



# CLINICAL GUIDELINES PROGRAM

NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE | HIV · HCV · SUBSTANCE USE · LGBT HEALTH

## Primary Care for Adults With HIV

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Lead authors	Mary Dyer, MD; Christine Kerr, MD
Writing group	Rona M. Vail, MD, AAHIVS; Sanjiv S. Shah, MD, MPH, AAHIVM, AAHIV; Steven M. Fine, MD, PhD; Joseph P. McGowan, MD, FACP, FIDSA; Samuel T. Merrick, MD; Asa E. Radix, MD, MPH, PhD, FACP, AAHIVS; Anne K. Monroe, MD, MSPH; Jessica Rodrigues, MPH, MD; Christopher J. Hoffmann, MD, MPH; Brianna L. Norton, DO, MPH; Charles J. Gonzalez, MD
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## Purpose of This Guideline

This guideline on primary care for adults with HIV was developed by the New York State Department of Health AIDS Institute (NYSDOH AI) to guide clinicians in New York State who provide primary care for adults (aged  $\geq 18$  years) with HIV. The goals of the guideline include:

- Increasing access to comprehensive primary care in their setting of choice for adults with HIV in New York State.
- Clarifying that primary care for adults is generally the same for adults with and without HIV, while also clarifying medical care needs particular to adults with HIV.
- Providing effective tools for all clinicians delivering comprehensive primary care to adults with HIV, including family practice clinicians, internists, and HIV or infectious diseases specialists.

At the end of 2021, there were an estimated 1.2 million individuals age  $\geq 13$  years with HIV in the United States, and of the 32,100 newly diagnosed infections that same year, 3,000 were among people aged  $\geq 55$  years [CDC 2024]. As of December 2022, there were an estimated 104,124 individuals with HIV in New York State, 75% of whom were aged  $\geq 40$  years and 57% of whom were aged  $\geq 50$  years [NYSDOH 2023]. Advances in antiretroviral therapy (ART) over the past 2 decades have significantly improved lifespan [Gueler, et al. 2017; Samji, et al. 2013; Zwahlen, et al. 2009]: life expectancy for a patient newly diagnosed with HIV now approaches that of an individual without a diagnosis of HIV. ART lowers rates of opportunistic infections and mortality [Lundgren, et al. 2015; El-Sadr, et al. 2006], and the immune system reconstitution observed with the

use of ART is associated with significantly improved health outcomes in patients with HIV [Marin, et al. 2009; Emery, et al. 2008]. Clinicians should start and maintain ART in all patients with HIV.

**Structure and use of this guideline:** With the assumption that clinicians are familiar with performing a comprehensive patient history, examination, and review of systems, the authors focus on aspects of primary care that require additional attention in patients with HIV.

**Note on “experienced” and “expert” HIV care providers:** Throughout this guideline, when reference is made to “experienced HIV care provider” or “expert HIV care provider,” those terms are referring to the following 2017 NYSDOH AI definitions:

- Experienced HIV care provider: Practitioners who have been accorded HIV Experienced Provider status by the American Academy of HIV Medicine or have met the HIV Medicine Association’s definition of an experienced provider are eligible for designation as an HIV Experienced Provider in New York State. Nurse practitioners and licensed midwives who provide clinical care to individuals with HIV in collaboration with a physician may be considered HIV Experienced Providers as long as all other practice agreements are met (8 NYCRR 79-5:1; 10 NYCRR 85.36; 8 NYCRR 139-6900). Physician assistants who provide clinical care to individuals with HIV under the supervision of an HIV Specialist physician may also be considered HIV Experienced Providers (10 NYCRR 94.2)
- Expert HIV care provider: A provider with extensive experience in the management of complex patients with HIV.

## Patient-Centered Care

### RECOMMENDATIONS

#### Approach to Care

- Based on the type of visit and a patient’s diagnostic and HIV status, clinicians should use one of the flowcharts listed below to guide assessment, care planning, and follow-up (A\*):
  - [Initial Visit: New Patient, New HIV Diagnosis, NOT Taking ART](#)
  - [Initial Visit: New Patient, HIV Confirmed, IS Taking ART](#)
  - [Initial Visit: New Patient, HIV Confirmed, NOT Taking ART](#)
  - [Annual, Routine, New Illness, or Post-Hospitalization Visit: Established Patient Who IS Taking ART](#)
  - Also see the NYSDOH AI [Guidance: Addressing the Needs of Older Patients in HIV Care](#)
- In providing primary care for adults with HIV, clinicians should follow standard best practices for adult primary care and should add the HIV-specific care elements noted in this guideline. (A3)
- Clinicians should engage patients in shared decision-making regarding routine health screening tests, weighing the risks and benefits of screening based on such factors as life expectancy, cost, potential harms, and HIV-compounded risk. (A3)

#### Opportunistic Infection Prophylaxis

- Clinicians should initiate prophylaxis for specific OIs and discontinue prophylaxis as indicated in [Table 4: Opportunistic Infection Prophylaxis for Adults With HIV](#). (A\*)
- Clinicians may discontinue primary OI prophylaxis in patients who are taking effective ART and have evidence of immune recovery. (A\*)

**Abbreviations:** ART, antiretroviral therapy; OI, opportunistic infection.

Ideally, access to primary and HIV-related general medical care should be available to adults with HIV in a setting that minimizes barriers to care and allows patients to maintain a relationship with their preferred healthcare provider. The 4 flowcharts below can be applied to adult primary care in any setting to ensure that patients with HIV receive ART and appropriate monitoring based on their HIV and ART status, age, and identified health risks. The 4 flowcharts offer guidance for care providers with or without previous HIV care experience; working in any outpatient setting; and managing the care of new patients with a confirmed or unconfirmed HIV diagnosis, established patients in need of routine annual care and monitoring, or patients aging with HIV, which is discussed in the NYSDOH AI [Guidance: Addressing the Needs of Older Patients in HIV Care](#).

- Flowchart 1 steps through a first visit with a new patient with a new HIV diagnosis and prioritizes confirmation of the HIV diagnosis and ART initiation.
- Flowchart 2 describes a first visit with a new patient who has a confirmed HIV diagnosis and is taking ART. After establishing whether an ART switch is needed, attention is focused on standard primary care, with HIV-specific additions, such as HIV history.
- Flowchart 3 walks through a first visit with a new patient with a confirmed HIV diagnosis who is not taking ART either because it has not been initiated or because the patient stopped taking antiretroviral medications.
- Flowchart 4 illustrates a routine visit, “sick patient” visit, and a post-hospitalization visit with an established patient.

All 4 flowcharts address history-taking, assessment, laboratory testing, screening and preventive care, counseling, and follow-up with links to checklists, other guidelines, and multiple resources. Each flowchart also addresses risk reduction.

## Flowchart 1: Initial Visit: New Patient, New HIV Diagnosis, NOT Taking ART

### First visit with a new patient who has a new HIV diagnosis and is NOT taking ART

Note: Treat or refer for emergency care when a patient has red flag symptoms, e.g., fevers, dyspnea, severe headaches, mental status changes.



#### Confirmed HIV diagnosis:

- Assess HIV treatment readiness and facilitate shared decision-making regarding ART (see NYSDOH AI guideline [Rapid ART Initiation > Benefits and Risks of ART](#))
- Recommend and offer [same-day or rapid ART](#)
- If the patient is not ready to start ART:** Schedule a return visit within 1 week to allow the patient time to process the new diagnosis, then recall as needed to reassess treatment readiness

#### Unconfirmed HIV diagnosis:

- Explain the diagnosis confirmation process and order confirmatory HIV testing; see the [standard HIV testing algorithm](#)
- Assess HIV treatment readiness, recommend and facilitate shared decision-making regarding same-day or rapid ART; discuss harm reduction [a], including transmission prevention
- If the patient is taking PrEP, manage per the recommendations in the NYSDOH AI guideline [PrEP to Prevent HIV and Promote Sexual Health](#)



#### All patients:

##### Obtain:

- Pronoun(s) and gender identity
- Patient concerns and goals
- Standard medical, surgical, and family histories
- Standard ROS and physical exam, including sex organ inventory
- Current medications; note potential [drug-drug interactions](#)
- [Immunization status](#)

##### Provide counseling and patient education:

- ART options and benefits of ART, including rapid start and [U=U](#)
- HIV transmission prevention [a]
- HIV disclosure status
- Age-, sex-, and risk-based [screening](#) and [preventive care](#) recommendations, including immunizations
- Adherence requirements and support resources
- Substance use [treatment](#) and [harm reduction](#) options
- [Sexual health](#), including condom use, STI prevention, and other harm reduction options (e.g., [doxy-PEP](#))

##### Assess (also see [Checklist 1](#)):

- Comorbidities
- Symptoms of common opportunistic infections (PJP, TB, CMV, CM); initiate [OI prophylaxis](#) if the patient's CD4 count is <200 cells/mm<sup>3</sup>
- [Substance use](#), including tobacco; if high-risk, engage in shared decision-making regarding [SUD treatment](#)
- Harm reduction knowledge and needs
- Functional status
- Urgent psychosocial or behavioral needs
- Trauma experience, including medical trauma

##### Order:

- [Baseline laboratory testing](#)
- [Seasonal and other priority vaccines](#), e.g., influenza, COVID-19, mpox, pneumococcal; avoid live vaccines in patients with CD4 count <200 cells/mm<sup>3</sup>
- STI and other indicated age-, sex-, and risk-based screening and preventive care if not available on site

##### Refer, as indicated, for:

- Imaging
- Urgent specialty care
- Assistance with urgent psychosocial needs
- Screening and preventive care that cannot be provided on site



#### Follow-up:

##### After ART is initiated:

- 1 week after, in-person visit:** Review laboratory test results, including confirmatory HIV test result; assess and manage adverse effects and adherence challenges
- 2 weeks after, in-person, telephone, or telemedicine visit:** Assess and manage adverse effects and adherence challenges
- 4 weeks after, in-person visit:** Assess and manage adverse effects and adherence challenges; assess for symptoms of [IRIS](#); identify drug-drug interactions; order HIV viral load testing
  - Continue [immunizations](#) until the patient has received all indicated vaccines; avoid live vaccines until CD4 count is >200 cells/mm<sup>3</sup>
  - Assess [b]: Comorbidity management, preventive and specialty care needs, psychosocial status and urgent psychosocial needs
  - Provide counseling, as above
- HIV viral load and comprehensive metabolic panel:**
  - 4 weeks after ART initiation
  - At least every 8 weeks until complete virologic suppression is documented
- CD4 cell count:**
  - 12 weeks after ART initiation
  - Every 4 months until CD4 count >200 cells/mm<sup>3</sup> is obtained on 2 measurements at least 4 months apart, then at least every 6 months if CD4 count is ≤350 cells/mm<sup>3</sup>
  - Optional if CD4 count is >350 cells/mm<sup>3</sup> and viral load is suppressed, i.e., <20 to <50 copies/mL
  - See NYSDOH AI guideline [Virologic and Immunologic Monitoring in HIV Care](#)

##### If rapid ART is not initiated:

- 1 week after the first visit, in-person:** Review laboratory test results, including confirmatory HIV test result
  - Reassess treatment readiness and barriers
  - Engage the patient in motivational interviewing and shared decision-making regarding ART initiation
  - Provide counseling, as above
- Ongoing:** Schedule return visits to encourage ART initiation, monthly or at intervals that respect the patient's autonomy and at a frequency that the patient agrees to

**Abbreviations:** ART, antiretroviral therapy; CM, cryptococcal meningitis; CMV, cytomegalovirus; doxy-PEP, doxycycline post-exposure prophylaxis; HBV, hepatitis B virus; HCV, hepatitis C virus; HPV, human papillomavirus; IRIS, immune reconstitution inflammatory syndrome; OI, opportunistic infection; PEP, post-exposure prophylaxis; PJP, *pneumocystis jirovecii pneumonia*; PrEP, pre-exposure prophylaxis; ROS, review of systems; STI, sexually transmitted infection; SUD, substance use disorder; TB, tuberculosis; U=U, undetectable=untransmittable.

#### Notes:

- Ongoing discussion and education regarding HIV disclosure, [U=U](#), [PrEP and PEP](#) for sex partners, and [harm reduction](#) is recommended.
- Ongoing surveillance for diseases transmitted through the same routes as HIV, including HCV, HBV, HPV, and other STIs, is recommended.

## Flowchart 2: Initial Visit: New Patient, HIV Confirmed, IS Taking ART

### First visit with a new patient who has a confirmed HIV diagnosis and IS taking ART

Note: Review HIV and ART history, current immune status, and adherence history.

