Comprehensive Primary Care for Adults With HIV

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Purpose and Development 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 (NYS) who provide primary medical care for adults (≥18 years old) with HIV.

The purpose of this guideline is to provide NYS clinicians with evidence-based clinical recommendations for provision of comprehensive primary care to patients with HIV, whether care is provided in an HIV specialty or primary care setting. The goal is to ensure that individuals with HIV in NYS can access optimal primary care in multiple outpatient clinical settings.

Care Delivery During COVID-19

With the changes wrought by the COVID-19 pandemic, HIV and primary care providers and their patients have had to create and develop new ways to deliver and access care and treatment, including frequent use of telehealth. However, the goals of care remain the same, regardless of care delivery methods.

As best practices and evidence-based approaches evolve to ensure provision of comprehensive telehealth to people with HIV and other patients living with chronic conditions, clinicians providing care to people with HIV will have to incorporate these practices into their care.

Three recent publications from the NYSDOH AI Clinical Guidelines Program provide practical strategies adjusting practices and protocols for care delivery during COVID-19:

- Opioid Use Disorder Treatment During COVID-19
- Strategies for STI Screening and Treatment During COVID-19
- Rapid Antiretroviral (ART) Initiation During COVID-19

Primary Care for Adults With HIV

At the end of 2018, there were an estimated 1,173,900 individuals ≥13 years old with HIV in the United States [CDC 2020] and an estimated 108,683 in NYS [NYSDOH 2019]. Advances in ART over the past 2 decades have significantly improved life span [Zwahlen, et al. 2009; Samji, et al. 2013; Gueler, et al. 2017]: 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 [El-Sadr, et al. 2006; Lundgren, et al. 2015], and the immune system reconstitution observed with use of ART is associated with significantly improved health outcomes in patients with HIV [Emery, et al. 2008; Marin B, et al. 2009]. Clinicians should start and maintain ART in all patients with HIV.

- For evidence-based recommendations regarding ART initiation, see the NYSDOH AI guideline When to Initiate ART, With Protocol for Rapid Initiation.

Regardless of HIV treatment, however, when compared with individuals without HIV, those with HIV continue to have a higher risk of many comorbidities, including metabolic and infectious diseases and cancers. In one study, patients with HIV had significantly fewer morbidity-free years than patients without HIV [Marcus, et al. 2020]. (See Box 1: Conditions With Higher Incidence in People With HIV and Selected Citations.)
Box 1: Conditions With Higher Incidence in People With HIV and Selected Citations

<table>
<thead>
<tr>
<th>Metabolic diseases</th>
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<tbody>
<tr>
<td>Osteoporosis [Compston 2016]</td>
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<tr>
<td>Thromboembolic events [Malek, et al. 2011]</td>
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<tr>
<td>Renal disease [Althoff, et al. 2015; Swanepoel, et al. 2018]</td>
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<td>Liver disease [Soti, et al. 2018]</td>
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<tr>
<th>Malignancies</th>
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<tr>
<td>AIDS-defining malignancies (e.g., Kaposi sarcoma, non-Hodgkin Lymphoma) [Guiguet, et al. 2009]</td>
</tr>
<tr>
<td>Hepatocellular carcinoma [Pinato, et al. 2019]</td>
</tr>
<tr>
<td>HIV-associated cancers (e.g., lung cancer, Epstein-Barr virus–associated lymphoma) [Yarchoan and Uldrick 2018]</td>
</tr>
<tr>
<td>Human papillomavirus–related malignancies (e.g., anal cancer, cervical cancer, head and neck cancer) [Machalek, et al. 2012; Brickman and Palefsky 2015; Clifford, et al. 2017]</td>
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<tr>
<th>Infectious diseases</th>
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<tr>
<td>Fungal illness (candidiasis, aspergillosis, pneumocystis jiroveci pneumonia, coccidiomycosis, cryptococcosis) [Limper, et al. 2017]</td>
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<tr>
<td>Syphilis [Fujimoto, et al. 2018]</td>
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<tr>
<td>Tuberculosis [Bruchfeld, et al. 2015]</td>
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<table>
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<tr>
<th>Other</th>
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<tr>
<td>Neurocognitive impairment [Tozzi, et al. 2007; Cysique and Brew 2019]</td>
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<tr>
<td>Depression [Nanni, et al. 2015]</td>
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<tr>
<td>Frailty [Greene, et al. 2015]</td>
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The increased incidence of comorbid conditions is associated with several factors, some of which are disease-specific, such as increased risks associated with ongoing immune activation [Deeks 2011; Deeks, et al. 2015]; presumed medication-associated toxicities, such as accelerated bone density loss; length of time of HIV viremia [Lang, et al. 2012]; and others, such as increased rates of malignancy and hepatitis C virus (HCV) (see Box 1: Conditions With Higher Incidence in People With HIV and Selected Citations). Many of these conditions are seen regardless of immune reconstitution and HIV disease stage, and long-term HIV survivors face additional burdens from concomitant disease, medication-associated toxicity (particularly for those on, or with prolonged exposure to, early antiretroviral medications), and advanced aging [Maggi, et al. 2019].

Management of HIV disease in the primary care setting is similar to management of other chronic diseases, and screening for and managing comorbidities is standard for any primary care practice. This guideline offers practical recommendations and guidance for the ongoing clinical care of individuals with HIV, links to other NYSDOH AI guidelines for detailed recommendations on specific topics, and links to other helpful resources.

