype Resistance Testing**: GenoSure Prime or HIV-1 RT/PI inhibitor and HIV-1 integrase inhibitor at entry into care, regardless of whether ART will be initiated immediately. For patients who have HIV RNA levels < 500 cps/mL, amplification of virus for resistance testing may not always be successful.

  ➔ *See further discussion on Resistance Testing in Section 4.*

  ***NOTE:** Phenotype or combination Phenotype/Genotype (PhenoSense GT) should generally not be used without expert consultation.*
- **Urinalysis**
- **Pregnancy testing** for newly admitted female inmates

➢ Baseline Screening for Coinfections

The following screening tests are recommended to identify coinfections:

- **Tuberculin Skin Test (TST)**
- **Baseline chest radiograph** to rule out active tuberculosis
- **Toxoplasma IgG**
- **Viral hepatitis screening**
  - **Hepatitis B virus (HBV):** Screening for hepatitis B involves three laboratory studies:

    1) Hepatitis B core antibody (HB core Ab, total, or HBcAb)

    2) Hepatitis B surface antibody (HB surface Ab or HBsAb)

    3) Hepatitis B surface antigen (HB Surface Ag or HBsAg)

    ➔ *See the BOP Clinical Guidance on Chronic Hepatitis B Virus (HBV) Infection for management of hepatitis B infection.*
  - **Hepatitis C virus (HCV):** Screen for HCV antibody. HCV RNA should be ordered on all patients with a positive HCV antibody test to assess for active HCV disease.

    ➔ *See the BOP Clinical Guidance on Chronic Hepatitis C Virus (HCV) Infection for management of hepatitis C infection.*
  - **Hepatitis A virus (HAV):** Screen for anti-HAV total or IgG antibody.
- **Screening for herpes viruses**
  - **CMV antibody IgG/IgM:** Patients at lower risk of cytomegalovirus (CMV) infection (e.g., populations other than men who have sex with men (MSM) or injection drug users, both of which may be assumed to be seropositive) should be tested for latent CMV infection upon initiation of care.
  - **Varicella IgG:** This is particularly helpful information in managing exposures to varicella infections.
- **Laboratory screening for sexually transmitted diseases**
  - All patients should be screened for syphilis (RPR), gonorrhea, and chlamydia infections upon initiation of care.
  - Women should be screened for trichomoniasis.

➢ Recommended Immunizations for HIV-Positive Adults

Immunizations are an important part of preventive care for HIV-infected patients.

- Inactivated vaccines are generally safe and acceptable in HIV-infected individuals.
- Vaccination of HIV-infected individuals might not confer the same degree of protection gained by immunocompetent persons.
- Guidance for immunizing persons with HIV is described below in ***TABLE 1***.
- Certain live vaccines have sufficient safety data and are thus appropriate if indicated for HIV-infected individuals with CD4 counts ≥200 cells/µL.

➔ *It is recommended that providers frequently reference the CDC website for Updated Vaccine Schedules established by the Advisory Committee on Immunization Practices (ACIP).*

➔ *Refer to the BOP Clinical Guidance on Immunization for more information: https://www.bop.gov/resources/pdfs/immunization_201908.pdf*

TABLE 1. RECOMMENDED VACCINATIONS FOR HIV-POSITIVE PATIENTS

VACCINE	CRITERIA (in addition to HIV-positive status)	COMMENTS
Hepatitis A	• No evidence of immunity and one of the following additional risk factors: ▸ MSM ▸ Injection or non-injection drug use ▸ Liver disease or cirrhosis (including hepatitis B or C) ▸ History of homelessness ▸ Clotting factor disorders	• For patients who require both Hep A and Hep B vaccines, Twinrix® may be used.
Hepatitis B	• HBsAg, HBsAb, HBcAb negative **or** • HBcAb positive only	• For HBsAg, HBsAb, HBcAb negative: ▸ Recheck HBsAb 1–2 months after completion of series. ▸ If > 10 mIU/mL, no further vaccination is required. ▸ If < 10 mIU/mL, repeat 3-dose revaccination series. • For HBcAb positive only: ▸ Administer 1 standard dose. ▸ Recheck HBsAb 1–2 months after injection. ▸ If > 100 mIU/mL, no further vaccination is required. ▸ If < 100 mIU/mL, complete 3-dose vaccination series. • For patients who need both Hep A and Hep B vaccines, Twinrix® may be used.
HPV	• 3-dose series for all patients ≤ 26 years old who did not get any or all doses when younger	—
Influenza	• All patients	• Administer annually.
Meningococcal (MenACWY)	• All patients	• Administer 2-dose series at least 8 weeks apart. • Revaccinate every 5 years. • Administer at least 4 weeks after PCV13. • Menveo® is the formulary-approved MenACWY vaccine.
MMR	• All patients with no evidence of immunity to measles, mumps, or rubella	• Administration is **CONTRAINDICATED** in patients with CD4 < 200 cells/µL.

Table 1, page 1 of 2

VACCINE	CRITERIA (in addition to HIV-positive status)	COMMENTS
Pneumococcal • PPSV23 • PCV13	• Dosing schedule dependent upon patient's immunization history. See comments in next column.	• Administer 1 dose PCV13 followed by 1 dose PPSV23 at least 8 weeks later; then, another dose PPSV23 at least 5 years after previous PPSV23. ▸ If CD4 count is < 200 cells/µL at the time of the PPSV23 vaccination, the vaccine may be less effective. Consider administering PPSV23 ≥ 8 weeks after PCV13, once the CD4 count increases to > 200 cells/µL in response to ART. • At age 65 years or older, administer 1 dose PPSV23 at least 5 years after most recent PPSV23. • No more than three lifetime doses of PPSV23 are generally given. • Refer to BOP *Clinical Guidance on Immunization* for approach to patients with incomplete pneumococcal vaccination history.
Tdap or Td	• All patients who have not received the Tdap vaccine or whose Tdap vaccine status is unknown should receive a single, one-time dose of Tdap. • Boost with Tdap every 10 years.	• Tdap can be administered regardless of when the most recent tetanus or diphtheria-toxoid containing vaccine was given.
Varicella	• On a case-by-case basis, in varicella exposure situations, after consultation with Regional/Central Office	• Administration is **contraindicated** in patients with CD4 < 200 cells/µL.
Zoster	• Patients ≥ 50 years old	• Administration is **contraindicated** in patients with CD4 < 200 cells/µL. • Recombinant zoster vaccine (RZV) is the only zoster vaccine approved for use it the BOP. • Administer 2-dose series, 2–6 months apart, regardless of previous herpes zoster or previously received ZVL (administer RZV at least 2 months after ZVL).

Table 1, page 2 of 2

For additional information for other recommended immunizations for some HIV-Positive adults see:

- *CDC Recommended Adult Immunization Schedule by Medical Condition and Other Indications, available at: http://www.cdc.gov/vaccines/schedules/hcp/imz/adult-conditions.html*
- *Recommendations and guidelines of the Advisory Committee on Immunization Practices (ACIP), available at: https://www.cdc.gov/vaccines/hcp/acip-recs/index.html*

➢ Treatment Plan and Subspecialty Referrals

All inmates receiving a baseline evaluation for HIV infection should have a **treatment plan** that is developed by the evaluating clinician and approved by a physician.

Subspecialty referrals should be initiated as medically necessary and should include:

- Referral for baseline examination by a dentist
- Psychology referral, if clinically indicated, in addition to the mandatory referral made as part of post-test counseling, in accordance with BOP policy

> **In the BOP, Regional HIV Clinical Pharmacist Consultants** are specially trained and certified to manage HIV and are available to consult with providers on the proper care of HIV patients. Providers are encouraged to utilize these pharmacists when establishing a treatment plan, initiating or changing antiretroviral therapy, assessing possible treatment failure, etc. These pharmacists perform a quarterly review of all patients taking ART, with treatment recommendation being forwarded to the appropriate providers. Providers are encouraged to review these recommendations and adjust therapy as appropriate.

4. PERIODIC MEDICAL EVALUATIONS FOR HIV-INFECTED INMATES

Viral load (HIV RNA) and CD4 T lymphocyte (CD4) cell count are the two surrogate markers of ART (antiretroviral) response and HIV disease progression:

- **Viral load** is a marker of response to ART. A patient's pre-ART viral load level, together with the magnitude of viral load decline after initiation of ART, provides prognostic information about the probability of disease progression.
- **CD4 cell count** provides information on the overall immune function of a person with HIV. The CD4 cell count is critical in evaluating the risk of opportunistic infections and in establishing thresholds for initiating and discontinuing prophylaxis.

The goal of ART is optimal viral suppression:

- **Viral suppression** is defined generally as a viral load persistently below the level of detection (HIV RNA < 20 to 75 copies/mL, depending on the assay used). However, isolated blips (viral loads transiently detectable at low levels) are not uncommon in successfully treated patients and are not predictive of virologic failure.
- **Virological failure:** This guidance and the DHHS guidelines define virologic (i.e., ART) failure as a confirmed viral load > 200 copies/mL.

  ➔ *See Periodic HIV RNA Testing to Measure Viral Load in this section for more details.*

➢ Monitoring for Potential Complications of HIV Infection

HIV-infected patients have a higher risk of certain medical conditions compared to the general population. These include metabolic complications (e.g., dyslipidemia, diabetes mellitus, and bone disease), CVD, chronic kidney disease (CKD), neuropsychiatric disorders, certain malignancies (e.g., lymphoma, Kaposi's sarcoma), and certain coinfections. These may be associated with the HIV-infection itself, risk factors prevalent in HIV-infected populations, or the use of ARV drugs.

To reduce chronic non-AIDS morbidity and mortality, care of HIV-positive patients must focus on:

- Maintaining ART-mediated viral suppression
- Addressing strategies to reduce risk factors (e.g., smoking cessation, healthy diet, and exercise)
- Managing chronic comorbidities such as hypertension, hyperlipidemia, CKD, and diabetes

Optimal care of the HIV-infected patient requires knowledge about and evaluation for potential complications:

- **Patient interviews and physical exams** targeting the diagnosis of complications of HIV infection associated with suppression of T cell-mediated immunity, as well as the primary disorders likely resulting from the direct effects of the virus (e.g., HIV-associated neurocognitive disorder, peripheral polyneuropathy, musculoskeletal impairments, malignancies).
- **Dental referrals** with any new oral manifestation.

  ➔ *For more information, see Section 13, Dental Management.*

- **CVD Evaluations**: Rates of ASCVD, heart failure, pulmonary hypertension, and sudden cardiac deaths are significantly greater for persons with HIV than the general population, even in the setting of effective antiretroviral therapy. People with HIV should be regularly assessed for ASCVD risk and provided treatment per guidelines for management of CVD and reduction of risk. An evidence-based frequency for performing these assessments specifically in patients with HIV has not been established.
- **Diabetes:** Expert opinion suggests screening for diabetes mellitus with a hemoglobin A1C or fasting blood glucose at entry into care, prior to starting ART, 1 to 3 months after starting initiating ART, and every 3 to 6 months.
- **Screening for elevated lipid levels** follows a similar schedule as diabetes, with the exception of routine testing suggested every 6 to 12 months.

  ➔ *See Appendix 4, which outlines the 2019 DHHS recommendations on the frequency of testing. As noted in that table, some tests may be repeated more frequently if clinically indicated.*

  ➔ *See Appendix 1 for additional resources.*

➢ Periodic HIV RNA Testing to Measure Viral Load

While all recommended laboratory tests are important for evaluating HIV-infected patients, periodic HIV RNA is critical to assessing ART efficacy:

- Viral load should be measured within 4 to 8 weeks after ART initiation or modification.
- Viral load should be repeated every 4 to 8 weeks until the viral load is suppressed to < 200 copies/mL.

(section continues on next page)

NOTE: *If no viral resistance is present, then undetectable viral load should be achieved by 24 weeks after the start of treatment. If ART does not provide an optimal response after this time, HIV genotypic resistance testing should be considered. See Resistance Testing below.*

- Patients on ART with viral suppression should have viral loads checked every 3 to 4 months.
- Clinicians may extend the interval to 6 months for adherent patients whose viral load has been suppressed for more than 2 years and whose clinical and immunologic status is stable.

➔ *See Appendix 4b, which outlines the 2019 DHHS recommendations on the frequency of testing, including the ones discussed below. As noted in that table, some tests may be repeated more frequently if clinically indicated.*

➢ Periodic CD4 Counts to Assess Immune System

CD4 counts should be repeated 3 to 6 months after initiation or modification of ART, with testing on the earlier side of this range being most important and useful for patients with more advanced disease.

While on ART, CD4 counts are typically checked every 3–6 months. Patients with suppressed viral loads during the first 2 years of ART and with CD4 counts in the 300 to 500 range for at least two years could be considered for checking every year.

For patients on ART with consistent viral load suppression and CD4 count >500 cells/mm^3 for at least 2 years, CD4 monitoring is optional.

➢ Resistance Testing to Guide Selection of ARV Regimen

Resistance testing should be used to guide initiation or modification of an ARV regimen:

➔ *See also Section 7a. General Considerations When Selecting an Initial ARV Regimen.*

➔ *See also list of ARV Drug Abbreviations.*

The **preferred test** is the HIV-1 GenoSure Prime baseline test for resistance to all major classes of HIV medications (covers NRTIs, NNRTIs, PIs, INSTIs). However, it may not be available in all areas, and alternative resistance tests may need to be ordered (see below).

Alternative resistance tests, if GenoSure Prime is unavailable, are listed below and are typically ordered together:

- **HIV-1 Genotype** (resistance mutation analysis) baseline test for resistance to three of the four major classes of HIV medications (covers NRTIs, NNRTIS, PIs only).
- **HIV-1 Integrase Resistance** baseline test for resistance to one of the four major classes of HIV medication (covers INSTIs only).

Viral load: Successful resistance testing generally requires a viral load of > 500 cps/mL

(this section continues on the next page)

Interpretation: Genotype reports can be difficult to interpret.

- Providers are encouraged to consult with their regional HIV Consultants to interpret results.
- See the following online resources for helpful guidance in interpreting genotypic resistance test results:
  - *https://hivdb.stanford.edu/hivdb/by-mutations/*
  - *https://www.iasusa.org/resources/hiv-drug-resistance-mutations/*

The following resistance tests may have significant costs and are not commonly indicated. These tests should **only** be ordered in consultation with an HIV specialist:

- HIV-1 Co-Receptor Tropism (Trofile)
- HIV-1 Entry Inhibitor (Fuzeon)
- HIV-1 Phenotype (PhenoSense)
- HIV-1 Phenotype/Genotype

5. PROPHYLAXIS FOR OPPORTUNISTIC INFECTIONS (OIs)

Primary prophylaxis for OIs is indicated in some instances to prevent acute illnesses in patients with HIV infection. Prophylaxis should be prescribed in accordance with the most recent DHHS recommendations.

For medication and dosing recommendations for prophylaxis, see: Appendix 6, Prophylaxis for HIV Related Opportunistic Infections.

For information on treating patients diagnosed with OIs related to HIV infection, providers are advised to consult with HIV clinical consultants, infectious disease specialists, and/or review current DHHS guidelines, available at:

See https://aidsinfo.nih.gov/guidelines/html/4/adult-and-adolescent-opportunistic-infection/0

Pneumocystis Pneumonia (PCP)

NOTE: *Pneumocystis jiroveci (pronounced "yee row vet zee") is the correct name for what was previously called pneumocystis carinii. PCP remains an appropriate abbreviation.*

Primary prophylaxis for PCP should be initiated for all patients with CD4 count < 200 cells/mm^3 **or** CD4 percentage < 14% of total lymphocyte count.

- Primary prophylaxis may be discontinued if the CD4 count increases to > 200 cells/mm^3 for at least 3 months.
- Providers may consider stopping PCP prophylaxis if CD4 count is 100–200 cells/mm^3 and HIV RNA remains below limits of detection for ≥ 3 months.
- **Restart** PCP prophylaxis if:
  - CD4 count < 100 cells/mm^3 regardless of HIV RNA
    or
  - CD4 count 100–200 cells/mm^3 and HIV RNA above detection limit of the assay used.

➢ Toxoplasmosis

Primary prophylaxis for toxoplasmosis should be initiated for all patients seropositive for Toxo IgG **and** CD4 count < 100 cells/mm^3.

- Primary prophylaxis may be **discontinued** if the CD4 count increases to > 200 cells/mm^3 for 3 months. Providers may consider **stopping** prophylaxis if CD4 count is 100–200 cells/mm^3 **and** HIV RNA remains below limits of detection for ≥ 3 months.
- **Restart** prophylaxis if:
  - CD4 count < 100 cells/mm^3 regardless of HIV RNA
    or
  - CD4 count 100–200 cells/mm^3 **and** HIV RNA above detection limit of the assay used.

➢ Mycobacterium Avium Complex (MAC)

Primary prophylaxis is **not recommended** for patients who are immediately initiated on ART, regardless of CD4 cell count.

- Start primary prophylaxis if patient **is not on fully suppressive** ART **and** CD4 count < 50 cells/mm^3, after ruling out disseminated **MAC** disease.
- Primary prophylaxis may be discontinued when ART is initiated and HIV RNA is suppressed.
- Restart prophylaxis for **MAC** if CD4 count < 50 cells/mm^3 **and** patient is not on fully suppressive ART.