#### Stable ART regimen, i.e., no change needed if:

- HIV viral load is suppressed, i.e., <20 to <50 copies/mL
- ART regimen is optimized for the patient's needs (i.e., pill burden, pill size, dosing schedule, cost coverage)
- Patient reports no unmanageable adverse effects or adherence challenges
- Comorbidity-related conditions are managed effectively [a]

Order proviral DNA genotype (archived genotype) if unable to obtain complete or clear ART history, including previous regimen failure or results of prior resistance testing

#### ART switch is needed due to:

- Unsuppressed virus ([HIV viral load](#) >200 copies/mL obtained with a highly sensitive assay)
  - Assess possible causes, including nonadherence, accessibility challenges, intolerable adverse effects or [drug-drug interactions](#), and challenges with pill size
  - If appropriate, provide or recommend adherence support and counseling (repeat viral load testing within 4 weeks of the ART switch to assess whether adherence has improved)
  - Order [resistance testing](#)
- Change in liver or kidney function
- Patient requested [switch to injectable](#) or other [new ART regimen](#) to optimize dosing or pill burden, reduce cost, or improve adherence

#### If the patient is not ready to start a new ART regimen:

- Engage patient in motivational interviewing
- Address challenges related to comorbidities and psychosocial factors

### All patients:

#### Obtain:

- Pronoun(s) and gender identity
- Patient concerns and goals
- Comprehensive HIV history (see [Checklist 1](#))
- Standard and HIV-specific medical, surgical, and family histories [a]
- Standard and HIV-specific ROS and physical exam, including sex organ inventory
- Current medications; note potential [drug-drug interactions](#)
- [Immunization status](#)

#### Provide counseling and patient education:

- Benefits of ART, including [U=U](#)
- HIV transmission prevention [c]
- HIV disclosure status
- Age-, sex-, and risk-based [screening](#) and [preventive care](#) recommendations, including immunizations
- Adherence requirements and support resources
- Substance use [treatment](#) and [harm reduction](#) options
- [Sexual health](#), including condom use, STI prevention, and other harm reduction options (e.g., [doxy-PEP](#)) [d]

#### Assess (also see [Checklist 1](#)):

- Comorbidities [a]
- Symptoms of common opportunistic infections (PJP, TB, CMV, CM); initiate [OI prophylaxis](#) if the patient's CD4 count is <200 cells/mm<sup>3</sup>
- [Substance use](#), including tobacco [b]; if high-risk, engage in shared decision-making regarding [SUD treatment](#)
- Harm reduction needs
- Functional status
- Urgent psychosocial or behavioral needs
- Trauma experience, including medical trauma

#### Order:

- [Baseline laboratory testing](#) (note: HBV status will inform ART regimen)
- [Seasonal and other priority vaccines](#), e.g., influenza, COVID-19, mpox, pneumococcal; avoid live vaccines in patients with CD4 count <200 cells/mm<sup>3</sup>
- STI and indicated age-, sex-, and risk-based [screening](#) and [preventive care](#) if not available on site

#### Refer as indicated for:

- Imaging
- Urgent specialty care
- Assistance with urgent psychosocial needs
- Screening and preventive care that cannot be provided on site

#### Follow-up for a patient with no change in ART:

- **12 to 16 weeks after initial visit, in-person visit:** Routine monitoring visit
- **Every 4 to 6 months, in-person or telemedicine visit:** Routine visits, initiated once the patient's HIV and health status are stable
  - See [Flowchart 4: Annual, Routine, New Illness, or Post-Hospitalization Visit: Established Patient Who IS Taking ART](#)

#### Follow-up for a patient whose ART regimen is changing:

- **1 to 2 weeks after the initial visit, in-person, telephone, or telemedicine visit:**
  - If the ART switch was not already made during the initial visit, review laboratory test results and switch options
  - Engage the patient in shared decision-making to choose and implement a new ART regimen
  - Confirm that the patient is able to fill the prescription, understands adherence requirements, and is informed about adverse effect management
- **4 weeks after ART switch, in-person or telemedicine visit:**
  - Assess and manage adverse effects and adherence challenges; assess for symptoms of [IRIS](#); identify [drug-drug interactions](#)
  - Order viral load testing; repeat at least every 8 weeks until complete virologic suppression is documented (see NYSDOH AI guideline [Virologic and Immunologic Monitoring in HIV Care](#))
  - Continue [immunizations](#) until the patient has received all indicated vaccines (avoid live vaccines until CD4 count is >200 cells/mm<sup>3</sup>)
  - Assess [d]: Comorbidity management, preventive and specialty care needs, psychosocial status, and urgent psychosocial needs
  - Provide counseling, as above

**Abbreviations:** ART, antiretroviral therapy; CM, cryptococcal meningitis; CMV, cytomegalovirus; doxy-PEP, doxycycline post-exposure prophylaxis; HBV, hepatitis B virus; HCV, hepatitis C virus; HPV, human papillomavirus; IRIS, immune reconstitution inflammatory syndrome; OI, opportunistic infection; PEP, post-exposure prophylaxis; PJP, *pneumocystis jirovecii* pneumonia; PrEP, pre-exposure prophylaxis; ROS, review of systems; STI, sexually transmitted infection; SUD, substance use disorder; TB, tuberculosis; U=U, undetectable=untransmittable.

#### Notes:

- Monitor for potential long-term effects of HIV and ART (e.g., bone density changes, dyslipidemia, weight gain, and renal dysfunction) and for comorbidities that occur more often and at younger ages in people with HIV, including atherosclerotic heart disease, non-HIV-related malignancies, renal disease, liver disease, chronic obstructive pulmonary disease, neurocognitive dysfunction, depression, and frailty.
- Recent studies have found that smoking and hypertension contribute significantly to morbidity, regardless of HIV-related risk factors such as CD4 cell count or viral load [Althoff, et al. 2019].
- Ongoing discussion and patient education regarding HIV disclosure, principles of [U=U](#), [PrEP and PEP](#) for sex partners, and [harm reduction](#) is recommended.
- Ongoing surveillance for diseases transmitted through the same routes as HIV, including HCV, HBV, HPV, and other STIs, is recommended.

### Flowchart 3: Initial Visit: New Patient, HIV Confirmed, NOT Taking ART

#### First visit with a new patient who has a confirmed HIV diagnosis and is NOT taking ART

*Note: Treat or refer for emergency care when a patient has red flag symptoms, e.g., fevers, dyspnea, severe headaches, mental status changes.*



#### ART-experienced:

- Assess patient's reasons for discontinuing ART, including any challenges with adherence, accessibility, adverse effects, and drug-drug interactions
- Consultation with an experienced HIV care provider may be helpful if the patient stopped ART due to viremia or adverse effects, including unmanageable [drug-drug interactions](#)
- Assess HIV treatment readiness; facilitate shared decision-making regarding ART (see NYSDOH AI guideline [Rapid ART Initiation > Benefits and Risks of ART](#))

#### If the patient is ready and able to re-start ART:

- Resume the most recent well-tolerated regimen; if the previous ART regimen is not known, initiate an INSTI-based regimen
- If the patient has had previous virologic failure, consider resistance testing, including on proviral DNA (or archive genotype) at 2 to 4 weeks
- If the previous ART regimen failed or was not well-tolerated, including due to drug-drug interactions, construct a [new regimen](#) and order resistance testing; note that archived genotype may have a role in identifying RAMs when standard genotype testing may not yield results, i.e., in patients with prior treatment experience who have stopped taking ARVs for >4 weeks or have a viral load <1,000 copies/mL (see NYSDOH AI guideline [Second-Line ART After Treatment Failure or for Regimen Simplification > Table 1: Types of HIV Resistance Tests](#))

#### If the patient is not ready to re-start ART:

- Engage the patient in motivational interviewing and address challenges related to comorbidities and psychosocial factors
- Schedule a return visit within 1 to 2 weeks to review test results and encourage ART initiation



#### ART-naïve:

- Assess HIV treatment readiness and facilitate shared decision-making regarding ART initiation (see [Benefits and Risks of ART](#))
- Strongly recommend and offer [same-day or rapid ART](#)

#### If the patient is not ready to initiate ART:

- Engage patient in motivational interviewing
- Address challenges related to comorbidities and psychosocial factors
- Provide education and counseling regarding HIV transmission prevention, condom use, and STI prevention, including [doxy-PEP](#)
- Schedule a return visit within 1 to 2 weeks to review test results and encourage ART initiation

#### All patients:

##### Obtain:

- Pronoun(s) and gender identity
- Patient concerns and goals
- Comprehensive HIV history (see [Checklist 1](#))
- Standard and HIV-specific medical, surgical, and family histories [a]
- Standard and HIV-specific ROS and physical exam, including sex organ inventory
- Current medications; note potential [drug-drug interactions](#)
- [Immunization status](#)

##### Provide counseling and patient education:

- Benefits of ART, including [rapid start](#) and [U=U](#)
- HIV transmission prevention [c]
- HIV disclosure status
- Age-, sex-, and risk-based [screening](#) and [preventive care](#) recommendations, including immunizations
- Adherence requirements and support resources
- Substance use [treatment](#) and [harm reduction](#) options
- [Sexual health](#), including condom use, STI prevention, and other harm reduction options (e.g., [doxy-PEP](#)) [d]

##### Assess (also see [Checklist 1](#)):

- Comorbidities [a]
- Symptoms of common opportunistic infections (PJP, TB, CMV, CM); initiate [OI prophylaxis](#) if the patient's CD4 count is <200 cells/mm<sup>3</sup>
- [Substance use](#), including tobacco [b]; if high-risk, engage in shared decision-making regarding [SUD treatment](#)
- Harm reduction needs
- Functional status
- Urgent psychosocial or behavioral needs
- Trauma experience, including medical trauma

##### Order:

- [Baseline laboratory testing](#) (note: HBV status will inform ART regimen)
- [Seasonal and other priority vaccines](#), e.g., influenza, COVID-19, mpox, pneumococcal; avoid live vaccines in patients with CD4 count <200 cells/mm<sup>3</sup>
- STI and indicated age-, sex-, and risk-based screening and preventive care if not available on site

##### Refer as indicated for:

- Imaging
- Urgent specialty care
- Assistance with urgent psychosocial needs
- Screening and preventive care that cannot be provided on site



#### Follow-up for patient starting ART:

- **2 weeks after ART initiation, in-person, telephone, or telemedicine visit:** Confirm that the patient has filled the prescription and initiated ART; review laboratory test results; confirm patient's understanding of adherence requirements and adverse effect management; initiate OI prophylaxis if the patient has a CD4 count <200 cells/mm<sup>3</sup>
- **4 weeks after ART initiation in-person visit:** Assess and manage adverse effects and adherence challenges; assess for symptoms of [IRIS](#); identify [drug-drug interactions](#)
  - Order viral load testing and CMP; if the patient is restarting ART, consider genotype testing if there are significant concerns about baseline resistance
  - Continue [immunizations](#) until the patient has received all indicated vaccines; avoid live vaccines until CD4 count is >200 cells/mm<sup>3</sup>
  - Assess [d]: Comorbidity management, preventive and specialty care needs, psychosocial status, and urgent psychosocial needs
  - Provide counseling, as above

#### Follow-up if patient is not ready to start or re-start ART:

- **Schedule monthly, in-person visits to:**
  - Review laboratory test results; reassess treatment readiness, barriers, and options
  - Assess and address any challenges related to comorbidities and behavioral or psychosocial factors
  - Perform or order STI and other indicated age-, sex-, and risk-based [screening](#) and [preventive care](#)
  - Provide education and counseling regarding HIV transmission prevention, condom use, and STI prevention, including [doxy-PEP](#)
  - Address treatment readiness and engage the patient in motivational interviewing
- **Adjust the visit schedule:** Schedule visits at a frequency that respects the patient's autonomy and tolerance

**Abbreviations:** ART, antiretroviral therapy; ARV, antiretroviral; CM, cryptococcal meningitis; CMP, comprehensive metabolic panel; CMV, cytomegalovirus; doxy-PEP, doxycycline post-exposure prophylaxis; HBV, hepatitis B virus; HCV, hepatitis C virus; HPV, human papillomavirus; INSTI, integrase strand transfer inhibitor; IRIS, immune reconstitution inflammatory syndrome; OI, opportunistic infection; PEP, post-exposure prophylaxis; PJP, *pneumocystis jirovecii* pneumonia; PrEP, pre-exposure prophylaxis; RAM, resistance-associated mutation; ROS, review of systems; STI, sexually transmitted infection; SUD, substance use disorder; TB, tuberculosis; U=U, undetectable=untransmittable.

#### Notes:

- Monitor for potential long-term effects of HIV and ART (e.g., bone density changes, dyslipidemia, weight gain, and renal dysfunction) and [comorbidities](#).
- Smoking and hypertension contribute significantly to morbidity, regardless of HIV-related risk factors such as CD4 cell count or viral load [Althoff, et al. 2019].
- Ongoing discussion and patient education regarding HIV disclosure, principles of [U=U](#), [PrEP and PEP](#) for sex partners, and [harm reduction](#) is recommended.
- Ongoing surveillance for diseases transmitted through the same routes as HIV, including HCV, HBV, HPV, and other STIs, is recommended.

## Flowchart 4: Annual, Routine, New Illness, or Post-Hospitalization Visit: Established Patient Who IS Taking ART

Routine visit (annual), new illness work-up, or post-hospitalization visit with an established patient taking ART

Note: Review HIV and ART history, current immune status, and adherence history; if ART switch is needed, see [Flowchart 2](#).