All patients with HIV: 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 clearly reduces morbidity and mortality but can also contribute to comorbidities, such as weight gain [Bourgi, et al. 2020a; Bourgi, et al. 2020b] and osteoporosis [Grigsby, et al. 2010; Komatsu, et al. 2018].
Patients with CD4 count <200 cells/mm³: Morbidity and mortality are increased in individuals with low CD4 cell counts [May, et al. 2016; Althoff, et al. 2019; Castilho, et al. 2020]. Patients are at increased risk for morbidity and mortality if they experience unintentional weight loss or have poor functional status [Serrano-Villar, et al. 2014; Siika, et al. 2018]. 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 DHHS Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV.

Conditions related to lower 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 [Collazos, et al. 2016; Stirrup, et al. 2018]. 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].

Structure and Use of This Guideline

This guideline assumes that clinicians are familiar with performing a comprehensive patient history and examination and focuses on aspects of primary care that require additional attention in patients with HIV. The recommendations and supporting material in this guideline are structured as 6 sections with detailed tables (listed below) that provide specific recommendations, information, and resources on key issues to be addressed in primary care for individuals with HIV. Where appropriate, links are provided to other NYSDOH AI guidance and guidelines for more information.

- Table 1: HIV, Medications, and General Medical Status and History for Adults With HIV
- Table 2: Psychosocial, Behavioral Health, Sexual Health, and Well-Being Assessment of Adults With HIV
- Table 3: Recommended Laboratory Testing for Adults With HIV
- Table 4: Routine Screening for Adults With HIV
- Table 5: Primary Prevention for Adults With HIV
- Table 6: Prophylaxis for Opportunistic Infections in Adults With HIV

For additional information on aging and HIV, see the NYSDOH AI Guidance for Addressing the Needs of Older Patients in HIV Care.

Guideline Development

This guideline was developed by the NYSDOH AI Clinical Guidelines Program, which is a collaborative effort between the NYSDOH AI Office of the Medical Director and the Johns Hopkins University School of Medicine, Division of Infectious Diseases.

Established in 1986, the goal of the Clinical Guidelines Program is to develop and disseminate evidence-based, state-of-the-art clinical practice guidelines to improve the quality of care provided to people who have HIV, HCV, or sexually transmitted infections; people with substance use issues; and members of the LGBTQ community. NYSDOH AI guidelines are developed by committees of clinical experts through a consensus-driven process.

The NYSDOH AI charged the Medical Care Criteria Committee (adult HIV and related guidelines) with developing evidence-based clinical recommendations for comprehensive primary care of adults with HIV. The resulting recommendations are based on an extensive review of the medical literature and reflect consensus among this panel of experts. Each recommendation is rated for strength and for quality of the evidence (see below). If recommendations are based on expert opinion, the rationale for the opinion is included.
Goals of Primary Care for Adults With HIV

Patients with HIV receive care in diverse settings [Cheng QJ, et al. 2014]. A patient may receive primary care from an HIV or infectious diseases specialist with a strong, disease-specific focus or may seek HIV care from a primary care provider who does not specialize in HIV care. Some studies have suggested better outcomes when patients are followed by specialists, and other studies have demonstrated contradictory findings, in that patients who are followed only by specialists may experience gaps in care, particularly with regard to identification and management of comorbidities [Landon, et al. 2005; Kerr, et al. 2012; Rhodes, et al. 2017; Morales Rodriguez, et al. 2018]. Optimal care for people with HIV requires experience with both HIV and primary care.

This guideline seeks to ensure that individuals with HIV receive high-quality, comprehensive primary care in their setting of choice and provides recommendations for adult primary care for patients with HIV. The guideline is designed to support specialists in HIV care who may need additional information to provide comprehensive primary care and primary care providers who may need additional information to manage HIV-associated care.

The standard approach to primary care is the same for patients with and without HIV, whether care is delivered by a specialist or internist. An approach that is patient-centered and holistic will address the following:

- Routine cancer screening
- Other essential primary and secondary prevention screening (e.g., osteoporosis, heart disease)
- Routine and HIV-specific immunizations
- Substance use
- Mental health disorders
- Sexual health
- Trauma assessment
- Geriatric care
- Patient education and encouragement regarding healthy lifestyle
- Preconception counseling for those of childbearing potential

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 *When to Initiate ART, With Protocol for Rapid Initiation*

Additional essential components of primary care for patients with HIV are:

- Patient education and encouragement regarding adherence to ART to maintain viral suppression.
- Monitoring for potential long-term effects of HIV and ART, such as bone density changes, dyslipidemia, weight gain, and renal dysfunction.
- Opportunistic infection prophylaxis.
- 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: Conditions With Higher Incidence in People With HIV and Selected Citations*). 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 hepatitis C virus, 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 Undetectable = Untransmittable (U=U), pre- and post-exposure prophylaxis (PrEP and PEP) for sex partners, and harm reduction strategies.

- See the following for more information and evidence-based recommendations:
  - NYSDOH AI guidance: *U=U Guidance for Implementation in Clinical Settings*
  - NYSDOH AI guidelines: *PrEP to Prevent HIV and Promote Sexual Health and PEP to Prevent HIV Infection*

**Consent and confidentiality**: A patient’s past medical records should be obtained whenever possible. 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 release of HIV/AIDS-related information on the standard form.

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*).