➢ Latent Tuberculosis Infection (LTBI)

- Treatment of LTBI is indicated for HIV-positive patients who have tuberculin skin test results of 5 millimeters or greater or positive Interferon-Gamma Release Assay (IGRA) **and** no clinical or radiographic evidence of TB disease.
- Patients with HIV who are close contacts of a contagious TB case require treatment for LTBI, regardless of their tuberculin skin test measurement.
- Immune reconstitution with ART may result in unmasking of LTBI, resulting in the conversion of a previously negative tuberculin skin test to a positive result. Patients with a negative tuberculin skin test **and** advanced HIV disease (i.e., CD4 count < 200 cells/µL) should have a repeat test after initiation of ART and CD4 count increase to > 200 cells/µL.

➔ *For more complete information, including monitoring while on treatment, see the BOP Clinical Guidance on Tuberculosis, available at: http://www.bop.gov/resources/health_care_mngmt.jsp.*

➢ Cytomegalovirus

Primary prophylaxis is **not recommended** in most CMV patients**.** CMV end-organ disease is best prevented using ART to maintain the CD4 count > 100 cells/µL and recognizing the early symptoms of CMV disease. Since retinitis is the most common sign of CMV disease, patients with low CD4 counts should be monitored for changes in visual acuity such as increased floaters, and then referred to an ophthalmologist for evaluation and proper therapy.

➢ Fungal Infections

- **Candidiasis:** Primary prophylaxis for candida infections is not routinely indicated. Acute therapy with fluconazole for 1 to 2 weeks for oral candidiasis, and 2 to 3 weeks for esophageal disease, is highly effective. Long-term fluconazole use may promote candida resistance.
- **Histoplasmosis:** Infection is endemic to the central and south-central United States, especially in the Ohio and Mississippi River Valleys, and Latin America, including Puerto Rico. Primary itraconazole prophylaxis for histoplasmosis (CD4 count < 150 cells/mm^3) may be considered for patients who are incarcerated within an area with a hyperendemic (persistently high) rate of histoplasmosis (> 10 cases/100 patient years).
  - Primary prophylaxis can be discontinued in patients on ART once CD4 counts are ≥ 150 cells/mm^3 for 6 months **and** HIV-1 viral load is undetectable.
  - Prophylaxis should be restarted if the patient's CD4 count falls to < 150 cells/mm^3.
- **Coccidioidomycosis:** Primary antifungal prophylaxis is of little benefit to patients with low CD4 cell counts who live in regions where *Coccidioides* is endemic and is therefore, not recommended.
  - Yearly or twice-yearly serological testing for coccidioidomycosis is reasonable for serologically negative individuals who live in regions endemic for coccidioidomycosis (southwestern United States, Mexico, and South America).
  - Testing is also advised for individuals who have traveled to or lived in endemic areas in the past.
  - A new positive test suggests possible active disease in patients with low CD4 cell counts, and further clinical evaluation should be undertaken.
  - If active coccidioidomycosis is not identified, primary prophylaxis antifungal therapy with fluconazole 400 mg daily is recommended for those with CD4 counts < 250 cells/mm^3. This should be continued until the CD4 count is ≥ 250 cells/mm^3 and ART has fully suppressed HIV replication. Outside endemic regions, routine testing does not appear to be useful and should not be performed.

➢ Secondary OI Prophylaxis

Discontinuation of secondary prophylaxis of OIs should be considered on an individual basis, using the DHHS-based guidelines outlined below.

- **Pneumocystis pneumonia (PCP):** secondary prophylaxis may be discontinued in the following circumstances:
  - CD4 counts > 200 cells/mm^3 for > 3 months as a result of ART.
  - May consider discontinuation in patients with CD4 counts 100–200 cells/mm^3 **and** HIV RNA below the limit of detection of assay used for > 3 months.
  - If PCP occurred in a patient with CD4 count of > 200 cells/mm^3, consult with HIV specialist as patient may require PCP prophylaxis for life.

(this section continues on the next page)

- **Toxoplasmosis:** secondary prophylaxis may be discontinued if CD4 count is > 200 cells/mm^3 **and** asymptomatic for > 6 months.
- **Mycobacterium avium complex (MAC):** secondary prophylaxis for MAC may be discontinued if patient has completed ≥ 12 months of therapy **and** no symptoms of MAC and CD4 count > 100 cells/mm^3 for ≥ 6 months. Restart secondary prophylaxis if CD4 < 100 cells/mm^3.
- **Cytomegalovirus (CMV):** secondary prophylaxis for patients with a history of CMV retinitis can be discontinued on an individual basis in consultation with the treating ophthalmologist if the CD4 count increases to > 100 cells/µL for 3–6 months in response to ART.
  - Factors to consider before discontinuing secondary prophylaxis include patient adherence to ART, lesion activity, the location and extent of retinal disease, and the vision in the contralateral eye.
  - Prophylaxis should be reinitiated if the CD4 count decreases to < 100 cells/µL.
    NOTE*: Close follow-up with an ophthalmologist is indicated regardless of CD4 count.*
- **Fungal infection:** secondary prophylaxis for cryptococcal meningitis can be discontinued, on an individual basis, for asymptomatic patients who have received at least one year of maintenance therapy after successful treatment of cryptococcosis and whose CD4 count is ≥ 100 cells/mm^3 and have an undetectable viral load for > 3 months in response to ART. **Reinitiate fluconazole if** the CD4 count declines to < 100 cells/mm^3**.**
- **Cryptococcal meningitis:** secondary prophylaxis can be discontinued on an individual basis for asymptomatic patients who have received at least one year of maintenance therapy after a successful treatment of cryptococcosis **and** whose CD4 count is ≥ 100 cells/mm^3 with an undetectable viral load for > 3 months in response to ART. **Reinitiate fluconazole if** the CD4 count declines to < 100 cells/mm^3**.**
- **Histoplasmosis:** secondary prophylaxis can be discontinued if the following criteria are met:
  - itraconazole for ≥ 1 year
  - negative blood cultures
  - CD4 count ≥ 150 cells/ mm^3 for > 6 months in response to ART
  - serum histoplasma antigen < 2 units; and
  - undetectable HIV viral load.
  - **Reinitiate itraconazole if CD4 count declines to < 150 cells/µL**.
- **Coccidioidomycosis:**
  - Patients with prior diffuse pulmonary, disseminated non-meningeal, or meningeal diseases ordinarily require indefinite suppressive therapy.
  - Patients with only asymptomatic disease, but positive serology or focal coccidioidal pneumonia, can discontinue secondary prophylaxis with clinical response to ≥ 6 months antifungal therapy, CD4 count > 250 cells/mm^3, and receiving ART. Monitoring for recurrence should continue with serial chest radiographs and coccidioidal serology.
- **Oral candidiasis**: secondary prophylaxis with oral fluconazole should only be considered if recurrences are frequent or severe. Long-term fluconazole use may promote candida resistance. Secondary fluconazole prophylaxis can be discontinued when the CD4 count has risen to > 200 cells/mm^3 with ART.

6. INITIATING ART IN TREATMENT-NAÏVE PATIENTS

ART is recommended for all HIV-infected patients and should be initiated as soon as the patient is willing and able to accept treatment, and must be continued to achieve its primary goals.

➢ Keys to Successful ART

The decision to initiate treatment should always include: consideration of a patient's comorbid conditions, potential side effects, his or her willingness and readiness to initiate therapy, possible interactions with concomitant medications, results of pretreatment genotypic drug-resistance testing, and regimen convenience.

The benefits of acting early: Suppression of plasma viremia delays or prevents the development of drug resistance mutations, reduces risk of HIV transmission, preserves CD4 counts, and reduces HIV-related morbidity and mortality, all of which are important treatment goals.

- Deferring ART until CD4 count declines puts an individual at risk of AIDS-defining conditions and has been associated with higher risk of morbidity and mortality.
- High plasma HIV RNA is a major risk factor for HIV transmission; effective ART can reduce viremia and persons who take ART daily and maintain an undetectable viral load have effectively no risk of sexually transmitting HIV to their HIV-negative partners.
- The magnitude of CD4 recovery is directly correlated with CD4 count at ART initiation, providing further reason for earlier treatment.
- START and TEMPRANO trials demonstrated a decreased risk of severe HIV-related illness or death in patients who initiated ART with baseline CD4 counts > 500 cells/mm^3.
- HIV suppression with ART may also decrease inflammation and immune activation thought to contribute to higher rates of cardiovascular and other end-organ damage.

Continuation of ART: Treatment interruption has been associated with rebound viremia, worsening of the immune function, and increased morbidity and mortality.

Patient adherence: The key to successful ART in maintaining viral suppression is adherence to the prescribed regimen. Potential barriers to adherence need to be identified and addressed before and after initiation of therapy. Complex medication regimens, as well as patient-related factors—such as active substance abuse, depression, psychiatric disorders, neurocognitive impairment, or experience of adverse effects—can all **contribute to poor adherence to ART.** Emergence of drug resistance mutations, as a consequence of poor adherence, may result in treatment failure and compromise future treatment options.

Baseline genotype drug-resistance testing: Achieving viral suppression requires the use of ARV regimens with active drugs from two or more drug classes. Baseline genotype resistance testing and patient characteristics should guide the specific regimen design.

➔ *For more information,* see *Section 4, Resistance Testing* and *Section 7, Initial Combination Regimens for the Art-Naïve Patient.*

(this section continues on the next page)

Viral load reduction: Viral load reduction to below detection limits in ART-naïve patients usually occurs within the first 8–24 weeks of therapy. Virologic success can be predicted, based on excellent adherence to highly potent ARV regimens, low baseline viremia, higher baseline CD4 counts, and rapid reduction of viremia in response to treatment.

When viral suppression is not achieved, or is lost, prompt assessment of treatment compliance, genotype resistance testing, and rapidly improving compliance or changing to a new regimen is required.

➔ *See Section 9, Assessment of Virologic Failure.*

Sustained viral suppression and immune function: Sustaining viral suppression and maintaining higher CD4 count levels may delay, prevent, or reverse some non-AIDS-defining complications such as abnormally high levels of immune activation and inflammation, HIV-associated kidney disease, liver disease, CVD, neurologic complications, and malignancies.

➢ Rapid Initiation of ART

In some cases, ART may need to be initiated prior to genotypic testing results. Conditions that may favor initiation of ART prior to genotypic testing results becoming available are listed below:

- Pregnancy
- AIDS-defining conditions
- Acute OIs
- Lower CD4 counts (< 200 cells/µL)
- HIV-associated nephropathy (HIVAN)
- Acute/early HIV infection
- HIV/HBV or HIV/HCV coinfection

➔ *For ARV medications to be used in these situations, see early initiation in **Table 2** (the fifth clinical scenario for "Pre-ART Characteristics").*

***NOTE:** Consultation with a regional HIV clinical pharmacist consultant or other clinician experienced in the management of HIV infection is encouraged prior to selecting ART for early initiation.*

7. INITIAL REGIMENS FOR THE ART-NAÏVE PATIENT

FDA-approved antiretroviral medications and their dosing recommendations are enumerated in the DHHS guidelines. Clinicians managing patients with HIV infection should regularly review the DHHS guidelines to keep abreast of new FDA-approved antiretroviral medications, changes in antiretroviral dosages, drug side effects and adverse reactions, monitoring parameters, and complex drug interactions.

While there are many DHHS-recommended options for initiation of therapy, not all are BOP-preferred or formulary. Practitioners should refer to the BOP National Drug Formulary and most recent P&T Minutes for BOP-preferred, formulary medications for HIV.

➔ *The DHHS guidelines are available at: https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/0.*

***NOTE:** Consultation with a regional HIV clinical pharmacist consultant or other clinician experienced in the management of HIV infection is encouraged prior to selecting ART for early initiation.*

➢ General Considerations When Selecting an Initial ARV Regimen

***NOTE:** Some medications referenced in the following sections are BOP non-formulary medications. Refer to current BOP National Formulary for BOP-preferred agents for HIV.*

- **Abbreviations***: See* the list of *ARV Drug Abbreviations*
- **Advantages and Disadvantages***: See Appendix 7* for pros and cons of ARV components.
- **Chronic Kidney Disease:** Refer to DHHS guidelines for information on dosing of ARV with CKD and hemodialysis. *See Appendix 1* for listing.

Initial therapy generally consists of **one or two NRTIs** combined with one of the following:

- An **INSTI** (preferred regimen)
- A pharmacologically boosted **PI or an NNRTI** (alternative regimens in certain clinical scenarios)

The **NRTI** backbone component in most recommended and alternative regimens is one of the following:

- **TAF/FTC** (Descovy®)
- **TAF + 3TC**
- **TDF/FTC** (Truvada®)
- **TDF/3TC** (Cimduo®)
- **ABC/3TC** (Epzicom®)

The choice of an initial ARV regimen should be guided by the regimen's efficacy, genetic barrier to resistance, pretreatment HIV viral load, pretreatment CD4 count, adverse effects profile, convenience, the patient comorbidities, concomitant medications, and the potential for drug-drug interactions.

Whenever possible, a **once-daily regimen with low pill burden** should be considered in order to increase the likelihood of medication adherence.

For patients unable to take ABC, TDF, or TAF, consult with an HIV Clinical Pharmacist Consultant, or other clinician experienced in the management of HIV infection is recommended, and/or refer to DHHS guidelines.

Possible drug-drug interactions should be taken into consideration when selecting an ARV regimen. Several ARV medications have been identified as inducers, inhibitors, and/or substrates of metabolic pathways. Furthermore, certain medications can induce ARV failure in adherent patients. A detailed review of concomitant medications is vital to creating a regimen that minimizes undesirable interactions. The potential for drug interactions should be assessed when initiating ARV therapy—or when any new drug (including over-the-counter agents) is added to an existing regimen.

- *Since information on drug-drug interactions are updated as new information becomes available, medical literature and drug interaction websites should be checked routinely.Providers can review the Drug-Drug Interactions section of DHHS guidelines (https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/367/overview) and the drug interactions website of the University of Liverpool (http://www.hiv-druginteractions.org/).*

(this section continues on the next page)

Possible drug-disease interactions should be taken into consideration when selecting an ARV regimen, including when there are concurrent disease states such as viral hepatitis, CVD, hyperlipidemia, TB, CKD, DM, osteoporosis, cancer, psychiatric illness, neuropathic pain.

➢ Recommended Initial Regimens for Most People with HIV

The DHHS guidelines provide tables listing characteristics of the ARV drug classes discussed below, as well as guidance on selecting regimens for specific clinical scenarios.

Prescribers are encouraged to consult with the institution pharmacist, regional HIV clinical consultant pharmacist, or other clinician experienced in the management of HIV in selecting the most cost-effective, patient-specific option.

Tenofovir used in this guidance refers to either the alafenamide (TAF) or disoproxil fumarate (TDF) form. TAF and TDF are the two forms of tenofovir approved by the FDA. TAF has fewer long-term bone and kidney toxicities than TDF, while TDF is associated with lower lipid levels.

In general, the BOP recommends TAF as the preferred tenofovir product due to negligible cost difference and lower adverse effects compared to TDF**.** TDF should be avoided in patients with chronic kidney disease (CrCl < 50 ml/min) or osteoporosis. TDF has higher kidney toxicities and more adverse bone outcomes when co-administered with ritonavir or cobicistat. TDF is recommended in place of TAF when treatment with rifamycins (i.e., rifabutin, rifampin, rifapentine) is medically necessary.

Abacavir (ABC) concerns: Avoid use of abacavir-containing NRTI backbone combinations in chronic hepatitis B co-infected patients unless combined with effective hepatitis B antiviral therapy. Abacavir should be avoided in patients at high risk for cardiac events. If HIV viral load > 100,000, use only with dolutegravir. Abacavir should not be initiated without confirmation of a negative HLA-B*5701 test.

Raltegravir (RAL) can be given as 400 mg twice daily or 1200 mg (two HD 600 mg tablets) once daily. The HD 600 mg and 400 mg tablets are **not** interchangeable.

Cobicistat (/c) or Ritonavir (/r) boosted regimen should be avoided in hyperlipidemia when feasible, due to association with more drug-drug interactions.

Efavirenz (EFV) and Rilpivirine (RPV) should be avoided in psychiatric illness.

➢ INSTI-Based Regimens: Recommended Initial Therapy

INSTI-based regimens are recommended as initial therapy for most people with HIV. In large clinical trials and in clinical practice, INSTI-based regimens have achieved high rates of virologic suppression and often have greater tolerability than PI- or NNRTI-based regimens.

Due to their higher barrier to resistance, bictegravir or dolutegravir are preferred over elvitegravir- and raltegravir-containing regimens.

NOTE: *Some medications referenced in the following sections are BOP non-formulary medications. Refer to current BOP National Formulary for BOP-preferred agents for HIV.*

➔ **Abbreviations***: See* the list of *ARV Drug Abbreviations*

(this section continues on the next page)

The following regimens are recommended by the DHHS as initial therapy for HIV:

- **BIC/TAF/FTC** *(Biktarvy®)* (once daily)
  - Low number of drug-drug interactions.
  - Well-tolerated
  - TAF is **not** recommended if CrCL < 30 ml/min.

- **DTG/ABC/3TC** *(Triumeq®)* (once daily)
  - Low number of drug-drug interactions.
  - Only for patients who are HLA-B 5701 negative. Positive HLA-B 5701 status should be recorded as an allergy to abacavir.

- **DTG 50 MG *PLUS* TENOFOVIR/FTC OR TENOFOVIR/3TC** (once daily)
  - Low number of drug-drug interactions.
  - DTG is **not** recommended during the first trimester of pregnancy.