### All patients:

#### Obtain:

- Update medical, surgical, social, and family histories as indicated
- Standard and [HIV-specific](#) ROS and physical exam
- Current medications; note potential [drug-drug interactions](#)

#### Assess (also see [Checklist 1](#); see [Flowchart 2](#) if ART switch is needed):

- Patient concerns
- Comorbidities [a]; changes in symptoms or treatment since the last visit
- [Substance use](#), including tobacco [b]; if high-risk, engage in shared decision-making regarding [SUD treatment](#)
- Harm reduction needs
- Functional status
- Current behavioral and psychosocial status

#### Order:

- Annual (routine) [laboratory testing](#)
- [Seasonal and other priority vaccines](#), e.g., influenza, COVID-19, mpox, pneumococcal; avoid live vaccines in patients with CD4 count <200 cells/mm<sup>3</sup>
- STI and indicated age-, sex-, and risk-based [screening](#) and [preventive care](#) if not available on site

#### Provide counseling and patient education:

- Age- and risk-based [screening](#) and [preventive care](#) recommendations, including immunizations
- Adherence support
- As indicated, ongoing discussion of HIV disclosure status and [U=U](#)
- Substance use [treatment](#) and [harm reduction](#) options
- [Sexual health](#), including condom use, STI prevention, and other harm reduction options (e.g., [doxy-PEP](#)) [c]
- Advance directives

#### Refer as indicated for:

- Imaging
- Preventive care, including cancer screenings
- Specialty care, e.g., case management, optometry, nutrition, dental care, peer support

#### Schedule return visit:

- In-person, in 12 to 24 weeks for a routine monitoring visit
- Other as indicated

**Abbreviations:** ART, antiretroviral therapy; doxy-PEP, doxycycline post-exposure prophylaxis; HBV, hepatitis B virus; HCV, hepatitis C virus; HPV, human papillomavirus; ROS, review of systems; STI, sexually transmitted infection; SUD, substance use disorder; U=U, undetectable = untransmittable.

#### Notes:

- Monitor for potential long-term effects of HIV and ART (e.g., bone density changes, dyslipidemia, weight gain, and renal dysfunction) and for comorbidities that occur more often and at younger ages in people with HIV, including atherosclerotic heart disease, non-HIV-related malignancies, renal disease, liver disease, chronic obstructive pulmonary disease, neurocognitive dysfunction, depression, and frailty.
- Smoking and hypertension contribute significantly to morbidity, regardless of HIV-related risk factors such as CD4 cell count or viral load [Althoff, et al. 2019].
- Ongoing surveillance for diseases transmitted through the same routes as HIV, including HCV, HBV, HPV, and other STIs, is recommended.

#### If the patient is ill:

- Evaluate current immune status, keeping in mind the possibility of opportunistic infections in patients with compromised immunity
- Assess for comorbid conditions
- Order additional laboratory testing as indicated
- Treat according to the suspected diagnosis
- Schedule appropriate follow-up

#### If the patient was recently hospitalized:

- Review laboratory test results and imaging from hospitalization to identify the need for follow-up and assess liver and kidney function
- Review any new diagnoses and treatment plans
- Perform medication reconciliation and assess for potential drug-drug interactions
- Coordinate care with new specialists, including rehabilitation facilities, nursing homes, and hospice; note any changes in the patient's social/familial support network and assess related needs
- If indicated, assess the effects of newly disclosed HIV status
- Review or perform functional status and safety assessment; make referrals as indicated
- Address patient's financial concerns if indicated, e.g., new medications, hospital or specialist care co-pays
- Assess long-term care planning and resources
- Assist with end-of-life planning if indicated



## Goals of Primary Care for Adults With HIV

The standard approach to primary care is the same for patients with and without HIV, whether care is delivered by a specialist or generalist. In addition to mainstays of primary care, there are unique considerations for patients with HIV, including treatment of HIV itself. Clinicians should inform patients of the benefits of antiretroviral therapy (ART) and strongly encourage patients to initiate ART as soon as possible (for evidence-based recommendations, see the NYSDOH AI guideline [Rapid ART Initiation](#)).

## Health Maintenance

Regardless of HIV treatment, however, when compared with individuals without HIV, the risk of many comorbidities, including metabolic and infectious diseases and cancers, is higher in people with HIV (see Box 1, below). In one study, patients with HIV had significantly fewer morbidity-free years than patients without HIV [Marcus, et al. 2020].

### Box 1: Conditions With Higher Incidence in People With HIV and Selected Citations

#### Metabolic Diseases

- Cardiovascular disease [Avgousti and Feinstein 2023; Silverberg, et al. 2022; Shah, et al. 2018; Drozd, et al. 2017]
- Osteoporosis [Chang, et al. 2021; Compston 2016]
- Thromboembolic events [Morales, et al. 2022; Rokx, et al. 2020; Malek, et al. 2011]
- Type 2 diabetes [McMahon, et al. 2018; Nansseu, et al. 2018; Monroe, et al. 2015]
- Renal disease [Cervantes and Atta 2023; Swanepoel, et al. 2018; Althoff, et al. 2015]
- Liver disease [Morales, et al. 2022; Soti, et al. 2018]

#### Malignancies

- AIDS-defining malignancies (e.g., Kaposi sarcoma, non-Hodgkin Lymphoma) [Guiguet, et al. 2009]
- Hepatocellular carcinoma [McGee-Avila, et al. 2024; Sun, et al. 2021; Pinato, et al. 2019]
- HIV-associated cancers (e.g., lung cancer, Epstein-Barr virus-associated lymphoma) [Yarchoan and Uldrick 2018]
- Human papillomavirus-related malignancies (e.g., anal cancer, cervical cancer, head and neck cancer) [Morales, et al. 2022; Clifford, et al. 2017; Brickman and Palefsky 2015; Machalek, et al. 2012]
- Non-AIDS-defining malignancies [Veyri, et al. 2021; Park, et al. 2016; Althoff, et al. 2015; Deeken, et al. 2012]

#### Infectious Diseases

- Hepatitis A virus [Bosh, et al. 2018; Penot, et al. 2018]
- Hepatitis B virus [Bosh, et al. 2018; Singh, et al. 2017]
- Hepatitis C virus [Bosh, et al. 2018; Graham, et al. 2001]
- Systemic viral illnesses (e.g., cytomegalovirus, Epstein-Barr virus, human herpesvirus-8, varicella-zoster virus, herpes simplex virus) [Yang, et al. 2024; Morales, et al. 2022; Gilbert, et al. 2019; Basso, et al. 2018]
- Fungal illness (e.g., candidiasis, aspergillosis, *pneumocystis jiroveci* pneumonia, coccidiomycosis, cryptococcosis) [Morales, et al. 2022; Cilloniz, et al. 2019; Limper, et al. 2017]
- Syphilis [Fujimoto, et al. 2018]; see [CDC: Sexually Transmitted Infections Surveillance, 2022](#)
- Tuberculosis [van Geuns, et al. 2024; Bruchfeld, et al. 2015]

#### Other

- Chronic obstructive pulmonary disease [Thudium, et al. 2023; Bigna, et al. 2018; Risso, et al. 2017]
- Neurocognitive impairment [Deng, et al. 2021; Cysique and Brew 2019; Tozzi, et al. 2007]
- Depression [Vollmond, et al. 2023; Nanni, et al. 2015]
- Frailty [Lellouche, et al. 2021; Verheij, et al. 2021; Kooij, et al. 2016; Greene, et al. 2015]

The increased incidence of comorbid conditions is associated with several factors, some of which are HIV disease-specific, such as ongoing immune activation-associated risks [Deeks, et al. 2015; Deeks 2011]; presumed medication-associated toxicities, such as accelerated bone density loss; duration of HIV viremia [Lang, et al. 2012]; and others, including increased rates of malignancy and hepatitis C virus (HCV) infection. Many of these conditions occur regardless of immune reconstitution and HIV disease stage, and long-term HIV survivors may face the burdens of concomitant disease, medication-associated toxicity (particularly for those on or with prolonged exposure to early antiretroviral medications), and advanced aging [Maggi, et al. 2019].

Regardless of viral suppression or CD4 count, HIV infection is associated with an increased risk of comorbidities related to persistent inflammation associated with the virus itself. ART reduces morbidity and mortality but can also contribute to comorbidities, such as weight gain [Bourgi(a), et al. 2020; Bourgi(b), et al. 2020] and osteoporosis [Komatsu, et al. 2018; Grigsby, et al. 2010].

**Immune function:** Morbidity and mortality are increased in individuals with low CD4 cell counts [Castilho, et al. 2022; Althoff, et al. 2019; May, et al. 2016], and the risk is greater in patients with unintentional weight loss or poor functional status [Siika, et al. 2018; Serrano-Villar, et al. 2014]. Some conditions, such as AIDS-defining malignancies, are more common in individuals with low CD4 cell counts and may be associated with markedly poor outcomes [Borges, et al. 2014]. See the U.S. Department of Health and Human Services: [Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents With HIV](#).

**Conditions related to low nadir CD4 cell count:** A low nadir CD4 cell count (lowest lifetime CD4 cell count) reflects severe pretreatment immune dysfunction. Immune recovery in patients with low nadir CD4 cell counts may take longer or be less complete than in those with higher nadir CD4 cell counts [Stirrup, et al. 2018; Collazos, et al. 2016]. Studies have found increased morbidity and mortality for 5 years after ART is initiated [May, et al. 2016], and nadir CD4 cell count is a predictor of cognitive impairment and disorders [Ellis, et al. 2011]. Some patients may have persistently low CD4 cell counts despite achieving viral load suppression and will be at increased risk of clinical progression to AIDS-related and non-AIDS-related illnesses and death [Baker, et al. 2008].

**HIV-specific components of care:** Additional essential components of primary care for patients with HIV include:

- Patient education and encouragement regarding adherence to ART to maintain viral suppression
- Opportunistic infection prophylaxis
- Immunizations (note [recommendations](#) specific to adults with HIV, which may differ from those for adults without HIV)
- Monitoring for potential long-term effects of HIV and ART, such as bone density changes, dyslipidemia, weight gain, renal dysfunction, and impaired cognitive functioning
- Identification and management of comorbidities that occur more often and at younger ages in people with HIV, including atherosclerotic heart disease, non-HIV-related malignancies, renal disease, liver disease, chronic obstructive pulmonary disease, neurocognitive dysfunction, depression, and frailty (see Box 1, above). Recent studies have found that smoking and hypertension contribute significantly to morbidity, regardless of HIV-related risk factors, such as CD4 cell count or viral load [Althoff, et al. 2019].
- Ongoing surveillance for diseases transmitted through the same routes as HIV, including [HCV](#), [hepatitis B virus](#), [human papillomavirus](#), and other [sexually transmitted infections](#)
- Screening and treatment for [substance use](#), including tobacco use
- Ongoing discussion and patient education regarding disclosure of HIV status, principles of [U=U \(undetectable = untransmittable\)](#), [pre- and post-exposure prophylaxis](#) for sex partners, and harm reduction strategies

## Improving Access to Care

**Health equity:** Improving access to care within communities and facilitating access through primary care providers can be a solution to significant healthcare disparities among people living with HIV. Addressing health inequities through interventions such as culturally appropriate counseling, peer support, motivational interviewing, and cognitive behavioral therapy in the healthcare setting can lead to improved adherence and outcomes [Bogart, et al. 2023; Bogart, et al. 2021]. Though more research is needed, it appears that healthcare workers who recognize and address their implicit biases may reduce gaps in care. In addition, diversification of the healthcare workforce and attention to social determinants of health may reduce inequities.

**Stigma and medical mistrust:** Among people with HIV, stigma and medical mistrust remain significant barriers to healthcare utilization, HIV diagnosis, and medication adherence, which can affect disease outcomes [Kalichman, et al. 2020; Kemp, et al. 2019; Turan, et al. 2017]. Studies have found that both internalized stigma (manifested in feelings about self) and externalized stigma (enacted by others) can influence how often a patient seeks care, their engagement in care, and whether they maintain viral load suppression. Successful interventions to reduce stigma and medical mistrust include education of healthcare providers [Geter, et al. 2018], peer support [Flórez, et al. 2017], and social support [Rao, et al. 2018].

**Consent and confidentiality:** A patient's past medical records should be obtained whenever possible. Any HIV-related patient information is confidential, and by law, care providers must maintain this confidentiality (see New York Codes, Rules, and Regulations: [Part 63—HIV/AIDS Testing, Reporting and Confidentiality of HIV-Related Information](#)).

Sharing of patient medical records among care providers who participate in health information exchanges such as the Statewide Health Information Network for New York (SHIN-NY), can facilitate information exchange (see [New York eHealth Collaborative > What is the SHIN-NY?](#)). Patients must sign a standard medical record request form (see the New York State [standard consent form](#)). Information related to HIV care can be exchanged among care providers only if a patient consents specifically to the release of HIV/AIDS-related information on the standard form.