**Stigma and medical mistrust**: Among people with HIV, stigma and medical mistrust remain significant barriers to healthcare utilization, HIV diagnosis, and medication adherence and can affect disease outcomes [Chambers, et al. 2015; 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].

**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 [Brennan-Ing, et al. 2016].
Case management has been shown to dramatically improve viral load suppression among individuals who inject drugs or smoke crack cocaine, 2 groups who are difficult to retain in care. One study showed an increase in viral load suppression from 32% to 74% and another showed a mortality benefit from case management intervention [Kral, et al. 2018; Miller WC, et al. 2018].

**Peer support:** Peer support can provide an individual with emotional and practical guidance from a person with shared life experience and can be a tool to reduce stigma. Peer support has been found to improve retention in care [Cabral, et al. 2018] and improved viral suppression in a group of individuals with HIV who were recently incarcerated [Cunningham, et al. 2018]. However, data for the general population are inconclusive regarding the effects of peer interventions on viral load suppression or other outcomes, and more research is needed [Giordano, et al. 2016; Metsch, et al. 2016].

### History, Assessment, and Evaluation: Initial, Ongoing, and Annual

**Recommendations**

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<thead>
<tr>
<th>History, Assessment, and Evaluation</th>
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<tr>
<td>• For all adults with HIV who present for primary care, clinicians should perform the baseline assessments detailed in the following tables (A3):</td>
</tr>
<tr>
<td>- Table 1: HIV, Medications, and General Medical Status and History for Adults With HIV</td>
</tr>
<tr>
<td>- Table 2: Psychosocial, Behavioral Health, Sexual Health, and Well-Being Assessment of Adults With HIV</td>
</tr>
<tr>
<td>- Table 3: Recommended Laboratory Testing for Adults With HIV</td>
</tr>
<tr>
<td>• Clinicians should repeat these assessments as indicated in Tables 1, 2, and 3. (A3)</td>
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</table>

History-taking for patients with HIV requires attention to all of the elements standard in primary care while including several additional elements, which are detailed in Table 1: HIV, Medications, and General Medical Status and History for Adults With HIV and Table 2: Psychosocial, Behavioral Health, Sexual Health, and Well-Being Assessment of Adults With HIV, below. It is essential to identify, assess, and monitor HIV- and antiretroviral therapy (ART)-related complications and other HIV-specific comorbidities (see Box 1: Conditions With Higher Incidence in People With HIV and Selected Citations).

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.

**Anatomical inventory:** In addition to all elements of a standard patient history and physical examination, it is important for clinicians to perform an anatomical inventory and determine primary care needs based on which organs are present rather than on the gender expression of the patient. A matter-of-fact anatomical inventory will identify present and absent organs: penis, testes, prostate, breasts, vagina, cervix, uterus, and ovaries.

### HIV-Specific Medical History

Essential components of an HIV-specific medical history are detailed below and in Table 1: HIV, Medications, and General Medical Status and History for Adults With HIV. 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 Table 1 (also see the NYSDOH AI guideline HIV Testing > Steps in the HIV Diagnostic Testing Algorithm). If a patient was recently diagnosed with HIV, 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, which may include ongoing screening for sexually transmitted infections (STIs).

**Essential components of a HIV-specific medical history:**

- Viral load and CD4 cell count at diagnosis, if known
- Patient circumstances at time of diagnosis (housing, employment, food security, relationship status, etc.)
• ART history, including previous regimens, reasons for any changes in prior regimens, and any adverse effects
• Pauses in treatment and lapses in adherence
• Previous resistance testing results
• History of opportunistic infections
• 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) and hepatitis C virus (HCV)
• 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:** Essential elements of an ART history include all previous medications, why they were stopped, and reasons for stopping (e.g., allergies, adverse effects, pill-taking fatigue or discomfort, and resistance). Understanding these reasons and seeking ways to simplify ART regimens or reduce pill burden will support a therapeutic alliance around 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 *When to Initiate ART, With Protocol for Rapid Initiation.*

**Trauma-informed care:** A trauma-informed approach to care is important to mitigate any medical trauma, such as frightening experiences or stigma associated with the initial HIV diagnosis [Sherr, et al. 2011; Tang, et al. 2020]. See the following for more information:

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

**Adherence:** For patients already taking ART, assessing adherence and providing support for optimal adherence are crucial and should include careful assessment of adverse medication effects, which often lead to adherence problems or medication cessation. Other factors to discuss that may pose barriers to adherence include insurance coverage, housing instability, disclosure status, substance use, and mental health.

**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, progression of HBV- or HCV-associated liver fibrosis, cirrhosis, cancer, portal hypertension, and encephalopathy is more rapid than in those without HIV [Benhamou, et al. 1999; Graham, et al. 2001; Thio, et al. 2002; Weber, et al. 2006].

**HCV:** Because the risk of severe liver disease is increased in patients with HIV [Soti, et al. 2018], all patients with HCV and HIV should be treated for HCV infection as soon as possible. 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.

- For evidence-based recommendations, see the NYSDOH AI guideline *Treatment of Chronic HCV With Direct-Acting Antivirals.*

**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, it is important to assess baseline HBV status and choose combination HIV therapy to appropriately treat the HBV infection as well as HIV. It is also important to appropriately monitor for progression of fibrosis or hepatocellular carcinoma; however, ART initiation should not be delayed pending evaluation of HBV status and liver damage.
General Medical Status, History, and Physical Examination

- See Table 1: HIV, Medications, and General Medical Status and History for Adults With HIV
- See Table 2: Psychosocial, Behavioral Health, Sexual Health, and Well-Being Assessment of Adults With HIV

This guideline assumes that care providers are familiar with performing a comprehensive physical examination. Several areas may require additional attention because the incidence, associated complications, or severity may be increased in individuals with HIV or 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 ART and medications the patient is taking to treat comorbidities (see Box 1: Conditions With Higher Incidence in People With HIV and Selected Citations). 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.