- **RAL 400 MG BID OR 1200 MG (TWO 600 MG HD) QD *PLUS* TENOFOVIR/FTC OR TENOFOVIR/3TC** (once daily)
  - Low number of drug-drug interactions.
  - Higher pill burden compared to other regimens.
  - Some guidelines consider RAL-containing regimens to be less favorable due to increased pill burden and a lower barrier to resistance.

- **DTG/3TC (DOVATO®)** (once daily)
  - Consider when abacavir or tenofovir cannot be used
  - Avoid in patients with HIV RNA >500,000 copies/ml, Hep B co-infection or 3TC resistance (e.g. M184V)
  - Requires HIV genotype and hepatitis B testing before use.

➢ Recommended Initial Regimens in Certain Clinical Situations

The following regimens are effective and tolerable, but have some disadvantages when compared with the regimens listed above, or have fewer supporting data from randomized clinical trials. However, in certain clinical situations, one of these regimens may be preferred.

➔ *See the list of* ARV Drug Abbreviations*.*
➔ *See Appendix 7 for advantages and disadvantages of ARV components used in initial ART.*

PI-BASED REGIMENS

A boosted PI-based regimen may be preferred for patients who are at high risk for intermittent therapy because of poor adherence, or who have shown NRTI drug resistance. In general, boosted DRV is preferred over boosted ATV.

(this section continues on the next page)

- **DRV 800 mg + COBI OR RTV *PLUS* TENOFOVIR/FTC OR TENOFOVIR/3TC** (once daily)
  - Must be taken with food.
  - DRV/c/TAF/FTC is available as a single tablet regimen (Symtuza®).
  - DRV/c plus TDF is **not** recommended for patients with CrCl < 70 mL/min. Associated with higher kidney toxicity and adverse bone outcomes when compared to TAF-containing version.
  - Tenofovir/FTC can be substituted with ABC/3TC (Epzicom®) if HLA-B*5701 negative.

- **ATV 300 mg + COBI OR RTV *PLUS* TENOFOVIR/FTC OR TENOFOVIR/3TC** *(*once daily)
  - Must be taken with food.
  - ATV/c plus TDF is NOT recommended for patients with CrCl < 70 mL/min. Associated with higher kidney toxicity and adverse bone outcomes when compared to TAF-containing version.
  - Greater rate of discontinuation due to toxicities, when compared to darunavir or raltegravir.

NRTI-BASED REGIMENS

An NRTI-based regimen may be preferred for patients who require TB treatment or smaller STR pill size.

- **DOR/TDF/3TC OR DOR PLUS TAF/FTC**
  - Available both as a single-drug tablet to be used with two NRTIs and as part of an STR with TDF/3TC (Destrigo®).
  - Better CNS tolerability than EFV, and more favorable lipid effects than DRV/r and EFV.
  - Fewer potential drug interactions than EFV or RPV.

- **EFV PLUS TENOFOVIR/FTC OR TENOFOVIR/3TC** (once daily)
  - Low barrier of resistance, multiple drug-drug interactions, and higher adverse effects compared to other recommended regimens.
  - EFV has high rate of central nervous system (CNS)-related toxicities and a possible association with suicidality. EFV may exacerbate psychiatric illness.
  - EFV/TDF/FTC (Atripla®) is **not** recommended when CrCL ≤ 50 ml/min
  - EFV/TDF/3TC (Symfi®) is **not** recommended when CrCL ≤ 50 ml/min

- **RPV/TENOFOVIR/FTC** (once daily)
  - Must be taken with food.
  - Only for patients with pre-treatment HIV RNA < 100,000 cps/mL and CD4 count > 200 cells/µL.
  - Contraindicated in patients receiving proton pump inhibitors.
  - RPV/TDF/FTC (Complera®) is **not** recommended when CrCL ≤ 50 ml/min
  - RPV/TAF/FTC (Odefsey®) is **not** recommended if CrCL < 30 ml/min.

INSTI-BASED REGIMENS

EVG-containing regimens may have lower barriers to resistance and have higher risk of drug-drug interactions than other INSTI-based regimens.

- **EVG/COBI/TENOFOVIR/FTC** (once daily)
  - Must be taken with food.
  - TAF-containing version (Genvoya®) is only for patients with pre-ART CrCl > 30 mL/min.
  - TAF-containing version (Genvoya®) can be used in patients on hemodialysis with eGFRs <15ml/min.
  - TDF-containing version (Stribild®) is ONLY for patients with pre-ART CrCl > 70 mL/min. Associated with higher kidney toxicity and adverse bone outcomes when compared to TAF-containing version.
  - Higher incidence of drug-drug interactions compared to other INSTI regimens.

➢ Initial ARV Regimens: Considerations Based on Clinical Scenarios

TABLE 2 beginning on the following page is designed to guide clinicians in choosing an initial ARV regimen according to various patient and regimen characteristics and specific clinical scenarios.

When more than one scenario applies to a patient**,** clinicians should review considerations for the relevant scenarios and select the most appropriate regimen.

> FDA-approved antiretroviral medications and their dosing recommendations are detailed in the DHHS guidelines. Clinicians managing patients with HIV infection should regularly review the DHHS guidelines to keep abreast of new FDA-approved antiretroviral medications, changes in antiretroviral dosages, drug side effects and adverse reactions, monitoring parameters, and complex drug interactions. The most up-to-date DHHS guidelines are available at: *https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-treatment-guidelines/0*

TABLE 2. INITIAL ARV REGIMEN CONSIDERATIONS BASED ON SPECIFIC CLINICAL SCENARIOS

PATIENT/REGIMEN CHARACTERISTICS	CLINICAL SCENARIO	CONSIDERATION(S)	RATIONALE/COMMENTS
Pre-ART Characteristics	CD4 count < 200 cells/mm^3	Do not use the following regimens: • RPV-based regimens • DRV/r + RAL	Higher rate of virologic failure observed in those with low pre-treatment CD4 cell count.
	HIV RNA > 100,000 cps/mL	Do not use the following regimens: • RPV-based regimens • ABC/3TC with EFV or ATV/r • DRV/r + RAL	Higher rates of virologic failure observed in those with high pre-treatment HIV RNA.
	HIV RNA > 500,000 cps/mL	• RPV-based regimens • ABC/3TC with EFV or ATV/r • DRV/r + RAL • DTG/3TC	—
(TABLE 2, page 1 of 3. See ABBREVIATIONS at the end of the table.)			

PATIENT/REGIMEN CHARACTERISTICS	CLINICAL SCENARIO	CONSIDERATION(S)	RATIONALE/COMMENTS
Pre-ART Characteristics (cont.)	HLA-B*5701 positive or result unknown	Do **not** use ABC-containing regimen.	Abacavir hypersensitivity, a potentially fatal reaction, is highly associated with positivity for the HLA-B*5701 allele.
	Conditions warranting **early initiation**: Must treat patient before HIV drug resistance results are available (see list of conditions in Section 6).	*Use one of the following regimens:* • BIC/TAF/FTC • DRV/(r or c) plus tenofovir (TAF or TDF) plus FTC or 3TC • DTG plus tenofovir (TAF or TDF) plus FTC or 3TC	Transmitted mutations conferring NNRTI resistance are more likely than mutations associated with PI or INSTI resistance.
	CrCl < 50 ml/min	Avoid coformulation regimens containing TDF or 3TC.	• TDF has been associated with renal tubulopathy. • 3TC requires dose adjustment.
	CrCl < 30 ml/min	Avoid coformulation regimens containing FTC.	Dosage adjustment required.
		Avoid coformulation regimens containing TAF.	Use is NOT recommended.
ART-Specific Characteristics	One-pill, once-daily regimen desired	ART options include: • BIC/TAF/FTC • DOR/TDF/3TC • DRV/c/TAF/FTC • DTG/ABC/3TC • DTG/3TC • EFV/TDF/FTC • EFV/TDF/3TC • EVG/c/TDF/FTC • EVG/c/TAF/FTC • RPV/TDF/FTC • RPV/TAF/FTC	• Do **not** use RPV-based regimens if HIV RNA > 100,000 copies/mL and CD4 count < 200 cells/µL. • Do **not** use a regimen including ABC if HLAB* 5701 positive.
	ARV regimens that must be taken with food	ART options include: • ATV/r or ATV/c-based regimens • DRV/r or DRV/c-based regimens • EVG/c/TDF/FTC • EVG/c/TAF/FTC • RPV-based regimens	• Food improves absorption of these regimens. • RPV-containing regimens should be taken with ≥ 390 calories of food.
	Psychiatric illnesses	• Consider avoiding EFV- and RPV-based regimens. Patients on INSTI-based regimens with pre-existing psychiatric conditions should be closely monitored.	• EFV and RPV can exacerbate psychiatric symptoms and may be associated with suicidality.
	Medication-assisted treatment for opioid use disorder with methadone	Avoid EFV-containing regimens.	• Opioid withdrawal may occur due to EFV-induced reductions in methadone concentrations.
	Hyperlipidemia	The following ARV drugs have been associated with dyslipidemia: • PI/r or PI/c • EFV EVG/c	• BIC, DTG, RAL, DOR, and RPV have fewer lipid effects. • TDF has been associated with more favorable lipid effects than ABC or TAF.

(TABLE 2, page 2 of 3. See ABBREVIATIONS at the end of the table.)

PATIENT/REGIMEN CHARACTERISTICS	CLINICAL SCENARIO	CONSIDERATION(S)	RATIONALE/COMMENTS
ART-Specific Characteristics (cont.)	High cardiac risk	• BIC-, DTG-, RAL-, RPV-, or DOR-based regimens may be advantageous in this setting. • Consider avoiding ABC- and LPV/r -based regimens. • An ATV-based regimen may have advantages over a DRV-based regimen.	Increased cardiovascular risk in some studies.
	Pregnancy	*See the DHHS Perinatal Guidelines at:* *http://www.aidsinfo.nih.gov/guidelines/html/3/perinatal-guidelines/0/*	
Presence of Coinfections	HBV infection (Hepatitis B algorithm completion/non-formulary approval required)	• Use TDF or TAF/FTC (or TDF or TAF plus 3TC) whenever possible. • If TDF is contraindicated, treat HBV with FTC or 3TC and entecavir or another drug active against HBV.	TDF/TAF, FTC, and 3TC are active against both HIV and HBV. However, 33TC- or FTC-associated HBV mutations can emerge rapidly when these drugs are used without another HBV-active agent.
	HCV treatment required	Refer to recommendations for *Hepatitis C/HIV Coinfection*	
	TB infection	If rifampin is used: • EFV can be used without dosage adjustment. • If RAL is used, increase RAL dose to 800 mg BID. • Use DTG at 50 mg BID dose only in patients without selected INSTI mutations (refer to product label). • If using a PI-based regimen, rifabutin should be used in place of rifampin in the TB regimen. • If rifapentine once weekly is used: EFV or RAL (twice daily) with TDF/FTC or ABC/3TC can be used without dosage adjustment. • TAF or BIC is **not** recommended with any rifamycin-containing regimen.	• Rifampin is a strong inducer of CYP3A4 and UGT1A1 enzymes, causing significant decrease in concentrations of PI, INSTI, and RPV. • Rifampin has a less significant effect on EFV concentration than on other NNRTIs, PIs, and INSTIs. • Rifabutin is a less potent inducer and is a good option for patients receiving non-EFV-based regimens. • Rifapentine is both CYP3A4 substrate and inducer. Do NOT use with TAF. • Rifamycins may significantly reduce TAF exposure.
Adherence Concerns	Patients with history of poor adherence	Consider boosted PI-, BIC-, or DTG-based regimens.	PIs, BIC, and DTG have a higher relative barrier to resistance.

ABBREVIATIONS:
3TC = lamivudine; **ABC** = abacavir; **ATV/r** = ritonavir-boosted atazanavir; **ARV** = antiretroviral; **c** = cobicistat; **CKD** = chronic kidney disease; **CrCl** = creatinine clearance; **DOR** = doravirine; **DRV/r** = ritonavir-boosted darunavir; **DTG** = dolutegravir; **eGFR** = estimated glomerular filtration rate; **EFV** = efavirenz; **EVG** = elvitegravir; **FDA** = Federal Drug Administration; **FTC** = emtricitabine; **HBV** = hepatitis B virus; **HCV** = hepatitis C virus; **INSTI** = integrase strand transfer inhibitor; **LPV/r** = ritonavir-boosted lopinavir; **NNRTI** = non-nucleoside reverse transcriptase inhibitor; **NRTI** = nucleoside reverse transcriptase inhibitor; **PI** = protease inhibitor; **PI/c** = cobicistat-boosted protease inhibitor; **PI/r** = ritonavir-boosted protease inhibitor; **RAL** = raltegravir; **RPV** = rilpivirine; **RTV** = ritonavir; **TAF** = tenofovir alafenamide; **TDF** = tenofovir disoproxil fumarate

ADAPTED FROM:
Table 7, in Panel on Antiretroviral Guidelines for Adults and Adolescents. *Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services, AIDS info Web site*. Updated December 18, 2019. Available at: *https://aidsinfo.nih.gov/contentfiles/lvguidelines/AA_Tables.pdf*

(TABLE 2, page 3 of 3)

8. CONSIDERATIONS FOR SPECIAL POPULATIONS

➢ Elderly

Patients diagnosed early after infection and maintained on effective ART can expect the same life expectancy as persons without HIV. However, there are special, non-AIDS complications that clinicians should consider.

- As HIV patients age, their risk of non-AIDs complications—including CVD, kidney disease, and neurological disorders—increases at a rate higher than persons without HIV. Patients should be **closely monitored** for development of non-AIDs complications.
- **Adverse drug events** from ARV medications and medications for comorbidities may occur more frequently in older persons with HIV**.** Therefore, the bone, kidney, metabolic, cardiovascular, cognitive, and liver health of older individuals with HIV should be monitored closely.
- HIV-associated **neurocognitive disorder** (HAND) is a decline in neurocognitive functioning in persons with HIV and typically occurs earlier than neurocognitive disorders in persons without HIV. Patients with HAND may have difficulty with adherence to ART. Providers should consider referral to a neurology specialist for patients whose advanced HAND affects their activities of daily living (ADLs).

➢ Pregnancy

The treatment of pregnant HIV patients should be coordinated with an obstetrician experienced in the care of patients with HIV**,** due to the risk of ART's effects on the fetus, as well as the risk of transmitting HIV to the child.

- Two-drug regimens are **not** recommended for pregnant patients.
- There is insufficient data to assess for teratogenicity for TAF-, DOR-, and BIC-containing regimens. Patients who become pregnant while taking these medications should be referred to a specialist for evaluation for continuation.
- Pregnancy may decrease the drug levels of cobicistat-containing regimens, thereby resulting in loss of virologic suppression.
- Preliminary data have raised concerns about an increased risk of neural tube defects in infants born to patients who were receiving DTG at the time of conception. Clinicians should discuss the risks and benefits of DTG use with the patient.

NOTE: *Changes in ART should be made only when necessary and always in consultation with an HIV specialist, to avoid loss of viral control and increased risk of perinatal transmission.*

➔ *See the DHHS Perinatal Guidelines at: http://www.aidsinfo.nih.gov/guidelines/html/3/perinatal-guidelines/0/*

➢ Transgender

- Gender-affirming hormone therapies are associated with hyperlipidemia, elevated cardiovascular risk, and osteopenia; in such cases, clinicians should choose an ARV regimen that will not increase the risk of these adverse effects.
- Some ARVs may have interactions with hormone therapy. Clinical effects and hormone levels should be monitored and hormone therapy adjusted as needed.

➔ *Refer to the DHHS Considerations for Antiretroviral Use in Transgender People with HIV at:* *https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/538/transgender-people-with-hiv*

9. MANAGEMENT OF THE TREATMENT-EXPERIENCED PATIENT

➢ Assessment of Virologic Failure

Virologic failure is the inability to achieve or maintain suppression of viral replication to an HIV RNA level < 200 copies/mL. Clinicians should use good clinical judgement in assessing the effectiveness of ART. The time required (8–24 weeks) for viral load to reach < 20 copies/mL (viral suppression) after initiation or a change in ART will vary, based on interpatient variability and/or viral characteristics.

Providers should seek expert consultation for patients with viral loads > 200 copies/ml for more than 24 weeks. It is important to determine the reasons for a patient's virologic failure, because the approaches to therapy will differ.

The potential causes of a patient's virologic failure should be explored in depth:

- **Adherence:** Assess the patient's adherence to the regimen and address the underlying causes of nonadherence. Simplify the regimen if possible. Consider comorbidities that may affect adherence (e.g., active substance abuse, mental health disorders, neurocognitive impairment).

  NOTE: *If no drug resistance is identified, a "failing regimen" is almost always associated with suboptimal adherence.*

- **Medication intolerance:** Assess the patient's tolerance of the current regimen and consider the following management strategies:
  - Treating the symptoms (e.g., antiemetic, antidiarrheal).
  - Changing one ARV drug to another within the same drug class.
  - Changing from one drug class to another.
- **Pharmacokinetic issues:** Assess/review the following underlying causes:
  - Food/fasting requirements not followed for each medication.
  - Gastrointestinal symptoms (vomiting/diarrhea) causing short-term malabsorption.
  - Concomitant medications/dietary supplements resulting in drug interaction; make appropriate substitutions.
- **Suspected drug resistance:**

  ➔ *See discussion of Resistance Testing*
  - Obtain resistance testing while the patient is taking the failing regimen, or within 4 weeks after regimen is discontinued if the plasma HIV RNA level is > 500 cps/mL.