**Trauma-informed care:** A trauma-informed approach to care can help mitigate the effects of past medical trauma, such as frightening experiences or stigma associated with HIV [Tang, et al. 2020; Sherr, et al. 2011] and can facilitate improved outcomes [Brown, et al. 2024; Sikkema, et al. 2018]. See the following for more information:

- [New York State Office of Mental Health: Recovery From Trauma](#)
- [New York State Trauma-Informed Network & Resource Center](#)
- [Trauma Informed Care in Medicine: Current Knowledge and Future Research Directions](#) (article) [Raja, et al. 2015]

**Case management:** The goal of comprehensive case management is to improve patient outcomes and retention in care by providing the support and resources of a healthcare team that includes the clinical care provider. Comprehensive case management connects patients to community resources and can improve engagement with medical care, including screening and management of comorbid conditions, and HIV-specific outcomes, such as immune reconstitution and viral load suppression [López, et al. 2018; Brennan-Ing, et al. 2016].

Case management can dramatically improve viral load suppression among individuals who inject drugs or smoke crack cocaine, 2 groups that are difficult to retain in care: one study demonstrated an increase in viral load suppression from 32% to 74% and another found a mortality benefit from case management intervention [Kral, et al. 2018; Miller, et al. 2018]. For patients estranged from care, case management can facilitate effective re-engagement [Irvine, et al. 2021; Shacham, et al. 2018].

**Peer support:** Peer support from someone with shared life experience can provide emotional and practical guidance and help reduce stigma. Peer support has been found to improve retention in care [Cabral, et al. 2018] and viral suppression, including among recently incarcerated individuals [Feldman, et al. 2023; Cunningham, et al. 2018]. The positive effect was most pronounced when patients had a high level of trust in the organization providing peer services, such as the places where they already receive care [Sokol and Fisher 2016].

## HIV-Specific Primary Care

In the primary care setting, HIV management is similar to other chronic disease management, and comorbidity screening and management are standard, as in primary care for people who do not have HIV. Included below are practical recommendations and guidance for the initial visit and ongoing clinical care of individuals with HIV, with links to other evidence-based guidelines where appropriate.

## History-Taking

History-taking for patients with HIV requires attention to all of the elements standard in primary care and several additional elements detailed in Checklist 1: HIV-Specific Elements of Health Status and History, below. Identifying, assessing, and monitoring HIV- and antiretroviral therapy (ART)-related complications and other HIV-specific comorbidities is essential. A comprehensive baseline history includes sexual health, mental health, substance use (including illicit use of prescription drugs), and social history. Patients may choose not to disclose all pertinent personal information during the first visit, but a sympathetic and nonjudgmental attitude can help establish trust and facilitate further discussion and disclosure during subsequent visits.

**HIV history:** Essential components of an HIV-specific medical history are detailed below and in Checklist 1: HIV-Specific Elements of Health Status and History. Confirmation of a patient's HIV infection should include documented laboratory testing results. If results are not available, baseline testing should be performed as noted in Checklist 2: Initial (Baseline) and Annual Laboratory Testing for Adults With HIV, below (also see the NYSDOH AI guideline [HIV Testing > HIV Testing With the Standard 3-Step Algorithm](#)). If a patient was recently diagnosed with HIV, a discussion of the reasons for testing and the route of exposure will assist the clinician in identifying appropriate goals for risk reduction education, counseling, and intervention that may include ongoing screening for sexually transmitted infections (STIs).

Essential components of an HIV-specific medical history (see Checklist 1, below):

- Viral load and CD4 cell count at diagnosis, if known
- Patient circumstances at the time of diagnosis (housing, employment, food security, relationship status, travel history, pets, etc.)
- ART history, including previous regimens, reasons for any changes in prior regimens, and any adverse effects
- Pauses in ART and lapses in adherence
- Previous resistance testing results
- History of opportunistic infections (OIs)
- Immunization history
- History of HIV-related hospitalization(s)
- Disclosure status (whether partners, family, or friends are aware of HIV status) and partner notification
- History of other STIs with shared risk factors, including hepatitis B virus (HBV), hepatitis C virus (HCV), and human papillomavirus (HPV)
- Ongoing high-risk behaviors for transmission of HIV and acquisition of STIs or infections associated with injection drug use
- Experience of stigma and social support

**ART history:** An ART history includes all previous antiretroviral medications, adherence, and dates of and reasons for discontinuation (e.g., allergies, adverse effects, pill-taking fatigue or discomfort, and drug resistance). Understanding the reasons and, when possible, simplifying ART regimens or reducing pill burden will support a therapeutic alliance that may facilitate adherence going forward.

**ART initiation:** If a patient with HIV has not yet started ART, it should be initiated as soon as appropriate and possible, and any barriers to ART initiation should be assessed so support can be provided. For evidence-based recommendations, see the NYSDOH AI guideline [Rapid ART Initiation](#).

**Adherence:** For patients already taking ART, assessing and supporting optimal adherence are crucial and may include careful evaluation of adverse medication effects that often interfere with adherence or result in medication cessation. Other factors to discuss that may pose barriers to adherence include insurance coverage, housing instability, disclosure status, substance use, and mental health. A discussion about adherence can prompt regimen simplification, such as a switch to a single-tablet regimen or a referral to case management or peer support, and it can alert the clinical team to other barriers to effective care, especially among patients at higher risk of adherence challenges [Altice, et al. 2019; Bazzi, et al. 2019; Shah, et al. 2019].

**Metabolic changes:** Weight gain can be expected when initiating ART and is often attributed to a “return to health” with improved immune function. However, ART itself has been associated with metabolic changes. Integrase strand transfer inhibitors (INSTIs), including dolutegravir, bictegravir, raltegravir, elvitegravir, and cabotegravir, have been implicated in modest weight gain that reaches a plateau after 2 years of therapy [Kileel, et al. 2023]. Despite the weight gain associated with INSTI treatment, 2 studies found no difference in short- or long-term risk of cardiovascular disease events among treatment-naïve participants who started INSTI-based ART compared with other ART [Surial, et al. 2023; Neesgaard, et al. 2022]. Protease inhibitors are known to alter lipids unfavorably and can lead to lipodystrophy, a condition characterized by abdominal fat accumulation with peripheral lipoatrophy, insulin resistance, and hyperlipidemia [Waters, et al. 2023].

Switching from tenofovir disoproxil fumarate (TDF) to tenofovir alafenamide (TAF) is a [common strategy](#) to protect against adverse renal and bone effects, but a change from TDF to TAF has been associated with a significant increase in triglyceride, total cholesterol, and HDL cholesterol levels, but no significant changes in LDL cholesterol and total cholesterol/HDL ratio. However, a switch from TDF- to TAF-based therapy has been associated with an increased calculated cardiovascular risk. And in a large, diverse U.S. cohort of people with HIV, a switch from TDF to TAF was associated with pronounced weight gain immediately after the switch, regardless of the core ART class or core agent, suggesting an independent effect of TAF on weight gain [Mallon, et al. 2021; Plum, et al. 2021; Surial, et al. 2021]. Unintentional weight loss may prompt investigation of malignancy, infection, endocrine disorder, or psychosocial instability.

**Viral hepatitis status:** Many of the risk factors for acquisition of viral hepatitis are the same as those for HIV. Assessment of a patient’s viral hepatitis status, including a history of viral hepatitis infection and treatment, helps clinicians determine optimal treatment options. In individuals with HIV, the progression of HBV- or HCV-associated liver fibrosis, cirrhosis, cancer, portal hypertension, and encephalopathy is more rapid than in those without HIV [Sherman and Thomas 2022; Kim, et al. 2021; Sun, et al. 2021; Mocroft, et al. 2020; Klein, et al. 2016].

**HCV:** Because the risk of severe liver disease is increased in patients with HIV [Soti, et al. 2018; Klein, et al. 2016], all patients with HCV and HIV should be [treated for HCV infection](#) as soon as possible (see Table 2: Interpretation of HBV Screening Test Results and Table 3: Interpretation of HCV Test Results, below). Potential [interactions between ART and HCV medications](#) should be identified and addressed. Treatment of chronic HCV is the same for individuals with and without HIV [Sherman and Thomas 2022].

**HBV:** A history of [HBV infection](#) will influence HIV medication choice and requires attention to drug-drug interactions. Because tenofovir, emtricitabine, and lamivudine are effective against both HBV and HIV, assessment of baseline HBV status informs the choice of ART regimen that will treat HBV and HIV coinfection. However, ART initiation should not be delayed pending evaluation of HBV status, fibrosis, or hepatocellular carcinoma.

### Checklist 1: HIV-Specific Elements of Health Status and History

**Note:** The items listed below are in addition to routine primary care assessment. The standard approach to primary care is the same for patients with and without HIV, whether care is delivered by a specialist or internist; however, there are unique considerations for patients with HIV, including treatment of HIV itself.

- **HIV history:** Diagnosis date and source; ART regimens, prior PrEP use, challenges, adverse effects, pauses, and lapses; previous resistance testing results; HIV-related hospitalizations; disclosure status; history of OIs, including prophylaxis and treatment; history of AIDS-defining conditions and treatments; signs or symptoms of potential long-term effects of ART (e.g., bone density changes, dyslipidemia, weight gain, renal dysfunction).
  - Also see NYSDOH AI [Guidance: Addressing the Needs of Older Patients in HIV Care](#).
- **Medications:** Experienced and potential ART drug-drug interactions with any of the patient’s current medications (prescribed, OTC, herbal and nonpharmacologic agents); hormone use, including nonprescription, route of administration, and source.
- **Immunizations:** Status of immunizations recommended for adults with HIV; travel-related immunization status if indicated.
- **Sexually transmitted infections:** History and treatment of syphilis, gonorrhea, chlamydia, human papillomavirus, and other STIs; history of HIV transmission and ongoing risk factors; current and past experience with prevention, including doxy-PEP.
- **Hepatic:** History of and treatment for viral hepatitis (HAV, HBV, HCV); history of cirrhosis (compensated/decompensated) or previous hepatic compromise.
- **Neurologic:** Cognitive and neurobehavioral function; history of ischemia or thrombosis; history or symptoms of neuropathy, including symmetric distal polyneuropathy (common, particularly in patients exposed to earlier generations of ART).
- **Endocrine:** History of weight gain or loss; osteoporosis; lipodystrophy; symptoms of testosterone deficiency.
- **Nutritional status and food security:** Current dietary habits, appetite, and food security; history of malnutrition, vitamin deficiencies (particularly vitamin D and calcium), wasting, and disordered eating.
- **Gender:** Patient’s gender identity; history or plans for gender transition; gender-affirming hormone use, including source; gender-affirming surgical history; sex organ inventory (presence or absence of a penis, testes, prostate, breasts, vagina, cervix, uterus, and ovaries; patient’s preferred terms for body parts).
- **Renal:** Risk for HIV-associated nephropathy and potentially complicating diagnoses (e.g., diabetes, hypertension, other causes of chronic kidney disease). Consider ART history.
- **Behavioral health:** Screen for anxiety or suicide risk with new diagnosis; assess potential effect on adherence with untreated behavioral health diagnosis.
  - See USPSTF [Depression and Suicide Risk in Adults: Screening](#) (2023); [Generalized Anxiety Disorder 2-item \(GAD-2\)](#) brief screening tool; [PHQ-2](#); [PHQ-9](#); and [Columbia-Suicide Severity Rating Scale](#) standardized assessment tools.
- **Substance use (alcohol, nonprescribed drugs, prescribed drug misuse, tobacco):** History and current use; use of substances with sex; harm reduction; ongoing high-risk behaviors for transmission of HIV and acquisition of STIs or infections associated with injection drug use.
  - Also see NYSDOH AI guideline [Substance Use Screening, Risk Assessment, and Use Disorder Diagnosis in Adults](#).

### Checklist 1: HIV-Specific Elements of Health Status and History

- **Sexual health:** Sexual identity; current and past sex partner(s); HIV, ART, viral load, and PrEP status of sex partner(s); frequency and preferred sexual activities (to assess risk); history of sexual dysfunction or other challenges.
  - See NYSDOH AI guidance [GOALS Framework for Sexual History-Taking in Primary Care](#) and [Guidance: Adopting a Patient-Centered Approach to Sexual Health](#).
- **Financial health:** Current financial and employment status; access to resources if needed; healthcare coverage (including medical, hospitalization, mental health, prescriptions, and dental care) or access to resources for uninsured people; current or history of engagement in transactional sex. Assess for urgent needs.
- **Functional status:** Ability to perform activities of daily living; mobility; transportation; independence at home or in the community. Assess for urgent needs.
- **Relationships, responsibilities, and support:** Patient-defined family and significant relationships, including dependents; primary social network; people who know the patient has HIV; long-term care plans. Assess for urgent needs.
- **Social determinants of health:** Housing status and stability, food security, transportation, utilities, child care, employment, education, finances, personal safety, neighborhood safety, social support, criminal justice engagement, etc.
- **Trauma, stress, and stigma:** History of trauma, including medical and witnessed trauma; current and past experience with domestic, physical, emotional, verbal, and intimate partner violence; history or current experience with elder abuse; current major stressors; management and coping skills; experience with HIV-associated or other stigmas. Assess for urgent needs.

**Abbreviations:** ART, antiretroviral therapy; doxy-PEP, doxycycline post-exposure prophylaxis; HAV, hepatitis A virus; HBV, hepatitis B virus; HCV, hepatitis C virus; OI, opportunistic infection; OTC, over-the-counter; PHQ, Patient Health Questionnaire; PrEP, pre-exposure prophylaxis; STIs, sexually transmitted infections; USPSTF, U.S. Preventive Services Task Force.