Selected Resources for Information on ART Drug-Drug Interactions

- NYSDOH AI ART Drug-Drug Interactions
- NYSDOH AI Treatment of Chronic HCV With Direct-Acting Antivirals > Drug-Drug Interactions Between DAAs and ARVs
- University of Liverpool HIV Drug Interaction Checker
- UCSF HIV InSite Database of Antiretroviral Drug Interactions

Metabolic changes: There are significant metabolic concerns for people with HIV and AIDS [Mankal and Kotler 2014]. Weight gain often occurs after initiation of ART. Assessing weight loss or gain at every visit will assist with early identification of metabolic changes [Bourgi, et al. 2020a]. Female gender, Black race, pre-ART CD4 cell count depletion, and lower pre-ART body mass index have been associated with >10% weight gain at 2 years post-ART initiation [Bourgi, et al. 2020a]. Integrase strand transfer inhibitors (dolutegravir, bictegravir, raltegravir, elvitegravir, and cabotegravir) have been associated with greater weight gain than nonnucleoside reverse transcriptase inhibitors or protease inhibitors, particularly when used in combination with tenofovir alafenamide [Sax, et al. 2020]. Weight loss is more common in individuals with low CD4 cell counts and may prompt investigation of malignancy, infection, and psychosocial instability.

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/mm³. Cytomegalovirus (CMV) infection can lead to retinitis, vision loss, and death. Varicella zoster virus and herpesvirus infections can lead to retinitis and retinal necrosis [Nakamoto, et al. 2004]. After the introduction of highly active ART, the 10-year cumulative incidence for CMV retinitis was 33.6% for individuals with CD4 counts <50 cells/mm³ and 4.2% for those with CD4 counts <200 cells/mm³ [Sugar, et al. 2012]. Icterus may be present in individuals who are taking atazanavir as part of their ART regimen 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 [Small and Rosenstreich 1997; Brown J, et al. 2017; Chiarella and Grammer 2017]. Because sinusitis and otitis can present without significant facial pain or discomfort in patients with CD4 counts <50 cells/mm³, 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’s sarcoma, oral candidiasis, human papillomavirus (HPV)- and HIV-related parotitis, necrotizing gingivitis, requiring evaluation during in-person examinations [Epstein 2007; Sorensen 2011; Trevillyan, et al. 2018]. Clinicians should encourage patients to have annual dental examinations (see NIH > NIDCR > HIV/AIDS & Oral Health).
**Heme/lymph:** 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, tuberculosis, mycobacterium avium-intracellulare infection, and lymphogranuloma venereum, all of which can occur regardless of CD4 cell count, although 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 will ensure that concerns are identified early. Regardless of CD4 cell count, findings such as shingles and psoriasis are seen more frequently in people with HIV than in those without HIV [Erdmann, et al. 2018; Alpalhão, et al. 2019].

- 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, which could be consistent with psoriasis, seborrheic dermatitis, atopic dermatitis, eosinophilic folliculitis, or secondary syphilis [Green, et al. 1996; Alpalhão, et al. 2019]. 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 Table 1, clinicians should perform a neurologic and cognitive function examination in all patients 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* (requires an account), *Mini-Cog,* and *Standardized Mini-Mental State Examination (SMMSE).*

Compared with patients who have higher CD4 cell counts, patients with low CD4 cell counts may be at increased risk for neurologic conditions, which can include rare diseases, such as progressive multifocal leukoencephalopathy, HIV-associated neurologic disease, toxoplasmosis, and cryptococcal meningitis, and common diseases with atypical presentation, such as syphilis and tuberculosis.

In a patient with a low CD4 cell count or new or persistent symptoms regardless of CD4 cell count, neurologic symptoms, such as seizure, changes in mental status, or persistent headache, warrant imaging and diagnostic work-up.

**Respiratory:** Clinicians should perform a lung examination at baseline and at least annually, or more often if indicated. Community-acquired pneumonia is more common in people with HIV, regardless of CD4 cell count, than in those without HIV [Almeida and Boattini 2017], as is chronic obstructive pulmonary disease [Bigna, et al. 2018]. Chronic lung disease is increasingly common among older people with HIV, among smokers, and among those who have survived *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 radiographic 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.

**Comorbidities:** For patients with comorbidities, such as cardiovascular disease, lung disease, renal disease, diabetes mellitus, and malignancies, personal and family history should be collected, and individual risk factors should be discussed. Because HIV has been associated with increased risk and accelerated disease process for these comorbidities, care providers should be sure to discuss appropriate screening and have a low threshold for diagnostic testing referral if symptoms develop [Crothers, et al. 2006; Bower, et al. 2009; Shiels, et al. 2011; Islam, et al. 2012; Triant 2013; Kaspar and Sterling 2017]. 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 [Helleberg, et al. 2015; Trickey, et al. 2016; Althoff, et al. 2019].