(this section continues on the next page)

- If more than 4 weeks have elapsed since the ARV drugs were discontinued, resistance testing may still provide useful information to guide therapy; however, it is important to recognize that previously selected resistance mutations can be missed due to lack of drug-selective pressure.
- In persons failing INSTI-based regimens or with a past history of taking INSTIs, assure genotypic testing panel includes INSTIs.
- With treatment-experienced patients, all prior and current drug-resistance test results, if available, should be considered when constructing a new regimen for a patient.

Samples of two clinical scenarios involving treatment-experienced patients

1. A treatment-experienced patient is started on new ART, based on genotype results, and within 8 weeks achieves an undetectable viral load. Eight weeks later, the patient is found to have a viral load of 2500 copies/mL; adherence to ART is > 90%.

It is likely that this patient was harboring an undetected resistant viral strain prior to the treatment change, and ART should not be continued for the above-mentioned 24 weeks. The virus will not be suppressed with the current ART. Resistance testing should be ordered, and ART adjusted again based on genotype results.

2. Another treatment-experienced patient is started on new ART, based on genotype results, and experiences a one-log drop in viral load within the first 8 weeks. Eight weeks later, the patient experiences another one-log drop, but has not reached undetectable levels.

It is reasonable to continue current ART for another 8 weeks (total of 24 weeks) in an attempt to achieve viral suppression.

➢ Management of Virologic Failure

Below is a brief summary of DHHS guidance on managing virologic failure:

- When virologic failure is confirmed, generally the regimen should be changed as soon as possible to avoid progressive accumulation of resistance mutations.
- A new ARV regimen should contain at least two, and preferably three, fully active drugs based on drug treatment history, resistance testing, or new mechanistic class.
- Adding a single, fully active ARV drug to a failing regimen is **not** generally recommended because of the risk of rapid development of resistance.
- Factors associated with better virologic responses to subsequent regimens include:
  - Lower HIV RNA level and/or higher CD4 count at the time of therapy change.
  - Using a new (i.e., not yet taken) class of ARV drugs.
  - Using ritonavir or cobicistat-boosted PIs in PI-experienced patients.
- Plasma viral load should be measured within 2 to 4 weeks, but no later than 8 weeks, of initiation of a new ARV regimen. Repeat viral load measurement should be performed at 4- to 8-week intervals until the level falls below the assay's limit of detection.

(this section continues on the next page)

- Discontinuing or briefly interrupting therapy is **not** generally recommended and may lead to a rapid increase in HIV RNA, decrease in CD4 count, and risk of clinical progression**.**
- When switching an ARV regimen in a patient with chronic HBV/HIV coinfection, the new regimen must continue to provide effective hepatitis antiviral therapy. Discontinuation of these drugs may cause serious hepatocellular damage resulting from reactivation of HBV.

  ➔ *See: https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/15/virologic-failure-and-suboptimal-immunologic-response for complete DHHS discussion of virologic failure, including clinical scenarios.*

➢ Changing or Discontinuing ART

NOTE: *Consult with a physician who has HIV treatment expertise and/or a BOP HIV Clinical Pharmacist before initiating an alternative regimen or discontinuing treatment.*

The following scenarios may be indications to change or discontinue ART:

- Persistent HIV RNA levels > 200 copies/mL should be considered virologic failure (*See Management of Virologic Failure below*), and ART should be modified. Viremia "blips" (e.g., viral suppression followed by a detectable HIV RNA level, and then a subsequent return to undetectable levels) usually are **not** associated with subsequent virologic failure.
- Patients on older regimens with agents that are no longer recommended, due to higher risk of chronic toxicity or increased pill burden, may be considered for a switch to recommended and alternative regimens.
- Patients on ARV regimens with high pill burden may be candidates for **regimen simplification**.
- Patients with side effects limiting their ability to tolerate their current ARV regimen may be considered for a change in ART.
- Changes in ARV regimens may be required due to interactions with medically necessary medications.
- **Discontinuing ART** may result in viral rebound, immune decompensation, and clinical progression**.** An unplanned interruption of ART may become necessary in cases of severe drug toxicity, intervening illness, surgery that precludes oral therapy, or unavailable antiviral medication.

➢ Regimen Simplification

Regimen Simplification or Optimization can be defined broadly as a change in established effective therapy to reduce pill burden and dosing frequency, to enhance tolerability, or to decrease specific food and fluid requirements. Systematic reviews in the non-HIV literature have shown that adherence improves when the number of daily doses is reduced.

➔ *Review the DHHS Guidelines regarding regimen optimization, available at:*
https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/16/optimizing-antiretroviral-therapy-in-the-setting-of-virologic-suppression

NOTE: *ART simplification should normally be done in consultation with a physician who has HIV-treatment expertise and/or with a BOP HIV Clinical Consultant Pharmacist.*

10. ADVERSE DRUG REACTIONS

Generally, the overall benefits of ART greatly outweigh its risks. ARV medications available today have significantly fewer side effects than those used previously and are typically well-tolerated. Clinicians must carefully consider the toxicity potential of an ARV regimen, as well as the individual patient's underlying conditions, concomitant medication, and prior history of drug intolerances. To achieve sustained viral suppression over a lifetime, both long-term and short-term ART toxicities must be anticipated and overcome.

ART is now recommended for all patients with HIV regardless of CD4 cell count. Because therapy must be continued indefinitely, to achieve sustained viral suppression over a lifetime, both long-term and short-term ART toxicities must be anticipated and overcome. The focus of patient management has evolved from identifying and managing early ARV-related toxicities to individualizing therapy to avoid long-term adverse effects, including diabetes, accelerated vascular disease, kidney dysfunction, and bone loss.

Before prescribing or changing ART, review the DHHS guidelines and consider the following:

- **Adverse effects affecting adherence:** Adverse effects have been reported with all ARV drugs and are common reasons for medication nonadherence, switching or discontinuing therapy.
  - *See Table 3, Adverse Effects Associated with Commonly Used ARV Classes (below).*
  - *See also Appendix 7 for disadvantages of ARV components used in initial ART.*
- **Newer ARV Regimens:** Rates of treatment-limiting adverse events in ART-naïve patients enrolled in randomized trials appear to be declining with the newer ARV regimens, and are generally now less than 10%.

TABLE 3. ADVERSE EFFECTS ASSOCIATED WITH COMMONLY USED ARV CLASSES

ARV CLASS	ADVERSE EFFECTS
NRTIs	• Loss of bone mineral density/renal effects (TDF) • Smaller declines in BMD and less impact on renal biomarkers (TAF) • Cardiovascular disease (ABC) • Dyslipidemia (ABC, TAF) • Hypersensitivity (ABC: contraindicated if HLA-B 5701 positive) • Hepatic effect (reported with most NRTIs) HBV coinfected may experience severe hepatic flares when TAF, TDF, FTC or 3TC is withdrawn • Hyperpigmentation (FTC)
NNRTIs	• Dyslipidemia (EFV) • QTc prolongation (EFV, RPV) • Hepatotoxicity/hypersensitivity (NVP, EFV) • Nervous system/psychiatric effect (EFV > RPV, DOR> ETR) • Rash (all NNRTIs) • Stevens-Johnson Syndrome (NVP > EFV > ETR > RPV)
(TABLE 3, page 1 of 2)	

ARV CLASS	ADVERSE EFFECTS
PIs	• Associated with MI/stroke in some cohorts (SQV/r, ATV/r, LPV/r) • Increased CV risk (DRV) • Cholelithiasis (ATV – median onset is 42 months) • Dyslipidemia (all ritonavir or COBI boosted PIs) • Gastrointestinal effects (LPV/r > DRV/r & ATV/r) • Hepatitis and hepatic decompensation have been reported with all PIs; jaundice due to indirect hyperbilirubinemia with ATV • Loss of bone mineral density after initiation of therapy • Rash/Stevens-Johnson • Renal effects (ATV and LPV/r: increased CKD risk)
INSTIs	• Dyslipidemia (EVG/c/TDF/FTC: increased TG, LDL, HDL) • Gastrointestinal effects (EVG/c/TDF/FTC: nausea and diarrhea) • Myopathy/elevated creatine phosphokinase (RAL, DTG) • Hypersensitivity reactions (RAL) • Insomnia, depression and suicidality (infrequently reported with INSTIs) • Lipohypertrophy (RAL) • Rash All INSTIs
ABBREVIATIONS: **3TC** = lamivudine; **ABC** = abacavir; **ATV** = atazanavir; **c** = cobicistat; **DRV** = darunavir; **EFV** = efavirenz **ETR** = etravirine; **EVG/c/TDF/FTC** = elvitegravir/cobicistat/tenofovir/emtricitabine; **FTC** = emtricitabine; **INSTI** = integrase strand transfer inhibitor; **LPV** = lopinavir; **NNRTI** = non-nucleoside reverse transcriptase inhibitor; **NRTI** = nucleoside reverse transcriptase inhibitor; **NVP** = nevirapine; **PI** = protease inhibitor; **RAL** = raltegravir; **RPV** = rilpivirine; **r** = ritonavir; **SQV** = saquinavir; **TAF =** tenofovir alafenamide; **TDF =** tenofovir disoproxil fumarate **ADAPTED FROM:** *https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/0*	
(TABLE 3, page 2 of 2)	

11. ARV USE IN PATIENTS WITH COINFECTION

➢ HBV/HIV Coinfection

The progression of chronic HBV to cirrhosis, end-stage liver disease, and/or hepatocellular carcinoma is more rapid in HIV-infected persons than in persons with chronic HBV alone.

Conversely, chronic HBV does not substantially alter the progression of HIV infection and does not influence HIV suppression or CD4 cell responses following ART initiation.

➔ *In the DHHS Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents, review the section on Hepatitis B Virus/HIV Coinfection for additional information: https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/25/hbv-hiv*

DHHS guidance on HBV/HIV coinfection is summarized below:

- **Prior to initiation of ART**, patients who test positive for hepatitis B surface antigen (HBsAg) and/or hepatitis B core antibody (HBcAb) should be tested for HBV DNA using a quantitative assay to determine the level of HBV replication. Follow up testing should be completed as outlined in the *BOP Clinical Guidance on Hepatitis B*.

(this section continues on the next page)

- **All patients with chronic HBV** should be assessed for immunity to HAV infection (anti-HAV antibody total) and vaccinated if nonimmune.
- **To avoid viral resistance**, both HIV and HBV must be treated. 3TC, TAF, and TDF each have activity against both HIV and HBV**.**
  - **Preferred regimen:** ART should be initiated with the fixed-dose combination of TDF/FTC or TAF/FTC (BOP-preferred), or the combination of TDF or TAF plus 3TC, as the NRTI backbone of a fully suppressive antiretroviral regimen.
  - **Alternative regimens:** If TDF or TAF cannot be used safely, a different fully suppressive ARV regimen should be used along with entecavir for treating the HBV infection.
  - **Contraindicated:** FTC or 3TC monotherapy should **not** be used due to high HBV failure rate.
- **If ART needs to be modified** due to HIV virologic failure and the patient has adequate HBV suppression**,** continue the medications effective for HBV (typically TDF or TAF + FTC or 3TC) and combine with new ARV medications expected to achieve HIV suppression. Discontinuation of the effective drugs may potentially cause serious hepatocellular damage resulting from reactivation of HBV.

➢ HCV/HIV Coinfection

The management of HCV-infected patients is rapidly evolving as new drug regimens become approved**.** Practitioners are encouraged to refer regularly to the frequently updated HCV website *(www.hcvguidelines.org)* sponsored by the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA). The BOP Central Office Medical staff continues to monitor the website and provide revised guidance as necessary.

All HIV-infected patients should be screened for HCV infection. Data suggest that HIV/HCV-coinfected patients treated with all-oral HCV regimens have sustained virologic response rates comparable to those of HCV-mono-infected patients.

➔ *Consult the latest version of the BOP Clinical Guidance on Chronic Hepatitis C Virus (HCV) Infection at: http://www.bop.gov/resources/health_care_mngmt.jsp.*

- **Benefits of ART:** Even in the potent HIV antiretroviral therapy era, HIV infection remains independently associated with advanced liver fibrosis and cirrhosis in patients with HIV/HCV coinfection; however, ART may slow the progression of liver disease by preserving or restoring immune function and reducing HIV-related immune activation and inflammation.
- **ART in HIV/HCV-coinfected patients:** ART should be initiated in all HIV/HCV-coinfected patients, regardless of CD4 count. For most HIV/HCV-coinfected patients, including those with cirrhosis, the benefits of ART outweigh concerns regarding drug-induced liver injury.
- **Drug-Drug Interactions:** The ARV regimen should be selected with careful consideration of potential drug-drug interactions with the HCV treatment regimen.
- **Fluctuations in ALT and/or AST:** Mild to moderate fluctuations in ALT and/or AST are typical in individuals with chronic HCV infection. In the absence of signs and/or symptoms of liver disease or increases in bilirubin, these fluctuations do not warrant interruption of ART.
- **Considerations in cases with lower CD4 counts:** In patients with lower CD4 counts (e.g., < 200 cells/µL), it may be preferable to initiate ART and delay HCV therapy until the patient is stable on HIV treatment. Although ART should be initiated for all HCV/HIV coinfected patients

regardless of CD4 count, in ART-naive patients with CD4 counts > 500 cells/µL, some clinicians may choose to defer ART until HCV treatment is completed unless active HBV is present.

- **Testing for HBV Before Treating for HCV:** HBV reactivation or exacerbation has been observed in persons with HBV infection during HCV treatment.
  - All patients with HCV/HIV coinfection should be tested for HBV prior to being treated for HCV.
  - Persons with chronic HCV/HIV coinfection should be screened for active and prior HBV infection by testing for the presence of HBsAg and antibodies to hepatitis B surface (HBsAb) and core (HBcAb total).
  - Persons who are not immune to HBV infection (HBsAb-negative) should receive anti-HBV vaccination.
- **Concurrent Treatment of HIV and HCV**
  - **Potential Drug-Drug Interactions:** Initial ART combination regimens for most HIV/HCV coinfected patients are the same as those for individuals without HCV infection. However, when treatment for both HIV and HCV is indicated, consideration of potential drug-drug interactions and overlapping toxicities should guide ARV regimen selection or modification.

    ➔ *See the following links to tables showing drug interactions between the HIV antiretrovirals and the HCV Direct Acting Antivirals (DAAs):*

    https://aidsinfo.nih.gov/guidelines/htmltables/1/7363 (Table 15)

    https://www.hcvguidelines.org/unique-populations/hiv-hcv (Scroll to table end of the page)

  - **Modified ARV Regimen:** After HCV treatment is completed, if ART was modified to accommodate HCV treatment, the modified ARV regimen should be continued for at least 2 weeks before reinitiating the original regimen. Continued use of the modified ARV regimen is necessary because of the prolonged half-life of some HCV drugs, and the potential risk of drug-drug interactions if a prior HIV regimen is resumed too soon after HCV treatment is completed.
- **Persons with HCV/HIV coinfection and chronic HBV infection** should receive a complete ARV regimen that includes two NRTIs with activity against both HIV and HBV (usually TDF or TAF, plus FTC or 3TC) prior to initiating HCV therapy.

  NOTE: *Treatment should be selected in consultation with a Hepatitis Clinical Pharmacist Consultant or Hepatitis/Infectious Disease specialist.*

➢ TB/HIV Coinfection

Management of HIV-related tuberculosis is complex and requires consultation with experts in the management of **both** HIIV disease and tuberculosis.

- HIV infection significantly increases the risk of progression from latent to active TB disease.
- The CD4 count influences both the frequency and severity of active TB disease. Similarly, active TB may be associated with a higher HIV viral load and more rapid progression of HIV disease.

➔ *The treatment of active TB disease in HIV-infected inmates should follow the guidance provided in the most recent BOP Clinical Guidance on Tuberculosis, available at: http://www.bop.gov/resources/health_care_mngmt.jsp.*

NOTE: *Active pulmonary or extra pulmonary TB disease requires prompt initiation of TB treatment.*

12. IMMUNE RECONSTITUTION INFLAMMATORY SYNDROME (IRIS)

IRIS describes a collection of inflammatory disorders associated with paradoxical worsening of the symptoms of preexisting infections (e.g., *M. tuberculosis*, cytomegalovirus, and *M. avium* complex) in HIV-positive individuals following the initiation of ART.

- Preexisting infections in individuals with IRIS may have been previously diagnosed and treated, or they may have been subclinical and later unmasked by the host's regained capacity to mount an inflammatory response, due to ART.
- This inflammatory reaction is usually self-limited, especially if the preexisting infection is treated effectively. However, in rare cases, long-term sequelae and fatal outcomes may occur, particularly when central nervous system (CNS) or pulmonary structures are involved.
- Most patients with IRIS develop symptoms within one week to a few months after the initiation of ART**.** Although it is reasonable to perform studies looking for unmasked subclinical opportunistic infection, **the diagnosis of IRIS is generally one of exclusion.** Investigations to rule out the possibility of drug reaction, patient noncompliance, persistently active infection, and/or drug resistance are usually warranted before concluding that IRIS is present.