## Immunizations

Recommended immunizations for adults with HIV are available in the NYSDOH AI guideline [Immunizations for Adults With HIV](#) and include the following:

- [COVID-19](#)
- [Hepatitis A Virus \(HAV\)](#)
- [Hepatitis B Virus \(HBV\)](#)
- [Human Papillomavirus \(HPV\)](#)
- [Influenza](#)
- [Measles, Mumps, Rubella \(MMR\)](#)
- [Meningococcal Serotypes A, C, W, and Y \(MenACWY\)](#)
- [Mpox](#)
- [Pneumococcal](#)
- [Tetanus, Diphtheria, and Pertussis \(Tdap\) and Tetanus-Diphtheria \(Td\)](#)
- [Varicella](#)
- [Zoster](#)

## General Medical Status and Physical Examination

This guideline assumes that care providers are familiar with performing a comprehensive physical examination. Particular attention may be needed to potential complications of immune suppression in patients with unsuppressed HIV and low CD4 cell counts.

**Medications:** Ideally, a complete medication history should be acquired at baseline and updated as needed during future visits. A detailed medication history (with emphasis on ART) allows the clinician to identify possible adverse drug-drug interactions between antiretroviral and other medications the patient may be taking for treatment of comorbidities. Patients with HIV may have multiple comorbidities due to infection and related inflammatory processes or the effects of medications.

Examination of a patient's current medical status and medication regimen may identify the need for changes in the ART regimen, changes in medications prescribed for other medical conditions, options for simplification of medication regimens, and medications that may be discontinued; see the NYSDOH AI guideline [Selecting an Initial ART Regimen > Special Considerations for Comorbid Conditions](#).

The following resources are available for checking drug-drug interactions:

- NYSDOH AI [Resource: ART Drug-Drug Interactions](#)
- Northeast/Caribbean AETC: [HIV and HCV Drug Interactions: Quick Guides for Clinicians](#)
- University of Liverpool: [HIV Drug Interaction Checker](#)

**Head, eyes, ears, nose, and throat:** An ophthalmologic examination at baseline and at least annually thereafter is indicated for patients with a CD4 count  $<50$  cells/mm<sup>3</sup>. Infections, including cytomegalovirus (CMV), varicella-zoster virus, herpesvirus, and syphilis can lead to retinitis, retinal necrosis, and vision loss [Nakamoto, et al. 2004]. Before the introduction of highly active ART, the 10-year cumulative incidence of CMV retinitis was 33.6% for individuals with CD4 counts  $<50$  cells/mm<sup>3</sup> and 4.2% for those with CD4 counts  $<200$  cells/mm<sup>3</sup>. While incidence has decreased significantly, it is still important to consider, particularly in patients with significant immunocompromise, i.e., with CD4 count  $<50$  cells/mm<sup>3</sup> [Sugar, et al. 2012]. In patients taking atazanavir as part of their ART regimen, icterus may be present by causing a benign hyperbilirubinemia [Bertz, et al. 2013]. HIV viremia can also lead to a direct retinopathy at high viral loads and low CD4 cell counts [Jabs 1995].

Although HIV infection itself does not increase the likelihood of viral upper respiratory infections, symptoms such as cough, sinusitis, and otitis are common in patients with HIV [Brown, et al. 2017; Chiarella and Grammer 2017; Small and Rosenstreich 1997]. Because sinusitis and otitis can present without significant facial pain or discomfort in patients with CD4 counts  $<50$  cells/mm<sup>3</sup>, it is reasonable to perform imaging and evaluate for infection with atypical organisms, such as fungal sinusitis, more readily in these patients.

People with HIV also have a higher risk of oral malignancies than those without HIV, and those with low CD4 cell counts may have diverse oropharyngeal findings, including oral Kaposi sarcoma, oral candidiasis, human papillomavirus (HPV)- and HIV-related parotitis, and necrotizing gingivitis, requiring evaluation during in-person examinations [Trevillyan, et al. 2018; Sorensen 2011; Epstein 2007]. Clinicians should encourage patients to have annual dental examinations (see [National Institute of Dental and Craniofacial Research: HIV/AIDS & Oral Health](#) and NYSDOH AI guideline [Management of Periodontal Disease](#)).

**Cardiovascular:** People with HIV are at higher risk for coronary artery and cardiovascular disease and may develop disease earlier than those without HIV; this includes a risk of myocardial infarction more than twice that for those without HIV [Shah, et al. 2018; Freiberg, et al. 2013]. The CVD-associated mortality risk is increasing as well, especially as a proportion of overall mortality in those with HIV [Feinstein, et al. 2016]. CVD risk assessment is crucial, but standard risk calculators may underestimate the risk in people with HIV, particularly in Black people and cisgender women [Grinspoon, et al. 2024]. Shared decision-making may be necessary to compensate for underestimated risk when deciding whether to use statins or implement lifestyle changes. Pitavastatin has been shown to significantly reduce cardiovascular risk even in those not considered to be at high risk based on risk calculators [Grinspoon, et al. 2023]. Also see U.S. Department of Health and Human Services (DHHS): [Guidelines for the Use of Antiviral Agents in Adults and Adolescents With HIV > Recommendations for the Use of Statin Therapy as Primary Prevention of Atherosclerotic Cardiovascular Disease in People with HIV](#).

**Respiratory:** Clinicians should perform a lung examination at baseline and at least annually, or more often if indicated. Chronic lung disease, including chronic obstructive pulmonary disease, is increasingly common among older people with HIV, among smokers, and among those who have had *Pneumocystis jiroveci* pneumonia (PJP; formerly known as *Pneumocystis carinii* pneumonia or PCP), who may have residual blebs that can lead to pneumothorax [Risso, et al. 2017].

In patients with low CD4 cell counts who have respiratory examination findings or symptoms, clinicians should perform a chest X-ray or computerized tomography to evaluate for infection or neoplasm [Yee, et al. 2020]. Clinicians should also maintain a low threshold for suspicion of tuberculosis (TB) and pursue appropriate diagnostic and public health measures if TB is suspected.

**Hematologic/lymphatic:** Lymphadenopathy may occur at any stage of HIV disease, does not always correlate with disease progression or prognosis, and may be less pronounced in older patients. However, widespread, firm, or asymmetrical lymphadenopathy requires prompt consideration of lymphoma, syphilis, TB, mycobacterium avium-intracellulare infection, and lymphogranuloma venereum, all of which can occur regardless of CD4 cell count but are more likely at lower CD4 cell counts. Nonadherence to ART may also be considered.

Diffuse large B-cell lymphoma, Burkitt lymphoma, and primary central nervous system lymphoma are AIDS-defining conditions; lymphoproliferative diseases, such as Castleman disease, should be considered as well. Any evidence of lymph nodes larger than 1 cm or evidence of fixed, matted, or hard nodes should prompt consideration for biopsy, particularly if a patient has a low CD4 cell count.

**Dermatologic:** An annual comprehensive skin examination ensures that concerns are identified early. Regardless of CD4 cell count, findings such as shingles and psoriasis are more frequent in people with HIV than in those without [Alpalhão, et al. 2019; Erdmann, et al. 2018]. For more information, see National HIV Curriculum: [Cutaneous Manifestations](#).

Attention should be paid to any dermatologic history, such as a history of skin cancers and recurrent rash, that could be consistent with psoriasis, seborrheic dermatitis, atopic dermatitis, eosinophilic folliculitis, or secondary syphilis [Alpalhão, et al. 2019; Green, et al. 1996]. Symptoms can overlap and coexist.

Less common diseases, such as Kaposi sarcoma, eosinophilic folliculitis, disseminated zoster, molluscum contagiosum, and cutaneous HPV, may occur in patients with low CD4 cell counts. Familiarity with these diseases is important.

**Neurologic:** As noted in Checklist 1: HIV-Specific Elements of Health Status and History, above, clinicians should examine patients' neurologic and cognitive function at baseline, at least annually for those at risk (due to low CD4 cell count, age, or comorbidities), and more often if there are patient or family concerns. Several standardized tests are available, including the [MoCA Test](#), [Mini-Cog](#), and [Mini-Mental State Examination](#) (MMSE).

Compared with patients who have higher CD4 cell counts, patients with low CD4 cell counts may be at increased risk of rare neurologic conditions (e.g., progressive multifocal leukoencephalopathy, HIV-associated neurologic disease, toxoplasmosis, and cryptococcal meningitis) and common conditions with atypical presentation, such as syphilis and TB.

Imaging and diagnostic workups are warranted for new or persistent neurologic symptoms (e.g., seizure, changes in mental status, or persistent headache) regardless of CD4 cell count, but especially in patients with a low CD4 cell count.

**Comorbidities:** For patients with comorbidities, such as cardiovascular disease, lung disease, renal disease, diabetes mellitus, and malignancies, personal and family history should be obtained and individual risk factors assessed. Because HIV has been associated with increased risk and accelerated disease process for many comorbidities, care providers should be sure to discuss appropriate screening and have a low threshold for diagnostic testing referral if symptoms develop [Kaspar and Sterling 2017; Triant 2013; Islam, et al. 2012; Shiels, et al. 2011; Bower, et al. 2009; Crothers, et al. 2006]. In individuals taking ART, risk factors such as smoking and hypertension cause more morbidity and mortality than HIV-specific risk factors such as low CD4 cell count [Althoff, et al. 2019; Trickey, et al. 2016; Helleberg, et al. 2015].

History of particular comorbidities may also influence medication choice for patients starting ART. For example, patients with a history of metabolic disease may wish to avoid protease inhibitors, which are associated with central obesity, and patients with risk factors for significant renal disease may wish to avoid TDF. More frequent [adverse effect monitoring](#) may be warranted for patients taking ART or other medications that can affect these conditions [Crum-Cianflone, et al. 2010]. Nonalcoholic steatohepatitis is observed in 30% to 40% of people with HIV [Kaspar and Sterling 2017] and may affect both monitoring and medication choice.

Endocrine conditions, such as metabolic syndrome, insulin resistance, dyslipidemia, lipodystrophy, and osteoporosis, may be worsened by certain antiretroviral medications. A full medication history will help clinicians identify the possibility of ART-associated exacerbation of these conditions [Noubissi, et al. 2018; Gazzaruso, et al. 2003]. Because thyroid disease and hypogonadism occur more often in people with HIV than in those without, a low threshold for screening is appropriate.

**Functional status and aging:** As the population living with HIV ages, frailty, functional, and cognitive assessments are essential. Baseline discussion of memory loss, neuropathic symptoms, and chronic pain can help identify conditions that may affect ART adherence. Nadir CD4 cell count is a predictor of cognitive impairment and disorders [Ellis, et al. 2011]. Collecting structured data through the use of standardized assessments will help clinicians to determine illness course; standardized assessment tools include the [MoCA Test](#), [Mini-Cog](#), and [MMSE](#). An annual assessment of functional status is also indicated. For more information, see the NYSDOH AI [Guidance: Addressing the Needs of Older Patients in HIV Care](#).

**Psychosocial status:** Baseline and annual psychosocial assessments include a detailed sexual, trauma, substance use, and psychiatric history; more frequent assessment may be required for patients who require follow-up in any area. Care providers, particularly those new to HIV care, may initially feel uncomfortable conducting these assessments. Resources are provided below for structured assessments. When possible, a team approach may be helpful and allow for the incorporation of multidisciplinary assessments, including those of a case manager and clinical social worker.

**Sexual health:** Discussion of sexual health, including a patient's STI history at baseline and annually, provides an opportunity to identify a patient's concerns, questions, and knowledge of harm reduction. The frequency of the sexual health assessment is based on risk factors. Use of nonjudgmental, sex-positive language in any discussion of sexual health can facilitate open discussion and therapeutic alliance. Discussion of [U=U \(undetectable = untransmittable\)](#) in the clinical setting may reduce stigma and facilitate discussion of important considerations in sexual health. See the NYSDOH AI [Guidance: Adopting a Patient-Centered Approach to Sexual Health](#) and [GOALS Framework for Sexual History-Taking in Primary Care](#).

**Reproductive status:** Ascertainment of a patient's reproductive history and goals, including plans for conception in patients of childbearing potential, can facilitate discussion of contraception needs and current strategies to eliminate perinatal HIV transmission. The risk of perinatal transmission is less than 1% when patients are virally suppressed [Ioannidis, et al. 2001]. For patients who are pregnant or planning pregnancy, care providers should discuss appropriate preconception planning, including folate use, medication safety, and plans for breastfeeding, as well as the risk to a partner without HIV if the patient has a detectable viral load. Provide education about HIV [post- and pre-exposure prophylaxis](#) as appropriate.

Menopause, whether natural or surgical, has been associated with increased fatigue and muscle aches or pains in people with HIV [Schnall, et al. 2018].