History of particular comorbidities may also influence medication choice for those starting ART (see the NYSDOH AI guideline *Selecting an Initial Antiretroviral Regimen*). For example, patients with a history of metabolic disease may wish to avoid protease inhibitors due to the association with central obesity, and patients with risk factors for significant renal disease may wish to avoid tenofovir disoproxil fumarate. If patients do have significant risk for these conditions and are taking ART or other medications that can affect them, more frequent monitoring may be warranted [Crum-Cianflone N, et
Nonalcoholic steatohepatitis is 30% to 40% more common in 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 contribution to these conditions [Gazzaruso, et al. 2003; Noubissi, et al. 2018]. Because thyroid disease and hypogonadism occur more often in people with HIV than in those without, a low threshold for screening for these conditions is appropriate.

**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 use of standardized assessments will help clinicians determine illness course; standardized assessment tools include the MoCa Test (requires an account), Mini-Cog, or Standardized Mini-Mental State Examination (SMMSE). An annual assessment of functional status is also indicated. For more information, see the NYSDOH AI Guidance for Addressing the Needs of Older Patients in HIV Care.

**Psychosocial status:** Baseline and annual psychosocial assessments, as described in Table 2: Psychosocial, Behavioral Health, Sexual Health, and Well-Being Assessment of Adults With HIV, 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; a team approach when possible may be helpful and allow for incorporation of multidisciplinary assessments, including those of a case manager and clinical social worker.

**Sexual health:** Discussion of sexual health, including a patient’s history of STIs, is an important component of the baseline and annual assessments and is an opportunity to discuss a patient’s concerns and questions. The frequency of the sexual health assessment is based on risk factors. It is particularly important to use nonjudgmental, sex-positive language in this discussion to establish a strong connection and facilitate open discussion. Discussion of U=U (Undetectable = Untransmittable) in the clinical setting can facilitate reduction of stigma and discussion of important considerations in sexual health.

- See the following NYSDOH AI resources: U=U Guidance for Implementation in Clinical Settings and GOALS Framework for Sexual History Taking in Primary Care.

**Reproductive status:** Clinicians should ascertain reproductive history and goals with all patients and address contraception and plans for conception with patients of childbearing potential. Patients wishing to have children should be supported and provided with information on current strategies to eliminate perinatal HIV transmission. Risk of perinatal transmission is less than 1% when patients are virally suppressed and with informed management of the perinatal period [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. Education about HIV pre-exposure prophylaxis should be provided when indicated (see the NYSDOH AI guideline PrEP to Prevent HIV and Promote Sexual Health).

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

**Guide to the tables below:** Although the tables below are comprehensive in scope, this committee supports a flexible approach in using this guide to elements that should be included in a comprehensive initial history and physical. All aspects of the patient history and physical examination do not have to be covered in a single visit or by the primary care clinician per se. For some care providers and patients, the best approach may be to spend 2 or more visits completing the initial assessment and address some aspects of the history and physical during follow-up visits.
<table>
<thead>
<tr>
<th>Assessment</th>
<th>To Include</th>
<th>Frequency*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Current HIV-Specific Status and History</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV</td>
<td>• History of HIV testing</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>• Date and source of diagnosis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Route of exposure, if known</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>• HIV type; if unknown, see the NYSDOH AI guideline <em>Diagnosis and Management of HIV-2 in Adults</em></td>
<td></td>
</tr>
<tr>
<td>Antiretroviral therapy</td>
<td>• Date of ART initiation</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>• Current ART regimen</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>• Previous ART regimens and reasons for any changes in regimens</td>
<td>E</td>
</tr>
<tr>
<td></td>
<td>• History of drug resistance, if known</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Adverse effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Current adherence status and challenges</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Knowledge of Undetectable = Untransmittable, see NYSDOH AI <em>U=U Guidance for Implementation in Clinical Settings</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td>☑ If ART has not been initiated, see the NYSDOH AI guideline <em>When to Initiate ART, With Protocol for Rapid Initiation.</em></td>
<td></td>
</tr>
<tr>
<td>Viral load</td>
<td>• Most recent viral load</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>• Peak viral load</td>
<td>A</td>
</tr>
<tr>
<td>CD4 cell count</td>
<td>• Most recent CD4 cell count</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>• Nadir CD4 cell count</td>
<td>A</td>
</tr>
<tr>
<td>AIDS-defining conditions</td>
<td>• Previous diagnoses and treatments</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>• History of malignancies and treatments</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Investigation of symptoms such as weight loss, night sweats, or chronic cough</td>
<td></td>
</tr>
<tr>
<td>Opportunistic infections</td>
<td>• Previous OI prophylaxis</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>• Previous diagnoses and treatment, including latent TB infection</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Adverse reactions to medications for OI prophylaxis or treatment</td>
<td></td>
</tr>
<tr>
<td><strong>Current Medications</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complete medication list</td>
<td>• All medications: prescribed, over-the-counter, herbal preparations;</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>include nonpharmacologic agents</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>• Potential drug-drug interactions</td>
<td>E</td>
</tr>
<tr>
<td></td>
<td>• Adverse effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Challenges with adherence to prescribed medications</td>
<td></td>
</tr>
<tr>
<td><strong>Current General Medical Status and History</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immunizations</td>
<td>• History of immunizations</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>• Status of HIV- and age-related preventive immunizations</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>☑ See NYSDOH AI <em>Immunizations for Adults With HIV.</em></td>
<td></td>
</tr>
<tr>
<td>Age-related disease screening</td>
<td>• Results of previous age-related disease screening tests</td>
<td>I</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>• History of cardiac events, stroke, and treatment</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>• History of hypertension</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>• History of diabetes or insulin resistance</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Risk factors for CVD</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Family history of CVD</td>
<td></td>
</tr>
<tr>
<td>Respiratory</td>
<td>• History of COPD and treatment</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>• Current tobacco/vape use and smoking history</td>
<td>A</td>
</tr>
<tr>
<td>Cancer</td>
<td>• History of prior malignancies and treatment</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>• Previous age-appropriate screening and results</td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>• Family history of malignancies</td>
<td></td>
</tr>
</tbody>
</table>
# Table 1: HIV, Medications, and General Medical Status and History for Adults With HIV