NOTE: *If IRIS is suspected, consultation with an HIV Consultant or infectious disease specialist is recommended.*

→ *Refer to DHHS guidelines for the Prevention and Treatment of Opportunistic Infections for specific monitoring and management procedures for IRIS, available at: https://aidsinfo.nih.gov/guidelines/html/4/adult-and-adolescent-oi-prevention-and-treatment-guidelines/0*

13. DENTAL MANAGEMENT

→ *See **TABLE 4** below for a list of dental management considerations in treating HIV-infected patients, based on CD4 counts.*

The provision of dental care to patients with HIV disease should be based on the overall health status of the patient, not solely on HIV status (CD4 counts). A thorough review of a patient's health history should be conducted. Knowing the progression of HIV is important, as there is a broad spectrum of associated diseases and oral manifestations.

It is essential that dental staff work collaboratively with medical providers in fostering a team approach to patient care. Patients may not know their HIV status, and dental providers may be the first health care provider to encounter symptomatic disease.

- **Thorough oral health examination**, including soft tissue palpation of the head and neck, can help in identifying and managing the effects of this disease. Often, signs of declining immune status can first be identified in the oral cavity or during the head and neck exam.
- **Prompt identification and referral to medical providers** facilitates the team management of these patients. Likewise, medical staff should refer HIV patients to the dental clinic for co-management when oral conditions have been identified at the time of their medical encounters. The presence of rampant caries, aggressive periodontal disease, and soft tissue lesions/conditions require attentive treatment management or referral. Frequent periodontal evaluations—every 3 to 6 months—may be warranted for some patients.
- Emphasis on self-care and prevention is critical in this patient population.
- Any prescriptions must be based on careful consideration of possible adverse drug effects.

➢ Pretreatment Considerations for HIV-Infected Patients

When the possibility of significant immunosuppression, neutropenia, or thrombocytopenia has been ruled out, HIV-infected patients usually do not require special consideration when providing dental treatment.

Special attention to medications is particularly important when prescribing antibiotics, as patients may already be on aggressive regimens that may increase the possibility of **drug interactions**. Some medications may cause **xerostomia** resulting in extensive caries. Moreover, it should be noted that the presence of oral lesions in patients who otherwise appear to have responded well to ART might suggest **treatment failure**. Referral to the patient's primary care provider is indicated.

TABLE 4. DENTAL MANAGEMENT

DISEASE PROGRESSION: CD4 CELLS/µL	MANAGEMENT CONSIDERATIONS
400–600: Initial immune suppression **200–400: Emergence of opportunistic infections**	• Review health history. • Check recent labs (CBC with differential current within 6 months). • Emphasize preventive dentistry. • Use chlorhexidine rinses before dental procedures to reduce microbial load. • Consult with primary care provider if opportunistic infections are present. • Treat oral candidiasis and ulcerative lesions. • Consider biopsy for non-responsive oral lesions. • Regular periodontal appointments are recommended for patients with HIV-associated periodontal disease. • Use HIV Dental Encounter code (7113) for assessment and treatment when co-managing patients with medical staff.
≤ 200: Severe immune suppression	• All of the above. • Primary care provider should be contacted for pretreatment medical consultation. • Review health history and update labs: ► Determine if patient is neutropenic (absolute neutrophil counts < 500): Prophylactic antimicrobials for severe neutropenic patients. ► Determine if patient has Idiopathic Thrombocytopenia Purpura (ITP): Obtain pre-surgical platelet counts for invasive patient procedures, which include scaling and curettage. • Avoid aspirin and NSAIDs as analgesics.

14. WASTING SYNDROME

The CDC defines the HIV wasting syndrome as progressive, involuntary weight loss (10% reduction in baseline body weight), plus chronic diarrhea, chronic weakness, or documented fever in the absence of an explanatory concurrent illness or condition.

- Smaller reductions in weight (5-10%) without associated symptoms, however, may be clinically significant in persons with HIV infection, particularly when complicated by AIDS.
- Other potential causes of weight loss such as active TB, malignancies, drug side effects, depression, and OIs associated with AIDS should be actively identified and treated.
- Effective ART should be initiated or improved in order to maximize HIV RNA suppression. Oral nutritional supplements ordinarily do not provide any additional benefit to a healthy diet.

15. TRANSITION TO THE COMMUNITY

Continuity of prescribed treatments, particularly ARV medications, is medically critical for inmates who are released directly to the community or to community placement facilities, such as halfway houses.

Preparation for transitioning to the community is vital to ensure continued viral load suppression on release. Release planning should be initiated well in advance of anticipated release, in accordance with the following guidelines:

- **Release planning should be coordinated** with the inmate's case manager and community corrections staff, in accordance with BOP policy.
- **The inmate's primary provider** or other knowledgeable health care provider should meet with the inmate to finalize the treatment plan and ensure that the inmate understands the importance of adherence to prescribed treatments and specific follow-up instructions.
- **Consultation with BOP social workers** should be pursued to assist with release planning efforts. Social workers can connect inmates transitioning into the community with systems that will provide appropriate and needed services, resources, and opportunities to ensure continuity of HIV care.

  NOTE: *If the institution is without a staff social worker, regional social workers are available to assist with this transition. The DHHS HIV Services Locator is available at: https://locator.hiv.gov/*
- **A *Consent for Release of Medical Information*** should be obtained from the inmate, in accordance with BOP policy, so that the inmate's treatment plan can be discussed with the community health care provider.
- **An adequate supply of medications** should be provided to the inmate prior to release or during community placement, in accordance with BOP policy.

16. Pre-Exposure Prophylaxis (PrEP) for people at Risk for HIV

Approximately 36,000 people in the United States are infected with HIV each year and the decline in new infection rates has stalled. In 2019, the White House announced the initiative "Ending the HIV Epidemic: A Plan for America" to reduce new HIV infections 75% by 2025 and 90% by 2030.

A key strategy to end the HIV epidemic is the use of PrEP, a prevention method in which people who are not infected with HIV, but who may be at risk of exposure, take medicine daily to reduce their risk of acquiring the virus.

- When **taken daily**, studies show that PrEP can reduce the risk of acquiring HIV by up to 99%.
- The **risk of HIV acquisition** may be elevated upon re-entry into the community when re-exposure to high-risk interpersonal or behavioral risk factors may increase.
- **Barrier methods** (i.e., condoms) are both an adjunctive and an alternative method to PrEP for reducing HIV transmission from high-risk sexual practices. As an adjunctive method, condoms are recommended for those taking PrEP to reduce the risk of infection from other STIs and from HCV. Condoms may also be an alternative for reducing risk of HIV transmission in persons who prefer not to take PrEP medications or who are determined not to be appropriate candidates. As with PrEP, condom effectiveness is closely related to adherence.
- **Treatment options to reduce risk:** As they prepare to release to the community, it is important for inmates to be made aware of their treatment options for reducing their risk of acquiring HIV. Inmates may be educated about the availability and indications for PrEP through multiple means, including:
  - Health services staff-initiated discussions and/or risk factor screening
  - Flyers or handouts posted in high-traffic areas or on TruLincs
  - Reentry preparation classes or videos

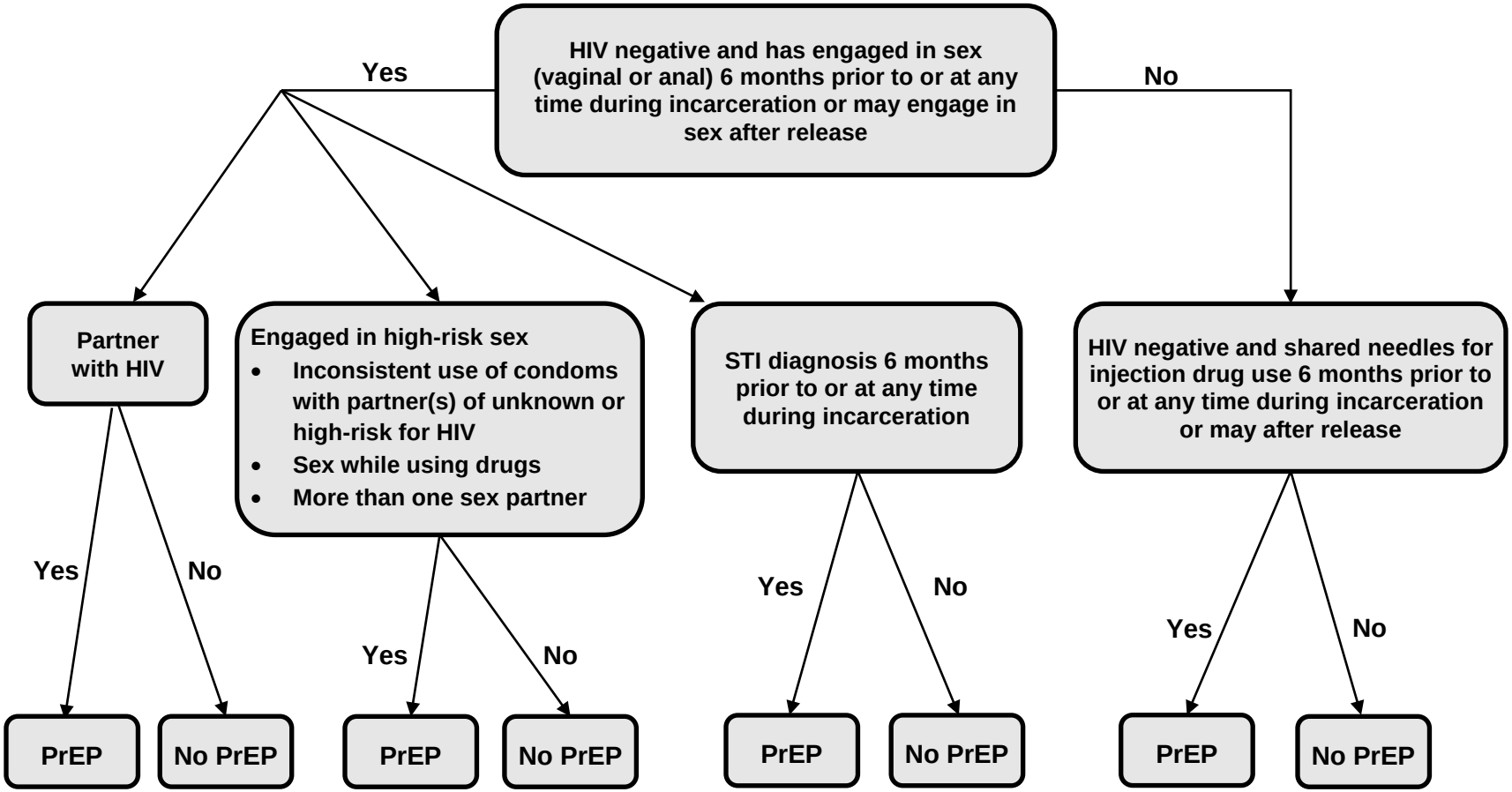
➢ Determining candidates for PrEP:

The primary indication for PrEP is high-risk for acquiring HIV infection. Determination of appropriate candidates should be made on a case-by-case basis and may include self-referral. In making this decision, undertake risk assessments for these factors:

- acquiring HIV infection
- adverse effects from PrEP medications
- medication non-adherence

- **Sexual activity and drug use history/risk assessment:** A sexual and drug use history is essential for assessing risk of acquiring HIV infection. Use *Diagram 1. Indications for PrEP* to assist in determining individuals who may be at high risk for contracting HIV and should be considered for PrEP.
- **Non-Adherence Risk Assessment:** Evaluate patients for non-adherence to other prescribed medications, uncontrolled mental health conditions, perceptions related to stigma of taking PrEP, etc. that may affect ability and willingness to adhere to a once-daily medication regimen. Adherence is essential to achieving maximal effectiveness of PrEP and reducing risk of viral resistance to PrEP medication.
- **Osteoporosis:** Obtain a history of or risk factors for osteoporosis. TDF may cause bone loss especially during the first 6 months of treatment. Consider using TAF/FTC in patients with or at risk for osteoporosis.

DIAGRAM 1. INDICATIONS FOR PREP



NOTE: *A formal or confirmed high risk behavior* ***is not*** *a requirement to provide PrEP to any releasing inmate who requests it. Although a detailed sexual activity and drug use history is an important part of the assessment for PrEP and should be attempted, barriers may exist to sharing this information with the health care provider. Following an individualized assessment, pre-release PrEP may be prescribed to any self-referring inmate provided there are no contraindications to treatment.*

Inmates with risk factors for drug use or a history of substance use disorders should be considered for a referral for interventions to reduce this risk.

➢ Lab Testing prior to initiation of PrEP

Table 5 lists the lab tests recommended prior to starting treatment with PrEP and provides additional information depending on results of these tests.

TABLE 5. LAB TESTS REQUIRED PRIOR TO INITIATION OF PREP

REQUIRED LABORATORY TEST	TIME PRIOR TO INITIATION[1]	ADDITIONAL COMMENTS
HIV-1/2 blood test (4th generation)	Within 7 days	Test done to ensure a negative HIV status prior to initiation of PrEP. If test results are expected to take longer than 7 days, a rapid POC HIV blood test may be performed at the same time as the HIV-1/2 blood test is collected. If the POC test is negative, PrEP may be started pending results of the HIV-1/2 blood test. A test for HIV RNA is recommended in addition to an HIV Ab/Ag test in the following scenarios: 1) Symptoms or signs suggestive of acute HIV infection; or 2) Indeterminate HIV Ab test result; or 3) High risk exposure in the preceding four weeks. Persons with HIV infection should be treated with an ARV regimen not a PrEP regimen.
Serum creatinine and eGFR	Within 3 months	• TDF/FTC is not recommended in eGFR < 60 ml/min. • TAF/FTC is not recommended in eGFR < 30 ml/min.
STI testing for gonorrhea, syphilis, and chlamydia	Within 3 months	A nucleic acid amplification test is recommended for gonorrhea and chlamydia. Pharyngeal, rectal, and urine specimens are recommended for MSM. Vaginal specimens are recommended for women, while anal specimens are also recommended if they have engaged in receptive anal sex. A nontreponemal test (VDRL or RPR) is commonly used to screen for syphilis, followed by a treponemal test (FTA-ABS) if positive. If test positive, treat accordingly. Still eligible for PrEP.

Table 5, page 1 of 2

Required Laboratory Test	Time Prior to Initiation[1]	Additional Comments
Hepatitis B serology (HBsAg, HBsAb, HBcAb)	Within 3 months	If test positive, treat accordingly. Still eligible for PrEP. Tenofovir is often used to treat HBV. Discontinuation of tenofovir in patients with HBV can result in a hepatitis flare and discontinuation of PrEP should be done so in consultation with a clinician experienced in the treatment of hepatitis.
Hepatitis C serology (HCV Ab, a.k.a. anti-HCV)	Within 3 months	HCV Ab may remain persistently positive in persons with a history of resolved HCV infection. An HCV RNA test is needed to assess for recurrent infection. Some HCV medications may increase the risk for TDF toxicity.
Pregnancy test	Within 3 months	The safety of PrEP during pregnancy has not been confirmed and a decision to treat during pregnancy will need to balance the uncertain safety risks with the risk of becoming infected with HIV.

[1] With the exception of HIV testing, current guidance does not specify a time frame for obtaining these tests prior to initiating PrEP. The suggested time frame of **3 months** is adapted from lab monitoring recommended after the start of treatment and provides for sufficient time to start a patient on PrEP prior to release. Testing for STIs, HBV, HCV, and pregnancy may need to be repeated closer to the time of initiating PrEP if there has been high-risk activity or exposure during the interval from the most recent result.

Table 5, page 2 of 2

➢ Medications for PrEP

Currently, there are **two FDA-approved medications** to prevent HIV infection. Providers are encouraged to consult a medical reference or their local pharmacist regarding drug interactions, adverse events, and contraindications to treatment when determining which medication to use.

- **Tenofovir disoproxil fumarate-emtricitabine (TDF/FTC or Truvada®):** One tablet daily.
- **Tenofovir alafenamide-emtricitabine (TAF/FTC or Descovy®):** One tablet daily.
  - FDA approval excludes people at risk through receptive vaginal sex. TAF/FTC has not yet been studied for HIV prevention in these patients.
  - At this time, **Descovy** is **not** approved for pregnant patients.

➢ Initiation of PrEP

Any BOP-authorized provider can prescribe PrEP. Specialization in infectious disease or HIV medicine is **not** required. If providers have questions about PrEP, they are encouraged to consult with, the institution Clinical Director, a BOP HIV Clinical Pharmacist or Regional Medical Director. All BOP providers are encouraged to discuss PrEP with any high-risk patient who is releasing soon**.**

- **Timing:** The time it takes to achieve maximal tissue drug levels and effectiveness has not been conclusively determined. Preliminary data suggest maximal effectiveness for receptive anal intercourse may be achieved in 7 days, but may require up to 21 days for vaginal intercourse. **The BOP suggests initiating treatment approximately 30 days before an inmate's release** to allow time for effective tissue levels to develop and for follow-up to address any questions or tolerability issues that develop. PrEP may be initiated less than 30 days prior to the patient's

release; however, the patient should be counseled regarding the time period required for maximum protection.

- **Patient education:** PrEP initiation must include patient education and a prevention plan, Patient including the importance of adherence, the possibility (albeit low) of acquiring HIV infection despite taking PrEP, condom use to prevent other sexually transmitted infections (STIs) and to reduce the occurrence of pregnancy in women of child bearing potential for whom that is a concern, and other risk reduction methods such as needle exchange programs for IV drug users.