## Laboratory and Diagnostic Testing

### Checklist 2: Initial (Baseline) and Annual Laboratory Testing for Adults With HIV

Also see clinical comments in [Table 1: Clinical Comments on Recommended Laboratory Testing for Adults With HIV](#)

#### Initial AND Annual Testing

- HIV-1 RNA quantitative viral load
- CD4 lymphocyte count (optional to repeat annually if CD4 count >350 cells/mm<sup>3</sup>)
- CBC
- CMP, including eGFR, hepatic panel (AST, ALT, ALP, total bilirubin), fasting random blood glucose
- Lipid panel
- Hepatitis screening, including anti-HAV-IgG, HBsAg, HBsAb, HbCAb [a], and HCV Ab. Repeat testing is not necessary with documented HAV or HBV immunity.
- HCV viral load if previous positive HCV Ab or treatment for HCV. Repeat annually or as indicated for patients with ongoing exposure risk.
- Gonorrhea and chlamydia: Perform baseline NAAT at oral, anal, urethral, and cervical sites for MSM, transgender women, and others as indicated by individual exposure. Repeat annually or as indicated for patients with ongoing risk of exposure.
- Syphilis: Use the same laboratory consistently; in New York State, the [syphilis screening reverse algorithm](#) is the preferred testing method. Repeat annually or as indicated for patients with ongoing risk of exposure.
- TB screening: Obtain IGRA TB test (such as T-SPOT or QuantiFERON-TB) or, if IGRA is not available, tuberculin skin test (commonly known as PPD) at baseline for diagnosis of latent TB infection, unless the patient has previously tested positive for or has documented TB. Repeat annually for patients at risk (e.g., unstable housing, incarceration, travel, immigration).
- Trichomonas: All sexually active patients with a vagina with ongoing risk of exposure. Repeat annually or as indicated.
- Urinalysis
- Serum TSH

**Abbreviations:** Ab, antibody; Ag, antigen; ALP, alkaline phosphatase; ALT, alanine aminotransferase; AST, aspartate aminotransferase; c, core; CBC, complete blood count; CMP, comprehensive metabolic panel; CMV, cytomegalovirus; eGFR, estimated glomerular filtration rate; G6PD, glucose-6-phosphate dehydrogenase; HAV, hepatitis A virus; HBV, hepatitis B virus; HCV, hepatitis C virus; IgG, immunoglobulin; IGRA, interferon-gamma release assay; MSM, men who have sex with men; NAAT, nucleic acid amplification test; PCR, polymerase chain reaction; PPD, purified protein derivative; s, surface; TB, tuberculosis; TSH, thyroid stimulating hormone.

#### Notes:

- a. If HBsAg-positive, perform an HBV DNA viral load test.
- b. Repeat if a patient experiences ART failure; consult with an experienced HIV care provider as needed.
- c. Screen for deficiency to avoid the use of oxidant drugs, including dapsone, primaquine, and sulfonamides. Prevalence of G6PD deficiency is highest among people of African, Asian, or Mediterranean descent, but consider for all patients given the diversity of backgrounds.

#### Initial Testing Only (unless otherwise indicated):

- [HIV-1/2 Ag/Ab](#) if not already performed
- HIV-1 genotypic resistance testing [b]
- G6PD [c]
- Measles titer
- Varicella titer
- Urine pregnancy test as needed

**If Clinically Appropriate** (i.e., the patient is symptomatic or has a CD4 count <200 cells/mm<sup>3</sup>):

- CMV PCR
- Toxoplasma titers
- Histoplasma titers
- Cryptococcal Ag

Table 1, below, provides additional clinical information to supplement the checklist above.

<b>Table 1: Clinical Comments on Recommended Laboratory Testing for Adults With HIV</b>	
<b>Laboratory Test</b>	<b>Comments</b>
HIV-1 RNA quantitative viral load	<ul style="list-style-type: none"> <li>Regular monitoring is the most accurate and meaningful measure of effective ART.</li> <li>Check every 3 to 6 months during years 1 and 2, and every 4 to 6 months thereafter.</li> <li>Monitor every 1 to 3 months if adherence is inconsistent or the patient has a detectable viral load.</li> <li>See NYSDOH AI guideline <a href="#">Virologic and Immunologic Monitoring in HIV Care</a>.</li> </ul>
CD4 lymphocyte count	<ul style="list-style-type: none"> <li>Check every 3 to 6 months if CD4 count &lt;200 cells/mm<sup>3</sup>; not indicated if viral load is consistently undetectable (CD4 count ≥200 cells/mm<sup>3</sup>).</li> <li>Monitor every 3 months if the HIV diagnosis is recent (&lt;2 years), viral load suppression is inconsistent, or CD4 count is close to or below 200 cells/mm<sup>3</sup>.</li> <li>For patients not taking ART, check CD4 cell count every 4 to 6 months.</li> <li>See NYSDOH AI guideline <a href="#">Virologic and Immunologic Monitoring in HIV Care</a>.</li> </ul>
HIV-1 resistance testing (genotypic)	<ul style="list-style-type: none"> <li>Perform at treatment initiation.</li> <li>Perform if HIV RNA (viral load) is ≥500 copies/mL; archive genotype may be considered if viral load is &lt;500 copies/mL.</li> <li>Consult with an expert in HIV care in the event of treatment failure.</li> <li>See NYSDOH AI guideline <a href="#">HIV Resistance Assays</a>.</li> </ul>
G6PD	<ul style="list-style-type: none"> <li>Screen for deficiency to avoid complications from the use of oxidant drugs, including dapsone, primaquine, and sulfonamides when starting dapsone or other oxidant drug.</li> <li>Prevalence of G6PD deficiency is highest among people of African, Asian, or Mediterranean descent, but should be considered in all patients given the diversity of backgrounds.</li> </ul>
CBC	<ul style="list-style-type: none"> <li>For patients who are <i>not</i> taking ZDV, check at ART initiation, and repeat as clinically indicated.</li> <li>For patients who <i>are</i> taking ZDV, check at initiation and 4 weeks after; follow every 3 months for the first year, then every 6 months.</li> <li>Consider CBC with any change in medication.</li> </ul>
Estimated glomerular filtration rate	<ul style="list-style-type: none"> <li>For patients who <i>are</i> taking TAF or TDF, check at initiation, then repeat at 4 weeks, 3 months, 6 months, and 12 months for the first year, then every 6 months thereafter.</li> <li>For patients who are <i>not</i> taking TDF, check at initiation, at 6 months during the first year, then annually thereafter.</li> <li>Check after initiation of medication with risk for renal disease (e.g., NSAIDs, ACE inhibitors).</li> <li>Check in patients with a history of diabetes or other renal diseases.</li> </ul>
Hepatic panel	<ul style="list-style-type: none"> <li>Check 3 months after initiating ART or medications with risk for liver disease (e.g., statins, azoles), or if there is a history of viral hepatitis, and then at 12 months.</li> <li>Check every year if a patient is stable and without the above risks.</li> </ul>
Random blood glucose (fasting or hemoglobin A1C if high)	<ul style="list-style-type: none"> <li>Check yearly if a patient has risk factors for diabetes (family history, obesity, use of PIs or INSTIs).</li> <li>If abnormal, repeat random glucose as a fasting glucose or A1C.</li> <li>Results are used to diagnose diabetes [Thompson, et al. 2021].</li> </ul>

<b>Table 1: Clinical Comments on Recommended Laboratory Testing for Adults With HIV</b>	
<b>Laboratory Test</b>	<b>Comments</b>
TB screening	<ul style="list-style-type: none"> <li>Obtain IGRA TB test (such as T-SPOT or QuantiFERON-TB) or, if IGRA is not available, tuberculin skin test (commonly known as PPD), at baseline for diagnosis of latent TB infection, unless the patient has previously tested positive for or has documented TB.</li> <li>Repeat annually for patients at risk (e.g., unstable housing, incarceration, travel, immigration).</li> <li>Recommend preventive therapy for patients with positive TB skin testing, including positive IGRA or <math>\geq 5</math> mm reaction to PPD (see CDC: <a href="#">TB Treatment for Persons with HIV</a> and DHHS: <a href="#">Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents With HIV &gt; Mycobacterium tuberculosis Infection and Disease</a>).</li> </ul>
HAV	<ul style="list-style-type: none"> <li>Repeat once after vaccination to ensure immunity.</li> <li>See NYSDOH AI guideline <a href="#">Prevention and Management of Hepatitis A Virus Infection in Adults With HIV &gt; Transmission and Prevention</a> for testing and vaccination recommendations.</li> </ul>
HBV	<ul style="list-style-type: none"> <li>If HBsAg-positive, perform an HBV DNA viral load test.</li> <li>Repeat the anti-HBs test once after vaccination to ensure immunity.</li> <li>See NYSDOH AI guideline <a href="#">Prevention and Management of Hepatitis B Virus Infection in Adults With HIV &gt; HBV Screening and Diagnosis</a> and <a href="#">HBV Vaccination</a> for testing and vaccination recommendations.</li> </ul>
HCV	<ul style="list-style-type: none"> <li>If a patient was previously treated for HCV or is antibody-positive, perform an HCV viral load test.</li> <li>Check at entry to care; repeat as clinically indicated for patients with exposure risk.</li> <li>See NYSDOH AI guideline <a href="#">Hepatitis C Virus Screening, Testing, and Diagnosis in Adults &gt; HCV Testing Sequence and Diagnosis</a>.</li> </ul>
Measles titer	Vaccinate if the patient is not immune and has a CD4 count $>200$ cells/mm <sup>3</sup> .
Varicella titer	<ul style="list-style-type: none"> <li>For patients with no evidence of immunity and CD4 count <math>&gt;200</math> cells/mm<sup>3</sup>, consider vaccination for chicken pox (Varivax; 2 doses, 3 months apart); engage patients in shared decision-making, taking into consideration the potential risks of a live vaccine.</li> <li>Live vaccines are contraindicated for patients with CD4 counts <math>&lt;200</math> cells/mm<sup>3</sup>.</li> <li>For patients aged <math>\geq 19</math> years, regardless of varicella titer status or CD4 cell count, recommend vaccination for herpes zoster with recombinant zoster virus (Shingrix; 2 doses, 2 to 6 months apart).</li> </ul>
Urinalysis	<ul style="list-style-type: none"> <li>Check yearly to evaluate for proteinuria.</li> <li>Check if symptoms of UTI or change in creatinine or other urinary symptoms (including glucosuria for patients on tenofovir).</li> <li>See NYSDOH AI guideline <a href="#">Laboratory Monitoring for Adverse Effects of ART</a>.</li> </ul>
Urine pregnancy test	<ul style="list-style-type: none"> <li>Perform for all individuals of childbearing potential who are sexually active.</li> <li>Repeat upon patient request.</li> </ul>
Lipid panel	<ul style="list-style-type: none"> <li>Perform at least every 3 years if a patient has increased risk for CVD.</li> <li>Consider annual screening if a patient is taking PIs.</li> <li>For adults aged <math>&gt;75</math> years, initiate discussion of possible benefits of age-appropriate preventive therapies in the context of comorbidities and life expectancy.</li> <li>HIV is considered a risk-enhancing factor for CVD; clinicians may opt to perform more frequent lipid testing in patients with cardiovascular comorbidities.</li> </ul>

Table 1: Clinical Comments on Recommended Laboratory Testing for Adults With HIV	
Laboratory Test	Comments
Serum TSH	<ul style="list-style-type: none"> <li>Insufficient evidence exists for routine screening of nonpregnant adults.</li> <li>Adults with HIV have a higher incidence of thyroid dysfunction than those without HIV. Discuss annual screening (see USPSTF: <a href="#">Thyroid Dysfunction: Screening</a>).</li> </ul>
Gonorrhea and chlamydia	<ul style="list-style-type: none"> <li>Perform baseline NAAT at oral, anal, urethral, and cervical sites for MSM, transgender women, and others as indicated by individual exposure.</li> <li>Repeat based on risk factors and sites of exposure.</li> <li>Repeat every 3 months for sexually active MSM and transgender women (see NYSDOH <a href="#">STI self-collection outside of a clinic setting in New York State Question &amp; Answer</a>).</li> <li>See <a href="#">CDC: Sexually Transmitted Infections Treatment Guidelines, 2021 &gt; Gonococcal Infections Among Adolescents and Adults</a>.</li> </ul>
Syphilis	<ul style="list-style-type: none"> <li>Use the same laboratory test consistently.</li> <li>Repeat at least annually</li> <li>Repeat every 3 months for patients with risk of exposure (e.g., MSM) (see NYSDOH <a href="#">STI self-collection outside of a clinic setting in New York State Question &amp; Answer</a>).</li> </ul>
Trichomonas	Perform screening test if the patient has a vagina and is sexually active.
HLA-B*5701	Must be performed before initiation of abacavir, otherwise not routine.

**Abbreviations:** ACE, angiotensin-converting enzyme; Ag, antigen; ART, antiretroviral therapy; CBC, complete blood count; CDC, Centers for Disease Control and Prevention; CVD, cardiovascular disease; DHHS, U.S. Department of Health and Human Services; G6PD, glucose-6-phosphate dehydrogenase; HAV, hepatitis A virus; HBV, hepatitis B virus; HCV, hepatitis C virus; IGRA, interferon-gamma release assay; INSTI, integrase strand transfer inhibitor; MSM, men who have sex with men; NAAT, nucleic acid amplification test; NSAID, non-steroidal anti-inflammatory drugs; PI, protease inhibitor; PPD, purified protein derivative; s, surface; STI, sexually transmitted infection; TAF, tenofovir alafenamide; TB, tuberculosis; TDF, tenofovir disoproxil fumarate; TSH, thyroid stimulating hormone; UTI, urinary tract infection; ZDV, zidovudine.