*Frequency Key: I = initial (baseline) visit; A = annual visit; E = every visit*

<table>
<thead>
<tr>
<th>Assessment</th>
<th>To Include</th>
<th>Frequency*</th>
</tr>
</thead>
</table>
| Renal       | • History of renal disease and treatment  
• Consider ART history  
• Consider associated comorbidities                                                                 | I          |
| Hepatic     | • History of and treatment for viral hepatitis (HAV, HBV, or HCV)  
• Adverse reactions to medications  
  - For more information, see the following NYSDOH AI guidelines:  
    Prevention and Management of HAV in Adults With HIV, HBV-HIV Coinfection, and Treatment of Chronic HCV With Direct-Acting Antivirals.  
• Risk factors for nonalcoholic steatohepatitis  
• Past alcohol use  
• Current alcohol use                                                                                   | I          |
| Endocrine   | • Symptoms of thyroid dysfunction or hypogonadism  
• Sexual dysfunction  
• Weight loss or weight gain  
• Family history of metabolic syndrome and thyroid disease  
• History of osteoporosis and treatment, fractures, and previous screening  
• History of lipodystrophy and treatment  
• Use of hormonal therapy (including treatments obtained without prescription)  
  ART (current and previous) may contribute to metabolic syndrome, lipodystrophy, and insulin resistance. | I A        |
| Gastrointestinal | • History of GI disease and treatment  
• GI-related adverse effects of medications and effect (if any) on adherence to prescribed medications  
• Family history of GI disease                                                                 | I A        |
| Vision      | • Changes in vision, including blurry vision, double vision, flashes of light, loss of vision, use of glasses, and blindness or legal blindness | I A        |
| Hearing     | • Changes in hearing  
• Recent audiology testing or new hearing aid use                                                                 | I A        |
| Neurologic  | • History of neurocognitive assessment and results  
• Assessment of current neurocognitive status, preferably using standardized tools, such as MoCA Test (requires an account), Mini-Cog, or Standardized Mini-Mental State Examination (SMMSE)  
• History of neuropathy and treatment  
  Symmetric distal polyneuropathy is common, particularly in patients exposed to earlier generations of ART. | I A        |
| Dermatologic| • History of psoriasis and treatment  
• History of seborrheic dermatitis and treatment  
• History of atopic dermatitis and xerosis and treatment  
• History of skin cancer and treatment  
  Dermatitis can worsen with degree and duration of immunosuppression. | I A        |
| Surgery     | • History of surgical procedures, including adverse reactions to anesthesia  
• History of or planned gender-affirming surgery  
  For more information, see UCSF Transgender Care > Overview of Gender-Affirming Treatments and Procedures. | I A        |
| Pain        | • History of evaluation and treatment for chronic pain (initial visit)  
• Current treatment for chronic pain (every visit)  
  For more information, see CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. | I E        |
Table 1: HIV, Medications, and General Medical Status and History for Adults With HIV

*Frequency Key: I = initial (baseline) visit; A = annual visit; E = every visit

<table>
<thead>
<tr>
<th>Assessment</th>
<th>To Include</th>
<th>Frequency*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>I A E</td>
</tr>
<tr>
<td>Sleep</td>
<td>• History of chronic obstructive sleep apnea and treatment</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>• History of sleep disturbances and treatment</td>
<td></td>
</tr>
<tr>
<td>Nutrition</td>
<td>• History of wasting</td>
<td>I E</td>
</tr>
<tr>
<td></td>
<td>• Dietary habits, appetite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Food insecurity</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Note: If indicated, see <a href="https://www.fns.usda.gov/foodsecurity">USDA Food Security Surveys</a></td>
<td></td>
</tr>
<tr>
<td>Frailty</td>
<td>• Functional status</td>
<td>I A</td>
</tr>
<tr>
<td></td>
<td>• History of gait instability or other problems associated with frailty</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Assessment of current status using standardized tools, such as those</td>
<td></td>
</tr>
<tr>
<td></td>
<td>available through the <a href="https://cga.ucsf.edu">Comprehensive Geriatric Assessment Toolkit Plus</a></td>
<td></td>
</tr>
<tr>
<td>Travel</td>
<td>• Recent travel; assess for potential exposure to infectious disease</td>
<td>I A</td>
</tr>
<tr>
<td></td>
<td>• Frequency and location of international travel (work or leisure)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Status of travel-related immunizations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Lifetime travel history, if indicated</td>
<td></td>
</tr>
<tr>
<td>Pets</td>
<td>• Current and past pet ownership, including exotic animals</td>
<td>I A</td>
</tr>
<tr>
<td></td>
<td>• History of zoonotic diseases and treatment</td>
<td></td>
</tr>
</tbody>
</table>

**Abbreviations:** ART, antiretroviral therapy; CDC, Centers for Disease Control and Prevention; COPD, chronic obstructive pulmonary disease; CVD, cardiovascular disease; GI, gastrointestinal; HAV, hepatitis A virus; HBV, hepatitis B virus; HCV, hepatitis C virus; NYSDOH AI, New York State Department of Health AIDS Institute; OI, opportunistic infection; TB, tuberculosis; U=U, undetectable = untransmittable; UCSF, University of California, San Francisco; USDA, United States Department of Agriculture.