➢ Monitoring, Follow-Up, and Continuity of Care for PrEP Patients

Monitoring: Inmates initiating PrEP prior to release should be counseled about the need to obtain a follow-up clinical encounter in the community every three months. Such encounters include an assessment of medication adherence and side effects, ongoing high risk sexual or drug use behaviors, and symptoms of acute HIV infection, as well as routine testing for HIV infection (4th gen. ab/ag test), pregnancy (in women with childbearing potential). A serum creatinine and eGFR is obtained after the first 3 months of treatment, then every 3 months for patients with risk factors for renal disease and every 6 months if there are no risk factors for renal disease. Periodic screening for STIs and HCV is recommended for people engaging in high-risk behaviors.

Connection to Community-Based Services: When PrEP is initiated, **ensuring timely connection to community care upon release is vital.** Upon release, every patient on PrEP should be counseled on the requirement for regular medical follow-up and provided information on how to connect with community resources. Prescribers are also encouraged to contact their local or regional social work for assistance in setting up services as needed.

NOTE: *To reduce the risk of lapse in coverage pending connection to community care, institutions should consider providing patients with a 60- to 90-day supply of PrEP medication upon release.*

➔ *See Appendix 8: PrEP Fact Sheet*, an information handout for inmates.

➢ Provider and Patient Resources

READY, SET, PrEP is a DHHS program created to distribute Truvada® and Descovy® free-of-charge to anyone without prescription drug coverage, regardless of income. Providers and patients may access *https://www.getyourprep.com/* to apply for this program.

DHHS HIV SERVICES LOCATOR: *https://locator.hiv.gov/*

CO-PAY ASSISTANCE: Manufacturers of PrEP medications offer copay assistance programs that can be accessed through the manufacturer's PrEP website.

PrEP INFORMATION FROM THE CDC: Flyers, brochures, fact sheets, and videos for patients and comprehensive guidelines for providers are available at:
https://www.cdc.gov/hiv/risk/prep/index.html

17. STANDARD PRECAUTIONS FOR INFECTION CONTROL

Standard precautions apply to blood and all other body fluids, secretions, and excretions (except sweat), whether or not they contain visible blood; nonintact skin; and mucous membranes.

The standard precautions relevant to the correctional setting include:

- **Maintain adequate hand hygiene measures** (whether or not gloves are worn) in accordance with CDC guidelines after touching blood, body fluids, secretions, excretions (including wound drainage), and contaminated items.
- **Routinely use personal protective equipment (PPE)** such as gloves, masks, eye protection or face shields, and gowns whenever contact with blood, body fluids, secretions, excretions (including wound drainage) is anticipated.
- **Ensure environmental surfaces** in the health care setting are routinely cleaned and disinfected.
- **Ensure that linens are handled and cleaned** in a manner that prevents staff exposure to contaminated laundry, and that avoids the transfer of microorganisms from person to person, or from place to place.
- **Safely dispose of needles and other sharp instruments and devices** in appropriate leak-proof and puncture-resistant containers.
- **Place in a private room those patients who may contaminate the environment** or cannot be expected to maintain adequate hygiene or a sanitary environment.
- **Disinfect full surfaces of the dental operatory** when invasive procedures are performed, exacerbated by the aerosolization of blood and saliva.

DEFINITIONS

4TH GENERATION TESTING—the protocol used by all BOP laboratories facilities to test for HIV—includes a screening for HIV antibodies and the p24 antigen, an antibody differentiation assay, and an HIV viral load test (HIV RNA test).

ACUTE HIV-1 INFECTION, the phase of HIV-1 disease that occurs two to four weeks after infection, is characterized by an initial burst of viremia. While anti-HIV-1 antibodies may be undetectable during acute HIV infection, HIV-1 RNA or p24 antigens are nonetheless present.

ACUTE RETROVIRAL SYNDROME (ARS), the first stage of HIV infection, should be suspected in patients who had high-risk exposure to HIV-1 within the past 2 to 6 weeks and who have signs, symptoms, or laboratory findings suggestive of HIV infection.

ANTIRETROVIRAL THERAPY (ART) uses a combination of highly effective **ANTIRETROVIRAL (ARV)** drugs to achieve sustained, undetectable HIV RNA levels in infected persons.

CD4+ T-CELL is a T-cell lymphocyte that is essential for human cellular immunity. HIV infection results in a decline of CD4+ T cells (i.e., **CD4 COUNT**), immunosuppression, and susceptibility to opportunistic infections.

CLINICIAN is a physician, dentist, advanced practice provider, or pharmacist with a collaborative practice agreement.

HIV RNA TEST is a laboratory assay used to quantitatively measure the presence of HIV viral particles in serum, expressed as copies per milliliter (**cps/mL**), and referred to as **VIRAL LOAD** or **VIRAL BURDEN**. HIV RNA levels are measured for the staging of HIV infection and therapeutic monitoring.

IMMUNE RECONSTITUTION is the regaining of functional **CD4+ T CELLS** (host cellular immunity) following treatment of a previously immunocompromised condition such as AIDS. Immune reconstitution in the context of HIV infection results from effective **ART.**

IMMUNE RECONSTITUTION INFLAMMATORY SYNDROME (IRIS) describes a collection of inflammatory disorders associated with paradoxical worsening of the symptoms of preexisting infections (e.g., *M. tuberculosis*, cytomegalovirus, and *M. avium* complex) in HIV-positive individuals following the initiation of ART.

OPPORTUNISTIC INFECTIONS (OIS) are those that occur more frequently and are more severe in people with weakened immune systems, including people with HIV.

PRE-EXPOSURE PROPHYLAXIS (PREP) is a prevention method in which people who are **NOT** infected with HIV, but who may be at high risk of non-occupational exposure, take medicine daily to reduce their risk of acquiring the virus.

PRIMARY PROPHYLAXIS refers to drugs or other forms of treatment used to prevent the development of an opportunistic infection in a person who is at risk for the disease, but has no prior history of it. (See also **SECONDARY PROPHYLAXIS** below.)

POST-EXPOSURE PROPHYLAXIS (PEP) for HIV is short-term **ARV** treatment to reduce the likelihood of HIV infection after potential occupational or non-occupational exposure.

RECENT HIV-1 INFECTION is the phase up to 6 months after initial infection, during which anti-HIV-1 antibodies are detectable.

RESISTANCE TESTING for HIV refers to genotypic and phenotypic assays that assess HIV resistance to specific antiretroviral drugs. **GENOTYPIC ASSAYS** measure specific mutations to viral enzymes (reverse

transcriptase/protease/integrase). **PHENOTYPIC ASSAYS** measure the ability of HIV to grow in various concentrations of ARV drugs.

SECONDARY PROPHYLAXIS refers to the ongoing use of or addition of a drug(s) or other treatment to prevent a reoccurrence of a prior, successfully controlled disease or infection.

STANDARD PRECAUTIONS apply to blood and all other body fluids, secretions, and excretions (except sweat), whether or not they contain visible blood; nonintact skin; and mucous membranes.

UNDETECTABLE HIV is the measurement of HIV RNA at levels that are below the level of detectability of specific assays.

VIRAL SUPPRESSION is defined by DHHS as the measurement of HIV RNA persistently below the levels of detection, < 20–75 cps/mL depending on the assay used.

VIROLOGIC FAILURE is defined by DHHS as the inability to achieve or maintain suppression of viral replication to an HIV RNA level < 200 cps/mL with ART.

ARV DRUG ABBREVIATIONS

DRUG CLASS	ABBREVIATION	DRUG	ABBREVIATION
INTEGRASE STRAND TRANSFER INHIBITORS	INSTI	Bictegravir	BIC
		Dolutegravir	DTG
		Elvitegravir	EVG
		Raltegravir	RAL
NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS	NRTI	Abacavir	ABC
		Emtricitabine	FTC
		Lamivudine	3TC
		Tenofovir (alafenamide)	TAF
		Tenofovir (disoproxil fumarate)	TDF
PROTEASE INHIBITORS	PI	Atazanavir	ATV
		Darunavir	DRV
		Lopinavir	LPV
		Cobicistat	COBI (/c)
		Ritonavir	RTV (/r)
NON-NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS	NNRTI	Doravirine	DOR
		Efavirenz	EFV
		Rilpivirine	RPV

Appendix 1. Resources and References Regarding Medical Care of HIV-Infected Persons

NOTE: Many of the following resources, including recent updates, can also be accessed at the AIDS*info* website's list of Federally approved HIV/AIDS medical practice guidelines at: *https://clinicalinfo.hiv.gov/en/guidelines*

TOPIC	NAME	LINKS	SOURCE
Antiretroviral Therapy (ART)	Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents	*https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/whats-new-guidelines*	DHHS
ART Optimization	Management of the Treatment-Experienced Patient: Optimizing ART in the Setting of Virologic Suppression	*https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/16/optimizing-antiretroviral-therapy-in-the-setting-of-virologic-suppression*	DHHS
ASCVD and HIV	Guidelines for the Management of Dyslipidaemias: Lipid Modification to Reduce Cardiovascular Risk	*https://academic.oup.com/eurheartj/article/41/1/111/5556353*	ESC/ EAS
	Characteristics, Prevention, and Management of Cardiovascular Disease in People Living with HIV	*https://www.ahajournals.org/doi/10.1161/CIR.0000000000000695*	AHA
Cervical Cancer Screening Results	Abnormal Cervical Cancer Screening Test Results	*https://www.acog.org/Patients/FAQs/Abnormal-Cervical-Cancer-Screening-Test-Results*	ACOG
Chronic Kidney Disease in HIV-Infected Patients	Antiretroviral Dosing Recommendations in Patients with Renal or Hepatic Insufficiency	*https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/antiretroviral-dosing-recommendations-patients-renal-or-hepatic?view=full*	DHHS
	Clinical Practice Guideline for the Management of Chronic Kidney Disease in Patients Infected with HIV	*https://www.idsociety.org/practice-guideline/chronic-kidney-disease-in-hiv/*	IDSA
Dental Care	Dental Management of the HIV-Infected Patient	*http://www.hivdent.org/_dentaltreatment_/DT_treatment1.htm*	JADA
	Oral Health Topics (HIV)	*https://www.ada.org/en/member-center/oral-health-topics/hiv*	ADA
	Principles of Oral Health Management for the HIV/AIDS Patient.	*https://aidsetc.org/sites/default/files/resources_files/Princ_Oral_Health_HIV.pdf*	DAAC
	Little JW, Falace DA, Miller CS, Rhodus NL. Dental Management of the Medically Compromised Patient, 8th ed. St. Louis, MO: Elsevier, Inc; 2013.	*https://www.academia.edu/37337303/Dental_Management_of_Medically_Compromised_Patient.pdf*	Book
Drug-Drug Interactions	Drug-Drug Interactions	*https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/367/overview*	DHHS
	Interaction Checker	*http://www.hiv-druginteractions.org/*	LIV
General HIV Management	Guide for HIV/AIDS Clinical Care	*https://hab.hrsa.gov/sites/default/files/hab/clinical-quality-management/2014guide.pdf*	HRSA

*(Appendix 1, Guidelines Regarding Medical Care of HIV-Infected Persons, page 1 of 4. **ABBREVIATIONS** defined at the end.)*

TOPIC	NAME	LINK	SOURCE
Genotypic Resistance Tests–Interpretation	HIV Drug Resistance Database	*https://hivdb.stanford.edu/hivdb/by-mutations/*	SU
	HIV Drug Resistance Mutations	*https://www.iasusa.org/resources/hiv-drug-resistance-mutations/*	IAS-USA
HBV/HIV Coinfection	Considerations for ARV Use in Patients with Coinfections: Hepatitis B Virus/ HIV Coinfection	*https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/25/hbv-hiv*	DHHS
HCV/HIV Coinfection	Considerations for ARV Use in Patients with Coinfections: Hepatitis C Virus/ HIV Coinfection	*https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/26/hcv-hiv*	DHHS
	Concomitant Use of ARV Drugs and HCV DAA Drugs (Table 15)	*https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/hepatitis-c-virushiv-coinfection?view=full*	DHHS
	Drug Interactions Between DAAs & ARV Drugs—Recommended Regimens (see table at end of page)	*https://www.hcvguidelines.org/unique-populations/hiv-hcv*	AASLD IDSA
HIV/AIDS Online Education and Resource Center	AIDS Education & Training Center (AETC) and National Resource Coordinating Center (NRCC)	*https://aidsetc.org/nhc* *https://aidsetc.org/consultation*	HRSA
HIV Community Services Locator	HIV Services Locator (including HIV treatment and PrEP.	*https://locator.hiv.gov/*	DHHS
HIV Testing	Revised Recommendations for HIV Testing in Health-Care Settings AND Laboratory Testing for the Diagnosis of HIV Infection: Update Recommendations	*https://www.cdc.gov/hiv/guidelines/testing.html*	CDC
	Case Report: Spectrum of false positivity for the 4th generation HIV diagnostic tests	*https://aidsrestherapy.biomedcentral.com/track/pdf/10.1186/s12981-015-0086-3*	AIDS Res Ther
Human Papillomavirus Disease (HPV)	Guidelines for Preventing Opportunistic Infections among HIV-Infected Persons, Human Papillomavirus Disease	*https://aidsinfo.nih.gov/guidelines/html/4/adult-and-adolescent-opportunistic-infection/343/human-papillomavirus*	DHHS
Immunizations	Recommended Adult Immunization Schedule by Medical Condition and Other Indications, United States	*https://www.cdc.gov/vaccines/schedules/hcp/imz/adult-conditions.html*	CDC ACIP
	ACIP Vaccine Recommendations and Guidelines	*https://www.cdc.gov/vaccines/hcp/acip-recs/index.html*	
	Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents	*https://aidsinfo.nih.gov/guidelines/html/4/adult-and-adolescent-opportunistic-infection/365/figure--immunization*	DHHS

(Appendix 1, Guidelines Regarding Medical Care of HIV-Infected Persons, page 2 of 4. ***ABBREVIATIONS*** defined at the end.)

TOPIC	NAME	LINK	SOURCE
Non-Occupational Exposures	Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the United States	*https://stacks.cdc.gov/view/cdc/38856*	CDC
	Clinician Consultation Center PEP Hotline (PEPline). For non-occupational PEP consultation, call 888-448-4911: 9AM–8PM (ET) Monday–Friday 11AM–8PM (ET) weekends/holidays.	*http://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis/*	UCSF
Occupational & Non-Occupational Exposures	Medical Management of Exposures: HIV, HBV, HCV, Human Bites and Sexual Exposures	*https://www.bop.gov/resources/health_care_mngmt.jsp*	BOP
Occupational Exposures	Clinician Consultation Center PEP Hotline (PEPline). For guidance in managing healthcare worker exposures, call 888-448-4911 for a phone consultation 11AM–8PM (ET) seven days a week.	*For occupational PEP questions at other times, see their PEP Quick Guide for Occupational Exposures at:* *http://nccc.ucsf.edu/clinician-consultation/post-exposure-prophylaxis-pep/*	UCSF
Opportunistic Infections (OI)	Guidelines for Preventing Opportunistic Infections among HIV-Infected Persons	*https://aidsinfo.nih.gov/guidelines/html/4/adult-and-adolescent-oi-prevention-and-treatment-guidelines/0*	CDC DHHS IDSA
Oral Health Care	HIVdent: HIV/AIDS Oral Healthcare Resource on the Internet	*http://www.hivdent.org/*	Non-profit coalition
Pregnant Women	Recommendations for the Use of Antiretroviral Drugs in Pregnant HIV-1 Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the United States	*https://clinicalinfo.hiv.gov/en/guidelines/perinatal/whats-new-guidelines*	DHHS
PrEP	PrEP FAQs; includes links to CDC guidelines for prescribing PrEP	*https://www.cdc.gov/hiv/clinicians/prevention/prep.html*	CDC
	PrEP information for consumers	*https://www.cdc.gov/hiv/risk/prep/index.html*	CDC
	What is “Ending the HIV Epidemic: A Plan for America”?	*https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview*	DHHS
	Ready, Set, PrEP: No-cost medication available for qualifying recipients.	*https://www.getyourprep.com/*	DHHS
Risk Assessment	Preventing New HIV Infections	*https://www.cdc.gov/hiv/guidelines/preventing.html*	CDC
Sexually Transmitted Diseases	Sexually Transmitted Diseases Treatment Guidelines	*http://www.cdc.gov/std/treatment/*	CDC
Transgender Individuals	Considerations for Antiretroviral Use in Transgender People with HIV	*https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/538/transgender-people-with-hiv*	DHHS

(Appendix 1, Guidelines Regarding Medical Care of HIV-Infected Persons, page 3 of 4. ***ABBREVIATIONS*** defined at the end.)