Table 2: Interpretation of HBV Screening Test Results				
HBsAg	Anti-HBs	Anti-HBc		Interpretations
		IgG	IgM	
Negative	Negative	Negative	Negative	Susceptible to HBV infection
Negative	Positive	Negative	Negative	Immune due to HBV vaccination
Negative	Positive	Positive	Negative	Immune due to natural HBV infection
Positive	Negative	Positive	Positive	Acute HBV infection
Positive	Negative	Positive	Negative/Positive	Chronic HBV infection
Negative	Negative	Positive	Negative/Positive	Isolated anti-HBc positivity [a]. Possible interpretations: <ul style="list-style-type: none"> <li>Resolved HBV infection with waning anti-HBs titers</li> <li>False-positive result</li> <li>Occult HBV infection</li> <li>Resolving acute HBV infection</li> </ul>

**Abbreviations:** anti-HBc, hepatitis B core antibody; anti-HBs, hepatitis B surface antibody; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; IgG, immunoglobulin G; IgM, immunoglobulin M.

**Note:**  
a. See NYSDOH AI guideline [Prevention and Management of Hepatitis B Virus Infection in Adults With HIV > HBV Vaccination](#).

<b>Table 3: Interpretation of HCV Test Results [a]</b>			
<b>Anti-HCV</b>	<b>HCV RNA</b>	<b>Interpretations</b>	<b>Response</b>
Positive	Detected	Acute or chronic HCV infection	Evaluate for treatment
Positive	Not detected	<ul style="list-style-type: none"> <li>Resolution of HCV by spontaneous or treatment-related clearance, <i>or</i></li> <li>HCV infection during a period of intermittent viremia, <i>or</i></li> <li>False-positive antibody screening result</li> </ul>	<ul style="list-style-type: none"> <li>Perform HCV RNA testing based on risk factors</li> <li>Repeat HCV RNA testing if acute exposure is known or suspected</li> </ul>
Negative	Detected	<ul style="list-style-type: none"> <li>Early acute HCV infection, <i>or</i></li> <li>Chronic HCV infection in immunosuppressed patients</li> </ul>	<ul style="list-style-type: none"> <li>Evaluate for treatment if a patient has risk factors</li> <li>Repeat testing if a patient has no risk factors or exposure and a false-positive result is suspected</li> </ul>
Negative	Unknown	Presumed absence of HCV infection if the HCV RNA testing was not performed or the status is unknown	Perform HCV antibody testing based on risk factors

**Abbreviation:** HCV, hepatitis C virus.

**Note:**

a. Adapted from [CDC 2013]. For more information about interpreting HCV test results, see [Association of Public Health Laboratories: Interpretation of Hepatitis C Virus Test Results: Guidance for Laboratories](#).

## Routine Screening and Primary Prevention

In patients with HIV, age- and risk-based screening and prevention are cornerstones of adult primary care, and for the most part, the standard recommendations are the same as for adults who do not have HIV. Notable exceptions include anal and cervical dysplasia and other STI screening.

**Anatomical inventory:** In addition to all elements of a standard patient history and physical examination, an anatomical inventory is necessary to avoid defining primary care needs based on a patient’s gender expression. A matter-of-fact anatomical inventory will identify present and absent organs: penis, testes, prostate, breasts, vagina, cervix, uterus, and ovaries.

<b>Checklist 3: Recommended Age-, Sex-, and Risk-Based Screening (alphabetical order)</b>
<ul style="list-style-type: none"> <li><input type="checkbox"/> <b>Abdominal aortic aneurysm:</b> See <a href="#">USPSTF recommendations (2019)</a> <ul style="list-style-type: none"> <li>Screen cisgender men and transgender women aged 65 to 75 years who have a history of smoking.</li> <li>Evidence is insufficient to recommend screening for cisgender women and transgender men.</li> </ul> </li> <li><input type="checkbox"/> <b>Anal dysplasia and cancer:</b> See <a href="#">NYSDOH AI recommendations (2022)</a> <ul style="list-style-type: none"> <li>Recommendations are specific to adults with HIV.</li> <li>Screen MSM, cisgender and transgender women, and transgender men who are aged ≥35 years.</li> </ul> </li> <li><input type="checkbox"/> <b>Bone density/osteoporosis:</b> See <a href="#">USPSTF recommendations (2018)</a> <ul style="list-style-type: none"> <li>Some experts [Thompson, et al. 2021; Aberg, et al. 2014] recommend baseline bone densitometry screening for osteoporosis in postmenopausal cisgender women and in cisgender men and transgender women aged ≥50 years who have HIV.</li> <li>Also see NYSDOH AI guideline <a href="#">Selecting an Initial ART Regimen &gt; Special Considerations for Comorbid Conditions</a>.</li> </ul> </li> <li><input type="checkbox"/> <b>Breast cancer:</b> See <a href="#">USPSTF recommendations (2024)</a> <ul style="list-style-type: none"> <li>An anatomical inventory is necessary to identify appropriate sex-based screening; this committee advises clinicians to screen for breast cancer in transgender and transfeminine men and cisgender females.</li> <li>Screen all women and transgender men aged 40 to 74 years.</li> <li>Evidence of benefit is insufficient for patients who are aged &gt;74 years.</li> <li>Also see <a href="#">USPSTF: BRCA-Related Cancer: Risk Assessment, Genetic Counseling, and Genetic Testing (2019)</a>.</li> </ul> </li> </ul>

### Checklist 3: Recommended Age-, Sex-, and Risk-Based Screening (alphabetical order)

- **Cardiovascular disease:** See [American College of Cardiology: ASCVD Risk Estimator Plus](#) and [American Heart Association: Characteristics, Prevention, and Management of Cardiovascular Disease in People Living With HIV \(2019\)](#)
  - Estimate the 10-year ASCVD risk at the initial visit and reassess during follow-up visits to incorporate risk factor changes over time. Note that the ASCVD Risk Estimator Plus may underestimate cardiovascular risk for women and people of color [Grinspoon, et al. 2024].
  - For recommendations on age-based statin initiation, risk assessment, statin-associated risks, and shared decision-making, see DHHS: [Guidelines for the Use of Antiviral Agents in Adults and Adolescents With HIV > Recommendations for the Use of Statin Therapy as Primary Prevention of Atherosclerotic Cardiovascular Disease in People with HIV](#).
- **Cervical dysplasia and cancer:** See [NYSDOH AI recommendations \(2022\)](#)
  - Recommendations are specific to adults with HIV; an anatomical inventory is necessary to identify appropriate sex-based screening.
  - Begin screening within 2 years of onset of sexual activity or by age 21.
  - Continue screening for patients aged ≥65 years; however, consider life expectancy and risk in shared decision-making with patients regarding continued screening.
- **Colorectal cancer:** See [USPSTF recommendations \(2021\)](#)
  - Screen patients aged 45 to 75 years; frequency depends on the screening method.
  - Confirm annually that appropriate testing has been completed.
  - In patients who are aged >75 years, the decision to perform screening should be individualized.
- **Depression:** See [USPSTF recommendations \(2023\)](#)
  - Screen for depression, with adequate systems in place to ensure accurate diagnosis, effective treatment, and appropriate follow-up.
  - Also see [PHQ-2](#); [PHQ-9](#); [Columbia-Suicide Severity Rating Scale](#).
- **Intimate partner violence, elder abuse, and abuse of vulnerable adults:** See [USPSTF recommendations \(2018\)](#)
  - Screen for domestic violence, including intimate partner violence, child abuse, and elder abuse.
- **Lung cancer:** See [USPSTF recommendations \(2021\)](#)
  - Screen patients aged 55 to 80 years who have a 20-pack-year history and currently smoke or have quit within the past 15 years.
- **Prostate cancer:** See [USPSTF recommendations \(2018\)](#)
  - An anatomical inventory is necessary to identify appropriate sex-based screening.
  - In patients who are aged 55 to 69 years, the decision to perform screening should be individualized.
  - Engage in shared decision-making for patients who are aged ≥70 years.
- **Substance use:** See [NYSDOH AI recommendations \(2024\)](#)
  - Screen all adults for alcohol, tobacco, and drug use; assess the level of risk and treat as indicated.
  - Laboratory screening is not recommended.

**Abbreviations:** ASCVD, atherosclerotic cardiovascular disease; BRCA, breast cancer; DHHS, U.S. Department of Health and Human Services; MSM, men who have sex with men; PHQ, Patient Health Questionnaire; USPSTF, U.S. Preventive Services Task Force.

### Checklist 4: Primary Prevention for Adults With HIV (alphabetical order)

- **Breast cancer:** See [USPSTF recommendations \(2019\)](#)
  - An anatomical inventory is necessary to identify appropriate sex-based prevention.
  - Risk-reducing medications, such as tamoxifen, raloxifene, or aromatase inhibitors, are recommended for women who are at increased risk of breast cancer and low risk of medication-related adverse effects.
  - Routine preventive medication is not recommended for women who are not at increased risk.
- **Cardiovascular disease:** See:
  - [Aspirin Use to Prevent Cardiovascular Disease: Preventive Medication](#) (USPSTF 2022)
  - [Guidelines for the Use of Antiviral Agents in Adults and Adolescents With HIV > Recommendations for the Use of Statin Therapy as Primary Prevention of Atherosclerotic Cardiovascular Disease in People with HIV](#) (DHHS 2024)
  - [Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medication](#) (USPSTF 2022)
  - [Healthy Diet and Physical Activity for Cardiovascular Disease Prevention in Adults With Cardiovascular Risk Factors: Behavioral Counseling Interventions](#) (USPSTF 2020)

**Checklist 4: Primary Prevention for Adults With HIV (alphabetical order)**

- **Falls prevention:** See [USPSTF recommendations \(2024\)](#)
  - Exercise interventions are recommended to prevent falls in community-dwelling adults 65 years or older who are at increased risk for falls.
  - Note: This committee advises clinicians to include osteoporosis screening.
- **Neural tube defects:** See [USPSTF recommendations \(2023\)](#)
  - Folic acid supplementation is recommended for individuals who are planning or capable of pregnancy.
  - An anatomical inventory is necessary to identify appropriate sex-based prevention.
- **Sexually transmitted infections:** Discuss [recommended vaccinations](#). See:
  - [Behavioral counseling recommendations](#) (USPSTF 2020)
  - NYSDOH AI guideline [Doxycycline Post-Exposure Prophylaxis to Prevent Bacterial Sexually Transmitted Infections](#)
  - CDC: [Sexually Transmitted Infections Treatment Guidelines, 2021 > Primary Prevention Methods](#)
  - Note: An anatomical inventory is necessary to identify appropriate sex-based prevention.
- **Skin cancer:** See [USPSTF recommendations \(2018\)](#)
  - Counsel patients to minimize exposure to ultraviolet radiation.
- **Smoking:** See [USPSTF recommendations \(2021\)](#)
  - Screen all adults for tobacco use. Recommend cessation. Provide behavioral interventions and FDA-approved pharmacologic therapy.
  - Also see [Millionhearts.hhs.gov: Protocol for Identifying and Treating Patients Who Use Tobacco](#), [Identifying and Treating Patients Who Use Tobacco: Action Steps for Clinicians](#), and [Tobacco Cessation Change Package](#)

**Abbreviations:** CDC, Centers for Disease Control and Prevention; DHHS, U.S. Department of Health and Human Services; FDA, U.S. Food and Drug Administration; USPSTF, U.S. Preventive Services Task Force.

## Opportunistic Infection Prevention

The incidence of and mortality related to OIs have decreased since the early days of the HIV epidemic, but OIs remain a concern [Masur 2015]. Although the median initial CD4 cell count in individuals newly diagnosed with HIV has risen through the years [NYSDOH 2019], a significant number of people have low CD4 cell counts at HIV diagnosis and are at risk for OIs [Tominski, et al. 2017; Ransome, et al. 2015]. Clinicians who care for patients with HIV should be able to identify common OIs and know when to provide and discontinue appropriate prophylaxis (see Table 4, below, and DHHS: [Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents With HIV](#)).