Table 2: Psychosocial, Behavioral Health, Sexual Health, and Well-Being Assessment of Adults With HIV

*Frequency Key: I = initial (baseline) visit; A = annual visit; N = as needed

<table>
<thead>
<tr>
<th>Assessment</th>
<th>To Include</th>
<th>Frequency*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>I A N</td>
</tr>
<tr>
<td>Gender and Sexual Identity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender identity</td>
<td>• Current gender identity and sex assigned at birth</td>
<td>I A N</td>
</tr>
<tr>
<td></td>
<td>• Pronouns</td>
<td></td>
</tr>
<tr>
<td>Current sexual identity</td>
<td>• History of sexual identity</td>
<td>I A N</td>
</tr>
<tr>
<td>Gender transition</td>
<td>• Gender transition goals; successes and challenges</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>• History of, planned, or desired gender-affirming surgery</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Current, past, or planned use of gender-affirming hormones</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Source of gender-affirming hormones</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Adverse effects of gender-affirming treatments</td>
<td></td>
</tr>
<tr>
<td>Inventory of sexual organs</td>
<td>• Presence or absence of penis, testes, prostate, breasts, vagina, cervix,</td>
<td>I A N</td>
</tr>
<tr>
<td></td>
<td>uterus, ovaries, and determination of patient’s preferred terms for body parts</td>
<td></td>
</tr>
<tr>
<td>Current Psychosocial Status and History</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Housing</td>
<td>• Housing stability or connection to resources if housing is unstable</td>
<td>I A N</td>
</tr>
<tr>
<td></td>
<td>• Relocation plans</td>
<td></td>
</tr>
<tr>
<td></td>
<td>☑ Monitor for signs of instability.</td>
<td></td>
</tr>
</tbody>
</table>
### Table 2: Psychosocial, Behavioral Health, Sexual Health, and Well-Being Assessment of Adults With HIV

**Frequency Key:** I = initial (baseline) visit; A = annual visit; N = as needed

<table>
<thead>
<tr>
<th>Assessment</th>
<th>To Include</th>
<th>Frequency*</th>
</tr>
</thead>
</table>
| Family and other significant relationships and responsibilities           | Immediate and extended family members as defined by the patient  
  • Significant relationships  
  • Disclosure status  
  • Financial and care-giving dependents, including children, spouse or life partner, aging parents, and extended or chosen family members  
  • Community support, including functional needs and agency or family assistance  
  • Transportation  
  • Pets in home  
  ☑️ Monitor for signs of instability.                                             | I A         |
| Interpersonal and social support network                                   | Members of the patient’s primary interpersonal and social support network  
  • People to whom the patient has disclosed their HIV status  
  • Discussion of experienced and perceived stigma  
  ☑️ Monitor for signs of instability.                                             | I A N       |
| Employment                                                                | Current employment status or employment goals  
  • Access to financial support if unemployed or under-employed  
  • Employment-associated risks to health or well-being, including stigma and discrimination | I A         |
| Medical insurance                                                         | Access to private medical insurance, Medicaid, ADAP, or Medicare  
  • Prescription coverage  
  • Hospitalization coverage  
  • Access to resources for coverage if uninsured | I A N       |
| Incarceration                                                             | History of incarceration  
  • Probation, parole, and other legal status | I           |
| End-of-life planning                                                      | Documented healthcare proxy  
  • Documented preferences for end-of-life care and living will  
  • Long-term care plans | I A         |

#### Current Mental Health Status and History

| Mental illness                                                             | History of mental illness and treatment  
  • Adverse reactions to medications  
  • History of psychiatric hospitalization  
  • Suicide risk assessment and past history of suicide attempts  
  • Family history  
  ☑️ See Depression: Screening and Diagnosis; assess mental health using standardized tools, such as The Patient Health Questionnaire-2 (PQH-2), The Patient Health Questionnaire-9 (PQH-9), and the Columbia-Suicide Severity Rating Scale (C-SSRS). | I A         |
| Trauma                                                                    | History of trauma, including domestic violence; physical, verbal, sexual, or emotional abuse; or witnessed trauma  
  • History or current experience of elder abuse  
  • Any effects on current function and coping strategies | I A N       |
| Stress                                                                    | Current major stressors  
  • Stress management and coping skills  
  • Current experience or history of HIV-associated or other stigmas | I A N       |
**Table 2: Psychosocial, Behavioral Health, Sexual Health, and Well-Being Assessment of Adults With HIV**