TOPIC	NAME	LINK	SOURCE
Virologic Failure	Management of the Treatment-Experienced Patient: Virologic Failure	*https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/virologic-failure?view=full*	DHHS

ABBREVIATIONS FOR SOURCES:

ACIP = Advisory Committee on Immunization Practices; **ACOG** = American College of Obstetricians and Gynecologists; **ADA** = American Dental Association; **AHA** = American Heart Association; **AIDS Res Ther** = AIDS Research and Therapy; **CDC** = Centers for Disease Control & Prevention; **DAAC** = Dental Alliance for AIDS/HIV Care; **DHHS** = U.S. Department of Health and Human Services; **EAS** = European Atherosclerosis Society; **ESC** = European Society of Cardiology; **HRSA** =Health Resources & Services Administration (in DHHS); **IAS-USA** = International Antiviral Society–USA; **JADA** = Journal of the American Dental Association**;** **IDSA** = Infectious Disease Society of America; **IAS-USA** = International AIDS Society-USA; **LIV** = University of Liverpool; **NYS** = New York State Department of Health; **SU** = Stanford University; **UCSF** = University of California, San Francisco; **USPHS** = U.S. Public Health Service

(Appendix 1, Guidelines Regarding Medical Care of HIV-Infected Persons, page 4 of 4)

Appendix 2. Criteria for Testing for HIV Infection

Test all inmates with the following conditions.	
CONDITION	**COMMENTS**
Unexplained signs/symptoms compatible with acute HIV infection	**Signs/symptoms Include, but are not limited to:** Fever, lymphadenopathy, pharyngitis, skin rash, diarrhea, and headache. myalgia/arthralgia, oral ulcers, leukopenia, thrombocytopenia, and transaminase elevation.
Signs/symptoms of HIV-related condition	**Signs/symptoms Include, but are not limited to:** Candida, herpes zoster, oral hairy leukoplakia, severe seborrhea, unexplained lymphadenopathy, and opportunistic infections.
Pregnancy	**HIV testing is recommended for all pregnant women as early as possible during pregnancy.** Current ART and obstetrical interventions markedly reduce the risk of transmitting HIV from infected mothers to their infants.
Recent exposure to HIV	**Follow-up HIV-antibody testing should be performed at the following intervals after the exposure date:** 6 weeks, 12 weeks, and 6 months (and 12 months for those who become infected with HCV after exposure to a source coinfected with HIV and HCV).
Active tuberculosis	HIV infection is a potent risk factor for developing active tuberculosis.
Otherwise clinically indicated	On a case-by-case basis

MANDATORY-TEST all inmates with the following RISK FACTORS:

- Injected illegal drugs and shared equipment
- (For males) had sex with another man
- Had unprotected intercourse with a person with a known or suspected HIV infection
- History of gonorrhea or syphilis
- Had unprotected intercourse with more than one sex partner
- From a high-risk country (sub-Saharan Africa or West Africa)
- Received blood products between 1977 and May 1985
- Hemophilia
- Percutaneous exposure to blood
- Positive tuberculin skin test

Inmates must participate in mandatory HIV testing programs.

Offer VOLUNTARY TESTING as indicated below:

OPT-OUT VOLUNTARY TESTING is offered to all inmates Many persons with HIV infection are asymptomatic and are unaware of their infection; therefore, consistent with CDC guidelines and the issued memorandum from the BOP Medical Director, all inmates should universally be offered HIV testing at the time of incarceration.

VOLUNTARY TESTING is also available to all inmates who request it, regardless of sentencing or duration of stay.

Appendix 3. HIV-Infected Inmates – Initial Assessment

REVIEW OF SYMPTOMS	PHYSICAL EXAMINATION
A complete review of systems should be performed, with special attention given to the following areas: ☐ **GENERAL:** Unexplained weight loss, night sweats, fever, changes in body habitus ☐ **SKIN:** Discoloration, rash, ulcers, or lesions ☐ **LYMPH NODES:** Localized or generalized enlargement of lymph nodes ☐ **EYES:** Vision change or loss ☐ **MOUTH:** Gum disease, ulcers, oral lesions or pain ☐ **CARDIOPULMONARY:** Chest pain, shortness of breath, palpitations, wheezing, dyspnea, orthopnea ☐ **GASTROINTESTIONAL:** Diarrhea, nausea, pain ☐ **ENDOCRINOLOGY:** Symptoms of hyperglycemia, thyroid disease, hypogonadism ☐ **NEUROLOGICAL & PSYCHIATRIC:** Persistent and severe headaches; memory loss, loss of concentration, cognitive difficulties, depression, apathy, anxiety, mania, mood swings; lower extremity paresthesia's, pain, numbness; paralysis or weakness; dizziness; seizures; sleep disorders ☐ **GENITOURINARY**: Dysuria, urethral or vaginal discharge or lesions, hematuria ☐ **ORTHOPEDIC:** Hip pain, joint pain, fractures; diagnosis of, or risk factors for, osteopenia/ osteoporosis	A complete physical examination should be performed, with special attention given to the following areas: ☐ **VITAL SIGNS:** Including height and weight ☐ **GENERAL:** Including body habitus; evidence of obesity, wasting, lipodystrophy; assessment of frailty and ambulatory ability ☐ **SKIN:** Seborrheic dermatitis, ecchymoses, purpura, petechiae, Kaposi sarcoma, herpes simplex or zoster, psoriasis, molluscum contagiosum, onychomycosis, folliculitis, condylomata, cutaneous fungal infections ☐ **LYMPH NODES:** Generalized or localized lymphadenopathy ☐ **EYES:** Retinal exudates or cotton wool spots, hemorrhages, pallor, icterus ☐ **OROPHARYNX:** Oral hairy leukoplakia, candidiasis (thrush, palatal erythema, angular cheilosis), aphthous ulcers, gingivitis, periodontal disease, Kaposi sarcoma, tonsillar or parotid gland enlargement ☐ **CARDIOVASCULAR:** Heart exam, peripheral pulses, presence/absence of edema ☐ **CHEST:** Lung examination ☐ **BREAST:** Nodules, nipple discharge ☐ **ABDOMEN:** Hepatomegaly, splenomegaly, masses, tenderness ☐ **GENITOURINARY:** Ulcers, warts, chancres, rashes, abnormal gynecologic exam, discharge ☐ **ANORECTAL:** Ulcers, warts, fissures, internal or external hemorrhoids, masses, Kaposi sarcoma ☐ **NEUROPSYCHIATRIC:** Depression, mania, anxiety, signs of personality disorder; difficulties in concentration, attention, and memory; signs of dementia; speech problems, gait abnormalities, focal deficits (motor or sensory); lower extremity vibratory sensation (distal sensory neuropathy, abnormal reflexes)

Appendix 4a. HIV-Infected Inmates – Baseline Screening and Diagnostic Evaluations

BASELINE TESTS	COMMENTS
HIV serology	If diagnosis is not previously confirmed and viral load is low or undetectable.
CD4 count and percentage	To assess urgency of ART and need for OI prophylaxis.
Plasma HIV RNA	To assess viral load.
HIV resistance testing	HIV genotype testing is preferred over phenotype testing for ARV-naive patients or patients not on ART.
Complete blood cell count with differential	—
Complete metabolic panel	To assess for evidence of liver damage, hepatitis, or systemic infection (e.g., elevated alkaline phosphatase occurs with some OIs). • High total protein is common with untreated HIV infection due to increased immunoglobulin fraction secondary to B-cell hyperplasia. • Low albumin may indicate nutritional deficiency or nephrotic syndrome.
Fasting lipid profile and blood glucose or hemoglobin A1c	—
Urinalysis	To assess for evidence of proteinuria, hematuria.
CMV screening	Use anti-CMV IgG for patients at low risk of CMV infection.
Gonorrhea, chlamydia screening	NAAT testing (preferred) or culture with sites based on exposure history (e.g., urine, urethral, vaginal, cervical, rectal, oropharyngeal).
Syphilis screening	Use local protocol (either RPR or treponemal-specific antibody tests).
Screening for latent Toxoplasma gondii infection	Use anti-toxoplasma IgG.
Screening for latent Mycobacterium tuberculosis infection	Use tuberculin skin test or IGRA. IGRA is preferred if patient has history of BCG vaccination.
Chest radiography	A chest x-ray (CXR) is recommended for all HIV-infected inmates at intake. A PA view is sufficient for asymptomatic inmates; PA and lateral views are recommended for symptomatic inmates.
Varicella virus screening	Use anti-varicella IgG if patient has no known history of chickenpox or shingles.
Viral hepatitis screening	HBsAg, HBsAb, anti-HBc, HCV antibody, HAV total (or IgG antibody). • If HbsAg(+) or HbcAb (+), order HBV RNA level. • If HCVAb+, order HCV RNA level and HCV genotype.

Appendix 4a, Baseline Screening and Diagnostic Evaluations, page 1 of 2

TESTS THAT MAY BE PERFORMED UNDER CERTAIN CIRCUMSTANCES	
TESTS	**COMMENTS**
Cytology: Pap test	Cervical; anal as indicated on a case-by-case basis. Abnormal results require follow-up with colposcopy and high-resolution anoscopy (procedure to identify an abnormality in the gastrointestinal tract), respectively.
Glucose-6-phosphate dehydrogenase	Screen for deficiency in appropriate racial or ethnic groups (persons of African, Asian, or Mediterranean descent) to avoid use of oxidant drugs.
HLA B*5701	**ONLY** if abacavir is being considered.
Screening for opportunistic infections	Perform depending on CD4 count and if clinically indicated.
Trichomoniasis screening	In all HIV+ women.

ABBREVIATIONS:

anti-HBc = hepatitis B core antibody; **ART** = antiretroviral therapy; **ARV** = antiretroviral; **BCG =** Bacillus Calmette-Guerin; **CMV** = cytomegalovirus; **HAV** = hepatitis A virus; **HbsAb** = hepatitis B surface antibody; **HbsAg** = hepatitis B surface antigen; **HCV** = hepatitis C virus; **HIV** = human immunodeficiency virus; **GFR** = glomerular filtration rate; **IgG** = immunoglobulin G; **IGRA** = interferon-γ release assay; **NAAT** = nucleic acid amplification test; **OI** = opportunistic infection; **PA** = posteroanterior; **RPR** = rapid plasma reagin

Appendix 4a, Baseline Screening and Diagnostic Evaluations, page 2 of 2

Appendix 4b. HIV-Infected Inmates – Laboratory Monitoring Schedule, Prior to and After Initiation of Art

TESTING	Entry into care	If ART initiation is delayed [1]	ART initiation or modification	2–8 wks after ART initiated or modified	Every 3–6 months	Every 6 months	Every 12 months	Treatment failure
HIV serology	X							
Viral load	X	optional	X	X	X	X [2]		X
CD4 count	X	q 3–6 mo.	X		during 1st 2 years of ART		*After 2 yrs of ART:* CD4 = 300–500 (CD4 > 500, optional monitoring) [2]	X
Resistance testing	X	optional	X					X
HLA-B 5701			if considering ABC					
Tropism testing			if considering CCR5 antagonist					if considering CCR5 antagonist
Hepatitis A serology	X							
Hep B serology	X		may repeat if non-immune & no chronic HBV infection				may repeat if non-immune & no chronic HBV infection	
Hep C serology	X		may repeat if negative at baseline				repeat HCV screening for at-risk patients	
Basic chemistry	X	q 6–12 mo.	X	X	X			
ALT, AST, T. bili	X	q 6–12 mo.	X	X	X			
CBC w/ differential	X	q 3–6 mo.	X				X [3]	
Fasting lipid profile	X	if normal, annually	X			if last measurement was *abnormal*	if last measurement was *normal*	
Fasting glucose or hemoglobin A1C	X	if normal, annually	X		if last measurement was *abnormal*		if last measurement was *normal*	
UA	X		X			if on TAF or TDF	X	
Toxoplama IgG	X							
CMV Ab IgG/IgM	X							
Varicella IgG	X							
RPR	X							
Gonorrhea	X							
Chlamydia	X							

Appendix 4b, Laboratory Monitoring Schedule, Prior to and After Initiation of ART, page 1 of 2

TESTING	Entry into care	If ART initiation is delayed [1]	ART initiation or modification	2–8 wks after ART initiated or modified	Every 3–6 months	Every 6 months	Every 12 months	Treatment failure
Trichomoniasis	Women only							
Pregnancy test			in women of child-bearing potential					
Coagulation testing	As needed. Needed prior to invasive dental procedures for high-risk HIV patients.							

1 q = "every"

2 For patients adherent to ART with consistently suppressed viral load and stable immunologic status for more than 2 years, monitoring can be extended as indicated above.

3 If monitoring CD4, test CBC w/diff concurrently with CD4; otherwise test CBC w/diff every 12 months.

Adapted from: Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. Updated July 10, 2019. Available at: *https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/tests-initial-assessment-and-follow?view=full*.

Appendix 4b, Laboratory Monitoring Schedule, Prior to and After Initiation of ART, page 2 of 2

Appendix 5a. Pap Test Instructions

PAP TEST INSTRUCTIONS

The cervix is scraped circumflexually with an Ayer spatula or a curved brush; a sample from the posterior fornix or the vaginal pool may also be included. The endocervical sample is taken with a saline-moistened, cotton-tipped applicator or a straight ectocervical brush, which is rolled on a slide and immediately fixed in ethyl ether plus 95% ethyl alcohol, or in 95% ethyl alcohol alone. The yield is 7-fold higher with the brush specimen.

Important points for obtaining an adequate sample:

- Collect the Pap smear prior to the bimanual exam, to avoid contaminating the sample with lubricant.
- Obtain the Pap smear before testing for sexually transmitted diseases.
- If a large amount of vaginal discharge is present, carefully remove it with a large swab before collecting the Pap smear.
- Obtain the *ectocervical* sample before obtaining the *endocervical* sample.
- Small amounts of blood will not interfere with cytologic sampling; defer Pap if bleeding is heavy.
- Collected material should be applied uniformly to the slide, without clumping, and should be fixed immediately to avoid air-drying.
- If spray fixatives are used, the spray should be held at least 10 inches away from the slide to prevent disruption of cells by the propellant.
- When performing speculum examination, if an ulcerative or exophytic lesion is detected and is suspicious for cancer, a referral for possible biopsy is warranted.

NOTE: New liquid-based collection and thin layer processing methods decrease the frequency of inadequate smears and provide more sensitive and specific results.

Adapted from:

Bartlett JG, Gallant JE. *Medical Management of HIV infection*. 2009-2010 ed. Baltimore: Johns Hopkins University; 2009.

Appendix 5b. Cervical Screening Pap Test Results

Cervical screening (Pap) test results can be normal or can include one of the following abnormal findings:

- **ASC-US (atypical squamous cells of undetermined significance)**
  Means that changes in the cervical cells have been found. The changes are almost always a sign of an HPV infection. ASC-US is the most common abnormal Pap test result.

- **LSIL (low-grade squamous intraepithelial lesion)**
  Means that the cervical cells show changes that are mildly abnormal. LSIL is usually caused by an HPV infection that often goes away on its own.

- **HSIL (high-grade squamous intraepithelial lesion)**
  Suggests more serious changes in the cervix than LSIL. It is more likely than LSIL to be associated with precancer and cancer.

- **ASC-H (atypical squamous cells, cannot exclude HSIL)**
  Means that changes in the cervical cells have been found that raise concern for the presence of HSIL.

- **AGC (atypical glandular cells)**
  Means that changes have been found in the glandular cells that raise concern for the presence of precancer or cancer.

➔ *Appropriate interventions and follow-up for abnormal Pap test results are described in Appendix 5c.*

Appendix 5c. BOP Recommendations for Cervical Cancer Screening in HIV-Infected Women

- *Obtain Pap tests in accordance with the procedure outlined in Appendix 5a.*
- *See Appendix 5b for brief explanations of the abnormal PAP test results referenced below.*

Cervical cancer screening results should be interpreted in accordance with the current CDC/NIH guidelines, as outlined in the table below:

HIV-INFECTED WOMEN AGED < 30 YEARS

*Unless Pap test is abnormal, co-testing for cervical cancer (Pap test plus human papillomavirus [HPV] test) is **not** recommended for HIV-infected women younger than 30 years of age.*

- **HIV-infected women younger than age 21**, known to be sexually active, screen with Pap test within 1 year of onset of sexual activity—regardless of mode of HIV infection.
- **HIV-infected women 21–29 years old:** Baseline Pap testing at initial HIV diagnosis, followed by routine testing if normal.
  - If the initial Pap test is normal, the next Pap test should be in 12 months.
  - If the results of three consecutive Pap tests are normal, follow-up Pap tests should be every 3 years throughout the woman's lifetime.

In the case of abnormal Pap test results:

- **If Pap test shows ASC-US:**
  - If a Pap test at any time reveals atypical squamous cells of undetermined significance (**ASC-US**), and a reflex HPV test is positive, referral to colposcopy is recommended.
  - If HPV testing is not available or not done, then a repeat cytology in 6–12 months is recommended. For any result ≥ **ASC-US** on repeat cytology, referral to colposcopy is recommended.
- **If Pap test shows LSIL or worse:** For low-grade squamous intraepithelial lesion (**LSIL**) or worse—including **ASC-US**, possible high-grade lesion (**ASC-H**), atypical glandular cells (**AGC**), and high grade squamous intraepithelial lesion **(HSIL**)—referral to colposcopy is recommended (regardless of reflex HPV result, if done).

HIV-INFECTED WOMEN AGED ≥ 30 YEARS

Either Pap testing alone or Pap and HPV co-testing is acceptable for cervical cancer screening for women age 30 and older.

Cervical cancer screening in HIV-infected women should continue throughout a woman's lifetime (and NOT, as in the general population, end at 65 years of age).

- **Pap testing at initial diagnosis, followed by routine testing if normal:**
  - If screening with Pap tests alone, the HIV-infected woman should have a baseline Pap test at the time of HIV diagnosis, then every 12 months.
  - If the results of three consecutive Pap tests are normal, follow-up Pap tests should be every 3 years throughout the woman's lifetime.
- **Co-testing with Pap and HPV:**
  - For women with a normal Pap test and negative HPV test at baseline, repeat cervical cancer screening every 3 years, throughout the woman's lifetime.