**Table 4: Opportunistic Infection Prophylaxis for Adults With HIV [a]**

Opportunistic Infection	Indications for Initiation and Discontinuation of Primary Prophylaxis	Preferred and Alternative Agent(s)	Indications for Discontinuation of Secondary Prophylaxis
<b>Cryptococcosis</b>	Primary prophylaxis is not routinely recommended.	N/A	<ul style="list-style-type: none"> <li>• Taking fully suppressive ART and CD4 count <math>\geq 100</math> cells/mm<sup>3</sup></li> <li>• Completed initial therapy, maintenance therapy for 1 year, and asymptomatic for cryptococcal infection</li> </ul>
<b>Cytomegalovirus</b>	Primary prophylaxis is not routinely recommended.	N/A	<ul style="list-style-type: none"> <li>• Taking ART and CD4 count <math>&gt; 100</math> cells/mm<sup>3</sup> for <math>&gt; 3</math> to 6 months</li> <li>• Completed 3 to 6 months of CMV treatment</li> <li>• No evidence of active disease</li> <li>• Engaged in routine ophthalmologic examination</li> </ul>

**Table 4: Opportunistic Infection Prophylaxis for Adults With HIV [a]**

Opportunistic Infection	Indications for Initiation and Discontinuation of Primary Prophylaxis	Preferred and Alternative Agent(s)	Indications for Discontinuation of Secondary Prophylaxis
<b><i>Mycobacterium avium</i> complex</b>	<b>Initiation:</b> Use only if CD4 count is <50/cells/mm <sup>3</sup> and patient does not initiate ART. Not recommended for individuals who are initiating ART or are taking ART and have an undetectable viral load. <b>Discontinuation:</b> Taking fully suppressive ART	<b>Preferred:</b> Azithromycin (weekly) or clarithromycin (twice daily)	<ul style="list-style-type: none"> <li>• Taking ART and CD4 count &gt;100 cells/mm<sup>3</sup> for &gt;6 months</li> <li>• At least 12 months of MAC treatment completed [b]</li> <li>• Asymptomatic for MAC</li> </ul>
<b><i>Pneumocystis jirovecii</i> pneumonia</b> (formerly <i>Pneumocystis carinii</i> pneumonia)	<b>Initiation:</b> CD4 count <200 cells/mm <sup>3</sup> (or <14%) or history of oropharyngeal candidiasis <b>Discontinuation:</b> Taking ART and CD4 count ≥200 cells/mm <sup>3</sup> for ≥3 months	<b>Preferred:</b> TMP/SMX single strength once daily <b>Alternatives:</b> <ul style="list-style-type: none"> <li>• TMP/SMX double strength every other day</li> <li>• Dapsone [c]</li> <li>• Dapsone [c] plus pyrimethamine plus leucovorin</li> <li>• Atovaquone</li> <li>• Aerosolized pentamidine</li> </ul>	<ul style="list-style-type: none"> <li>• Taking ART and CD4 count &gt;200 cells/mm<sup>3</sup> for &gt;3 months</li> <li>• Adequate viral suppression</li> <li>• Continue prophylaxis if PJP occurs with CD4 count &gt;200 cells/mm<sup>3</sup> (or &lt;14%)</li> <li>• Consider stopping prophylaxis if viral load is suppressed and CD4 count is stably &gt;100 to 200 cells/mm<sup>3</sup> for 3 to 6 months</li> </ul>
<b><i>Toxoplasma gondii</i> encephalitis [b,d]</b>	<b>Initiation:</b> CD4 count <100 cells/mm <sup>3</sup> and positive serology for <i>Toxoplasma gondii</i> (IgG+) <b>Discontinuation:</b> Taking ART and CD4 count >200 cells/mm <sup>3</sup> for >3 months	<b>Preferred:</b> TMP/SMX double strength once daily <b>Alternatives:</b> <ul style="list-style-type: none"> <li>• TMP/SMX double strength every other day</li> <li>• TMP/SMX single strength once daily</li> <li>• Dapsone [c] plus pyrimethamine plus leucovorin</li> <li>• Atovaquone with or without pyrimethamine plus leucovorin</li> </ul>	<ul style="list-style-type: none"> <li>• Taking ART and CD4 count &gt;200 cells/mm<sup>3</sup> for &gt;6 months</li> <li>• Initial therapy completed</li> <li>• Asymptomatic for TE</li> </ul>

**Abbreviations:** ART, antiretroviral therapy; G6PD, glucose-6-phosphate dehydrogenase; IgG, immunoglobulin G; MAC, *Mycobacterium avium* complex; PJP, *Pneumocystis jirovecii* pneumonia; TE, *Toxoplasma gondii* encephalitis; TMP/SMX, trimethoprim/sulfamethoxazole.

**Notes:**

- Source: U.S. Department of Health and Human Services: [Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents With HIV](#)
- Obtaining blood cultures or bone marrow cultures may be advisable to ascertain disease activity.
- Screen for G6PD deficiency before initiating dapsone.
- Lifelong prophylaxis to prevent recurrence is indicated in adults or adolescents with a childhood history of toxoplasmosis.

## Oral Health

*Dental Standards of Care Committee, May 2016*

Oral health care is a critical component of comprehensive HIV medical management. Development of oral pathology is frequently associated with an underlying progression of HIV disease status. A thorough soft-tissue examination may reveal pathology associated with dysphagia or odynophagia. Dental problems can result in or exacerbate nutritional problems. In



addition, psychosocial and quality of life issues frequently are associated with the condition of the oral cavity and the dentition.

**Medications and oral health:** Many of the medications taken by patients with HIV have adverse effects that may manifest in the oral cavity. Potential adverse effects include the following:

- Candidal growth: Antibiotics may cause or exacerbate
- Xerostomia: Antihistamines, antidepressants, antipsychotics, antihypertensives, and anticholinergic agents
- Increased risk of dental caries: Clotrimazole troches and nystatin suspension pastilles (contain sugar)
- Gingival hyperplasia: Phenytoin
- Oral ulcers: Zalcitabine (DDC)

**Selected good practices:**

- **Dental care referral:** Include as part of every primary healthcare initial visit; semiannual oral healthcare visits are essential to dental prophylaxis and other appropriate preventive care. In the later stages of HIV disease, greater numbers of oral lesions and aggressive periodontal breakdown are more likely and may necessitate oral healthcare visits more frequently than twice per year.
- **Oral examination:** Include a visual examination and palpation of the patient's lips, labial and buccal mucosa, all surfaces of the tongue and palate, and floor of the mouth in the overall physical examination performed during a primary care visit. The gingiva should be examined for signs of erythema, ulceration, or recession. Refer patients found to have oral mucosal, gingival, or dental lesions to an oral health care provider as soon as possible for appropriate diagnostic evaluation and treatment.
- **Oral care education:** Include preventive oral health care in primary care patient education to stress the importance of regular dental visits, brushing, flossing, and the use of fluorides and antimicrobial rinses.

## All Recommendations

### ☑ ALL RECOMMENDATIONS: PRIMARY CARE FOR ADULTS WITH HIV

#### Approach to Care

- Based on the type of visit and a patient's diagnostic and HIV status, clinicians should use one of the flowcharts listed below to guide assessment, care planning, and follow-up (A\*):
  - [Initial Visit: New Patient, New HIV Diagnosis, NOT Taking ART](#)
  - [Initial Visit: New Patient, HIV Confirmed, IS Taking ART](#)
  - [Initial Visit: New Patient, HIV Confirmed, NOT Taking ART](#)
  - [Annual, Routine, New Illness, or Post-Hospitalization Visit: Established Patient Who IS Taking ART](#)
  - Also see the NYSDOH AI [Guidance: Addressing the Needs of Older Patients in HIV Care](#)
- In providing primary care for adults with HIV, clinicians should follow standard best practices for adult primary care and should add the HIV-specific care elements noted in this guideline. (A3)
- Clinicians should engage patients in shared decision-making regarding routine health screening tests, weighing the risks and benefits of screening based on such factors as life expectancy, cost, potential harms, and HIV-compounded risk. (A3)

#### Opportunistic Infection Prophylaxis

- Clinicians should initiate prophylaxis for specific OIs and discontinue prophylaxis as indicated in [Table 4: Opportunistic Infection Prophylaxis for Adults With HIV](#). (A\*)
- Clinicians may discontinue primary OI prophylaxis in patients who are taking effective ART and have evidence of immune recovery. (A\*)

**Abbreviations:** ART, antiretroviral therapy; OI, opportunistic infection.

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# Supplement: Guideline Development and Recommendation Ratings

**Table S1: Guideline Development: New York State Department of Health AIDS Institute Clinical Guidelines Program**

<b>Developer</b>	<a href="#">New York State Department of Health AIDS Institute (NYSDOH AI) Clinical Guidelines Program</a>
<b>Funding source</b>	NYSDOH AI
<b>Program manager</b>	Clinical Guidelines Program, Johns Hopkins University School of Medicine, Division of Infectious Diseases. See <a href="#">Program Leadership and Staff</a> .
<b>Mission</b>	To produce and disseminate evidence-based, state-of-the-art clinical practice guidelines that establish uniform standards of care for practitioners who provide prevention or treatment of HIV, viral hepatitis, other sexually transmitted infections, and substance use disorders for adults throughout New York State in the wide array of settings in which those services are delivered.
<b>Expert committees</b>	The NYSDOH AI Medical Director invites and appoints committees of clinical and public health experts from throughout New York State to ensure that the guidelines are practical, immediately applicable, and meet the needs of care providers and stakeholders in all major regions of New York State, all relevant clinical practice settings, key New York State agencies, and community service organizations.
<b>Committee structure</b>	<ul style="list-style-type: none"> <li>• Leadership: AI-appointed chair, vice chair(s), chair emeritus, clinical specialist(s), JHU Guidelines Program Director, AI Medical Director, AI Clinical Consultant, AVAC community advisor</li> <li>• Contributing members</li> <li>• Guideline writing groups: Lead author, coauthors if applicable, and all committee leaders</li> </ul>
<b>Disclosure and management of conflicts of interest</b>	<ul style="list-style-type: none"> <li>• Annual disclosure of financial relationships with commercial entities for the 12 months prior and upcoming is required of all individuals who work with the guidelines program, and includes disclosure for partners or spouses and primary professional affiliation.</li> <li>• The NYSDOH AI assesses all reported financial relationships to determine the potential for undue influence on guideline recommendations and, when indicated, denies participation in the program or formulates a plan to manage potential conflicts. Disclosures are listed for each committee member.</li> </ul>
<b>Evidence collection and review</b>	<ul style="list-style-type: none"> <li>• Literature search and review strategy is defined by the guideline lead author based on the defined scope of a new guideline or update.</li> <li>• A comprehensive literature search and review is conducted for a new guideline or an extensive update using PubMed, other pertinent databases of peer-reviewed literature, and relevant conference abstracts to establish the evidence base for guideline recommendations.</li> <li>• A targeted search and review to identify recently published evidence is conducted for guidelines published within the previous 3 years.</li> <li>• Title, abstract, and article reviews are performed by the lead author. The JHU editorial team collates evidence and creates and maintains an evidence table for each guideline.</li> </ul>
<b>Recommendation development</b>	<ul style="list-style-type: none"> <li>• The lead author drafts recommendations to address the defined scope of the guideline based on available published data.</li> <li>• Writing group members review the draft recommendations and evidence and deliberate to revise, refine, and reach consensus on all recommendations.</li> <li>• When published data are not available, support for a recommendation may be based on the committee’s expert opinion.</li> <li>• The writing group assigns a 2-part rating to each recommendation to indicate the strength of the recommendation and quality of the supporting evidence. The group reviews the evidence, deliberates, and may revise recommendations when required to reach consensus.</li> </ul>

**Table S1: Guideline Development: New York State Department of Health AIDS Institute Clinical Guidelines Program**

<b>Review and approval process</b>	<ul style="list-style-type: none"> <li>• Following writing group approval, draft guidelines are reviewed by all contributors, program liaisons, and a volunteer reviewer from the AI Community Advisory Committee.</li> <li>• Recommendations must be approved by two-thirds of the full committee. If necessary to achieve consensus, the full committee is invited to deliberate, review the evidence, and revise recommendations.</li> <li>• Final approval by the committee chair and the NYSDOH AI Medical Director is required for publication.</li> </ul>
<b>External reviews</b>	<ul style="list-style-type: none"> <li>• External review of each guideline is invited at the developer’s discretion.</li> <li>• External reviewers recognized for their experience and expertise review guidelines for accuracy, balance, clarity, and practicality and provide feedback.</li> </ul>
<b>Update process</b>	<ul style="list-style-type: none"> <li>• JHU editorial staff ensure that each guideline is reviewed and determined to be current upon the 3-year anniversary of publication; guidelines that provide clinical recommendations in rapidly changing areas of practice may be reviewed annually. Published literature is surveilled to identify new evidence that may prompt changes to existing recommendations or development of new recommendations.</li> <li>• If changes in the standard of care, newly published studies, new drug approval, new drug-related warning, or a public health emergency indicate the need for immediate change to published guidelines, committee leadership will make recommendations and immediate updates and will invite full committee review as indicated.</li> </ul>

**Table S2: Recommendation Ratings and Definitions**

Strength	Quality of Evidence	
A: Strong B: Moderate C: Optional	1	Based on published results of at least 1 randomized clinical trial with clinical outcomes or validated laboratory endpoints.
	*	Based on either a self-evident conclusion; conclusive, published, in vitro data; or well-established practice that cannot be tested because ethics would preclude a clinical trial.
	2	Based on published results of at least 1 well-designed, nonrandomized clinical trial or observational cohort study with long-term clinical outcomes.
	2†	Extrapolated from published results of well-designed studies (including nonrandomized clinical trials) conducted in populations other than those specifically addressed by a recommendation. The source(s) of the extrapolated evidence and the rationale for the extrapolation are provided in the guideline text. One example would be results of studies conducted predominantly in a subpopulation (e.g., one gender) that the committee determines to be generalizable to the population under consideration in the guideline.
	3	Based on committee expert opinion, with rationale provided in the guideline text.