In the case of abnormal results:

- **Normal Pap and positive HPV test, but not genotype 16 or 16/18:** Repeat co-testing in one year. If either of the co-tests at one year is abnormal (i.e., abnormal cytology or positive HPV), referral to colposcopy is recommended.
- **Normal Pap and positive HPV test, with genotype 16 or 16/18 identified:** Referral to colposcopy is recommended.
- **PAP shows ASC-US and negative HPV test:** Repeat pap test in 6–12 months is recommended. For any result ≥**ASC-US** on repeat cytology, referral to colposcopy recommended
- **PAP shows ASC-US and positive HPV test:** Referral to colposcopy is recommended.
- **Pap test shows LSIL or worse:** If **LSIL**, ASC-H, **AGC**, or **HSIL**, referral to colposcopy is recommended (regardless of HPV result).

Appendix 5c, BOP Recommendations for Cervical Cancer Screening in HIV-Infected Women, page 1 of 2

CERVICAL INTRAEPITHELIAL NEOPLASIA (CIN) – ALL AGES
• **If Pap test shows low-grade CIN:** Patients with Pap smears with low-grade cervical intraepithelial neoplasia (CIN I) require careful follow-up, with repeat Pap smears every 6 months and referral for colposcopy if any repeat Pap smear is abnormal. • **If Pap test shows high-grade CIN:** Patients with high-grade cervical intraepithelial neoplasia (CIN II or III), also termed *carcinoma in situ*, require colposcopy for potential biopsy and follow-up monitoring. Patients with invasive carcinoma require immediate referral to a specialist for evaluation and treatment.
Appendix 5c, BOP Recommendations for Cervical Cancer Screening in HIV-Infected Women, page 2 of 2

Appendix 6. Prophylaxis for HIV-Related Opportunistic Infections (OIs)

➔ *For complete information, see DHHS Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents, available at: https://aidsinfo.nih.gov/guidelines.*

Refer to appropriate drug reference or consult with pharmacist for drug-related toxicities and side effects.

DRUG/DOSAGES	COMMENTS
PNEUMOCYSTIS PNEUMONIA	
FIRST CHOICE	
TMP-SMX (Bactrim, Septra) 1 DS daily ***OR*** 1 SS daily	• Prevents toxoplasmosis and bacterial infections. • Use 1 DS/day if toxo IgG+.
ALTERNATIVES	
Dapsone 100 mg/day ***OR*** 50 mg bid	• Screening for G6-PD deficiency recommended in high-risk patients.
Pentamidine 300 mg q month aerosolized	• Obtain screening chest x-ray for TB. • Administer pentamidine by Respirgard II nebulizer.
Atovaquone 1500 mg daily	• Must be taken with meals for absorption.
TOXOPLASMOSIS	
FIRST CHOICE	
TMP-SMX (Bactrim, Septra) 1 DS daily	• Repeat toxo IgG if titer was negative when CD4 count was < 100 cells/µL. • Monitor for anemia/leukopenia; CBC q 3–4 months.
ALTERNATIVE	
Dapsone 50 mg/day PLUS (pyrimethamine 50 mg + leucovorin 25 mg)/week	• Monitor for anemia/leukopenia; CBC q 3–4 months.
Atovaquone 1500 mg daily	• Must be taken with meals for absorption.
MYCOBACTERIUM AVIUM COMPLEX (MAC)	
FIRST CHOICES	
Azithromycin 1200 mg/week	—
Clarithromycin 500 mg bid	—
ALTERNATIVE	
Rifabutin Adjust dose based on concomitant ART	• Uveitis when given with fluconazole; creates rifampin resistance**; review drug interactions**. • Reduces serum concentrations of the NNRTIs rilpivirine and doravirine; as well as the INSTIs EVG and BIC. Dose adjustments may be required; **review drug interactions.**

* **q** = "every" **QD** = "once daily" **bid** = "twice daily"

DRUG/DOSAGES	COMMENTS
LATENT TUBERCULOSIS INFECTION (LTBI)	
FIRST CHOICES	
Isoniazid (INH) 300 mg QD **OR** 900 mg twice weekly ***plus*** **Pyridoxine** 50mg QD	Isoniazid is administered under direct observation for 9 months. Pyridoxine is prescribed to reduce risk of peripheral neuropathy while on INH
ALTERNATIVE	
Rifapentine is generally **not** recommended due to concerns of multiple ART drug interactions. Only efavirenz or raltegravir-based regimens—in combination with either abacavir/lamivudine **or** tenofovir disoproxil fumarate (TDF)/emtricitabine (NOT tenofovir alafenamide TAF)—can be used with once-weekly isoniazid plus rifapentine.	
* **q** = "every" **QD** = "once daily" **bid** = "twice daily"	

Appendix 6, Prophylaxis for HIV-Related Opportunistic Infections (OIs), page 2 of 2

Appendix 7. Advantages and Disadvantages of ARV Components Recommended as Initial Antiretroviral Therapy

ARV Class	ARV Agent(s)	Advantages	Disadvantages/Concerns
Dual-NRTI	**ABC/3TC**	• Co-formulated as an STR with DTG	• Inferior virologic responses in patients with baseline HIV RNA ≥100,000 cps/mL when given with EFV or ATV/r, as compared with TDF/FTC in ACTG 5202 study. (This difference was NOT seen when ABC/3TC was used in combination with DTG.) • May cause life-threatening hypersensitivity reaction in patients positive for the HLA B*5701 allele. As a result, HLA-B*5701 testing is required before use. • ABC use has been associated with cardiac events in some, but not all, observational studies.
	TAF/FTC	• Co-formulated as an STR with BIC, EFV, EVG/c, or RPV • Active against HBV • Safe in patients with eGFR ≥30 ml/min or on hemodialysis	• Fasting lipid levels, including LDL and HDL cholesterol and triglycerides, increased more in the TAF group than in the TDF group.
	TDF/FTC	• Co-formulated as an STR with EFV, EVG/c, or RPV • Active against HBV • Better virologic responses than with ABC/3TC in patients with baseline viral load ≥100,000 cps/mL, when combined with ATV/r or EFV	• Renal toxicity, including proximal tubulopathy and acute or chronic renal insufficiency. • Decreases BMD more than other NRTI combinations. • Osteomalacia has been reported as a consequence of proximal tubulopathy.
Single NRTI	**3TC**	• Co-formulated as an STR with DTG	• Not recommended for patients with HIV RNA > 500,000 copies/mL, for patients with HBV coinfection, or in patients without resistance testing and/or HBV testing.
INSTI (continues on next page)	**BIC**	• Co-formulated as an STR with TAF/FTC • Once-daily dosing • Higher barrier to resistance than EVG or RAL • No food requirement • BIC is not a CYP3A4 inducer or inhibitor	• Inhibits renal tubular secretion of Cr and can increase serum Cr, without affecting glomerular function.

ARV CLASS	ARV AGENT(S)	ADVANTAGES	DISADVANTAGES/CONCERNS
INSTI (continued from previous page)	**DTG**	• Once-daily dosing • Higher barrier to resistance than EVG or RAL • Co-formulated as an STR with ABC/3TC and 3TC • No food requirement • No CYP3A4 interactions	• Inhibits renal tubular secretion of Cr and can increase serum Cr, without affecting glomerular function. • Insomnia, depression, and suicidal ideation (rare, usually in patients with pre-existing psychiatric conditions). • **PREGNANCY:** DHHS recommendations against using DTG in individuals of child-bearing potential who have plans to conceive or are not taking effective contraception, due to possible neural tube defects.
	EVG/c	• Co-formulated as an STR with TDF/FTC or TAF/FTC • Once-daily dosing • Compared with ATV/r, causes smaller increases in total and LDL cholesterol • Can be used in patients on chronic hemodialysis	• EVG/c/TDF/FTC is only recommended for patients with baseline CrCl ≥70 mL/min; therapy should be discontinued if CrCl decreases to < 50 mL/min. • Cobicistat is a potent CYP3A4 inhibitor, which can result in significant interactions with CYP3A substrates. • Cobicistat inhibits active tubular secretion of Cr and can increase serum Cr, without affecting renal glomerular function. • May have lower genetic barrier to resistance than boosted PI- or DTG-based regimens • Insomnia, depression, and suicidal ideation (rare, usually in patients with pre-existing psychiatric conditions) • Food requirement. • **PREGNANCY:** Emerging data on cobicistat-containing regimens suggest decreased drug levels occur during pregnancy, with an associated risk of loss of virologic suppression. Cobicistat-containing regimens should therefore NOT be initiated in treatment-naïve pregnant women. Consider switching ART if an HIV-infected woman becomes pregnant.
	RAL	• Compared to other INSTIs, has longest post-marketing experience • Once- or twice-daily dosing • No food requirement • No CYP3A4 interactions	• May have lower genetic barrier to resistance than boosted PI- or DTG-based regimens. • Increases in creatine kinase, myopathy, and rhabdomyolysis have been reported. • Rare cases of severe hypersensitivity reactions (including SJS and TEN) have been reported. • Oral absorption of RAL can be significantly impaired by antacids containing Al or Mg; co-administration is NOT recommended. • Insomnia, depression and suicidal ideation (rare, usually in patients with pre-existing psychiatric conditions).

Appendix 7, Advantage/Disadvantages of ARV Components, page 2 of 4
(See ABBREVIATIONS on last page of Appendix.)

ARV CLASS	ARV AGENT(S)	ADVANTAGES	DISADVANTAGES/CONCERNS
NNRTI	DOR	• Available as an STR with TDF/3TC • No food requirement • Fewer drug-drug interactions compared to EFV or RPV • Compared with EFV - Fewer CNS adverse effects - Fewer lipid effects - Fewer rashes	• Transmitted resistance more common than with PIs and INSTIs. • **CONTRAINDICATED** with strong CYP3A inducers. • Renal toxicity, including proximal tubulopathy and acute or chronic renal insufficiency. • Decreases BMD more than other NRTI combinations. • Osteomalacia has been reported as a consequence of proximal tubulopathy.
	EFV	• Available as an STR with TDF/FTC • Long-term clinical experience • EFV-based regimens (except for EFV plus ABC/3TC) have well-documented efficacy in patients with high HIV RNA	• Transmitted resistance more common than with PIs and INSTIs. • Short- and long-term neuropsychiatric (CNS) side effects, including depression and, in some studies, suicidality. • Teratogenic in non-human primates. • QTc interval prolongation. • Dyslipidemia. • Greater risk of resistance at the time of treatment failure than with PIs. • Skin rash. • Should be taken on an **empty stomach** (food increases drug absorption and CNS toxicities).
	RPV	• Available as an STR with TDF/FTC • Smaller pill size than co-formulated DTG/ABC/3TC, EFV/TDF/FTC, and EVG/c/TDF/FTC • Compared with EFV: - Fewer CNS adverse effects - Fewer lipid effects - Fewer rashes	• Not recommended in patients with pre-ART HIV RNA > 100,000 cps/mL or CD4 count < 200 cells/µL because of higher rate of virologic failure in these patients. • Transmitted resistance more common than with PIs and INSTIs. • More NNRTI-, TDF-, and 3TC-associated mutations at virological failure than with regimen containing EFV and two NRTIs. • Meal requirement (> 390 kcal). • Requires acid for adequate absorption; **contraindicated with PPIs**. Use with caution when co-administered with H2 antagonists or antacids. • QTc interval prolongation; Consider alternative when taking medications known to increase the risk of torsades de pointes.
PI	ATV/c or ATV/r	• Higher genetic barrier to resistance than NNRTIs, EVG, and RAL • PI resistance at the time of treatment failure uncommon with pharmacologically-boosted PIs • ATV/c and ATV/r have similar virologic activity and toxicity profiles	• Commonly causes indirect hyperbilirubinemia, which may manifest as scleral icterus or jaundice. • Food requirement. • Absorption depends on food and low gastric pH. • GI adverse effects. • Nephrolithiasis, cholelithiasis, nephrotoxicity. • Cobicistat inhibits active tubular secretion of Cr and can increase serum Cr, without affecting renal glomerular function. • **Pregnancy:** Emerging data on cobicistat-containing suggest decreased drug levels during pregnancy and an associated risk of loss of virologic. Cobicistat-containing regimens should **not** be initiated in treatment-naïve pregnant women. Consider switching ART if an HIV-infected woman becomes pregnant.

Appendix 7, Advantage/Disadvantages of ARV Components, page 3 of 4
(See ABBREVIATIONS on last page of Appendix.)

ARV CLASS	ARV AGENT(S)	ADVANTAGES	DISADVANTAGES/CONCERNS
	DRV/c or DRV/r	• Available as an STR with TAF/FTC • Higher genetic barrier to resistance than NNRTIs, EVG, and RAL • PI resistance at the time of treatment failure uncommon with pharmacokinetically-boosted PIs	• Skin rash. • Food requirement. • GI adverse effects. • Cobicistat inhibits active tubular secretion of Cr and can increase serum Cr, without affecting renal glomerular function. • **Pregnancy:** Emerging data on cobicistat-containing regimens suggest decreased drug levels occur during pregnancy, with an associated risk of loss of virologic suppression. Cobicistat-containing regimens should therefore NOT be initiated in treatment-naïve pregnant women. Consider switching ART if an HIV-infected woman becomes pregnant.

ABBREVIATIONS FOR ARV AGENTS

DUAL NRTI = nucleoside reverse transcriptase inhibitor

- **ABC/3TC** = abacavir/lamivudine
- **TAF/FTC** = tenofovir alafenamide/emtricitabine
- **TDF/FTC** = tenofovir disoproxil fumarate/emtricitabine

INSTI = integrase strand transfer inhibitor

- **BIC** = bictegravir
- **DTG** = dolutegravir
- **EVG/c** = elvitegravir/cobicistat
- **RAL** = raltegravir

NNRTI = non-nucleoside reverse transcriptase inhibitor

- **DOR** = doravirine
- **EFV** = efavirenz
- **RPV** = rilpivirine

PI = protease inhibitor

- **ATV/c** = cobicistat-boosted atazanavir
- **ATV/r** = ritonavir-boosted atazanavir
- **DRV/c** = cobicistat-boosted darunavir
- **DRV/r** = ritonavir-boosted darunavir
- **LPV/r** = ritonavir-boosted lopinavir

OTHER ABBREVIATIONS

ARV = antiretroviral
BMD = bone mineral density
CNS = central nervous system
CrCl = creatinine clearance
HBV = hepatitis B virus
HCV = hepatitis C
STR = single tablet regimen

Appendix 7, Advantage/Disadvantages of ARV Components, page 4 of 4

Appendix 8: PrEP Fact Sheet

WHAT IS PRE-EXPOSURE PROPHYLAXIS (PREP)?

PrEP is an effective medicine that can reduce your chance of getting HIV. Studies have shown that PrEP reduces the risk of getting HIV from sex by about 99% when taken daily. Among people who inject drugs, PrEP reduces the risk of getting HIV by at least 74% when taken **daily** as prescribed.

- *PrEP is much less effective if not taken every day.*
- *PrEP does not protect you against other STIs (sexually transmitted infections).*

IS PREP RIGHT FOR YOU?

If you are HIV-negative and you expect **ANY** of the following to apply to you upon release from prison, talk to your health care provider about PrEP. **These behaviors put you at risk for becoming HIV-positive:**

- You expect to be sexually active (anal or vaginal) with an HIV-positive partner.
- You expect to be sexually active (anal or vaginal) with multiple partners, a partner with multiple partners, or a partner whose HIV status is unknown—AND you won't ALWAYS use a condom.
- You have been diagnosed with an STI in the past 6 months.
- You expect to inject drugs and may share needles, syringes, or other equipment with people who are HIV-positive or whose HIV status is unknown.

HOW LONG DO YOU HAVE TO TAKE PREP BEFORE IT IS EFFECTIVE?

- PrEP is fully active about 21 days after daily use. Until then, you are not fully protected.
- You must continue to take PrEP **DAILY** for it to remain active.

WHAT IS THE PROCESS FOR STARTING AND CONTINUING PREP?

- If you are being released from prison soon and believe you will be at risk for getting HIV, set up an appointment with your health care provider to discuss whether PrEP is an option for you. You are not required to tell your provider about expected high-risk behaviors in order to be prescribed PrEP.
- If you both decide to proceed with PrEP, before ordering the medication, the health care provider will order several tests to screen for the following: HIV, STIs, hepatitis B, and kidney functioning.
- After release, a follow-up appointment with a health care provider is required every 3 months for continued monitoring of your health, to check for HIV, and to refill your PrEP prescription. BOP staff will help to connect you with resources in the community for your continued health care.
- You can also find a provider through the DHHS HIV services locator: *https://locator.hiv.gov/*

HOW DO YOU PAY FOR PREP AFTER YOUR RELEASE?

There are many programs that provide help to pay for PrEP. Most patients can get PrEP free or at very low cost. Most private insurance and state Medicaid plans cover PrEP services.

- **Ready, Set, PrEP** is a program created to distribute PrEP free-of-charge to anyone without prescription drug coverage, regardless of income. Providers and patients may go to *https://www.getyourprep.com/* to apply for the program.
- Companies that manufacture PrEP medications offer copay assistance programs that can be accessed through the manufacturer's PrEP website.
- You can also contact the local health department or HIV/AIDS service organizations for programs that may assist in payment of PrEP services.
- You can learn more about paying for PrEP at *www.PrEPcost.org*.