*Frequency Key: I = initial (baseline) visit; A = annual visit; N = as needed*

<table>
<thead>
<tr>
<th>Assessment</th>
<th>To Include</th>
<th>Frequency*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Current Substance Use and History</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Alcohol                                        | • History of use, including use disorder diagnosis and treatment  
|                                              | • Adverse reactions to medications  
|                                              | • Screening for current use; if indicated, perform risk assessment using standardized tools. See the NYSDOH AI guideline *Substance Use Screening and Risk Assessment in Adults.*  
|                                              | ☑ If indicated, implement a harm reduction treatment plan.                                                                                       | I A N      |
| Tobacco use and vaping                         | • Current level of tobacco use and type  
|                                              | • History of use and prior treatment  
|                                              | • Adverse reactions to medications  
|                                              | ☑ Smoking prevalence is high in people with HIV [Pacek and Cioe 2015].                                                                            | I A N      |
| Use of nonprescription drugs and misuse of prescribed drugs | • All types of drug use, including misused prescription medications  
|                                              | • History of use, including use disorder diagnosis and treatment  
|                                              | • Route of use  
|                                              | • History of overdose  
|                                              | • Screening for current use; if indicated, perform risk assessment using standardized tools. See the NYSDOH AI guideline *Substance Use Screening and Risk Assessment in Adults.*  
|                                              | ☑ If indicated, implement a harm reduction treatment plan.                                                                                       | I A N      |
| **Sexual and Reproductive Health and History**   |                                                                                                                                                 |            |
| Sex partner(s) and activity                    | • Current sex partner(s)  
|                                              | • HIV, ART, and viral load status of partner(s), if known; PrEP and other measures to prevent STIs used by partner(s)  
|                                              | • Frequency of and preferred sexual activities; challenges  
|                                              | • History of sexual dysfunction  
|                                              | • History of or current engagement in transactional sex  
|                                              | ☑ NYSDOH AI Resources: *GOALS Framework for Sexual History Taking in Primary Care, U=U Guidance for Implementation in Clinical Settings*                                                                 | I A N      |
| Sexually transmitted infections                | • History of and treatment for syphilis, gonorrhea, chlamydia, human papillomavirus, and other STIs  
|                                              | • Source of prior treatment for any STI  
|                                              | • Assessment of ongoing risk factors and implementation of harm or risk reduction plan if indicated; use of condoms or other barrier protection  
|                                              | ☑ Screening should include all potentially exposed sites. For evidence-based recommendations, see *CDC > Sexually Transmitted Infections Treatment Guidelines, 2021 > Screening.*                                                                 | I A N      |
| Reproductive history                           | • Offspring  
|                                              | • Previous failed attempts at reproduction  
|                                              | • Previous treatment for reproductive issues and source  
|                                              | • Adverse effects  
|                                              | • Contraceptive history  
|                                              | • Previous abortion(s)                                                                                                                                 | I          |
| Reproductive goals                             | • Family planning goals  
|                                              | • Contraception use and options  
|                                              | ☑ Check for possible drug-drug interactions for individuals taking ART.                                                                             | I N        |

**Abbreviations:** ADAP, AIDS Drug Assistance Program; ART, antiretroviral therapy; NYSDOH AI, New York State Department of Health AIDS Institute; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection; U=U, undetectable = untransmittable.
**Laboratory and Diagnostic Testing**

Recommended laboratory testing is outlined in Table 3, below.

<table>
<thead>
<tr>
<th>Laboratory Test</th>
<th>Comments</th>
<th>Frequency*</th>
</tr>
</thead>
</table>
| HIV-1 RNA quantitative viral load            | • Regular monitoring is the most accurate and meaningful measure of effective ART.  
• Check every 3 to 6 months during years 1 and 2, and every 4 to 6 months thereafter.  
• Monitor every 1 to 3 months if adherence is unstable or patient has detectable viral load.  
☑️ See the NYSDOH AI guideline *Virologic and Immunologic Monitoring*.                                                                                                                                     | I A N      |
| CD4 lymphocyte count                         | • Check every 3 to 6 months if CD4 count <200 cells/mm³; not indicated if viral load is consistently undetectable (CD4 count >200 cells/mm³).  
• Monitor every 3 months if diagnosis is recent (<2 years), viral load suppression is inconsistent, or CD4 count is close to or below 200 cells/mm³.  
☑️ See the NYSDOH AI guideline: *Virologic and Immunologic Monitoring*.                                                                                                                                 | I A N      |
| HIV-1 resistance testing (genotypic)         | • Perform at treatment initiation.  
• Perform if viral load is >500 copies/mL (archive genotype may be considered if VL below 500 copies/mL).  
• Consult with an expert in HIV care in the event of treatment failure.                                                                                                                                                                                                   | I N        |
| G6PD                                         | • Screen for deficiency to avoid use of oxidant drugs, including dapsone, primaquine, sulfonamides.  
☑️ Prevalence of G6PD deficiency is highest among people of African, Asian, or Mediterranean descent, but consider in all patients given diversity of backgrounds.                                                                                                                  | I          |
| Complete blood count                         | • For patients not taking zidovudine, check at initiation of ART and repeat as clinically indicated.  
• For patients taking zidovudine, check at initiation, and 4 weeks after initiation; follow every 3 months for the first year, then every 6 months.  
☑️ Consider with any change in medication.                                                                                                                                                                                                                          | I A        |
| Estimated glomerular filtration rate         | • For patients taking 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.  
• For patients not taking TDF, check at initiation, 6 months during the first year, then annually thereafter.  
• Check after initiation of medication with risk for renal disease (e.g., use of nonsteroidal anti-inflammatory agents, angiotensin-converting enzyme inhibitors).  
• Check if patient has history of diabetes or other renal diseases.                                                                                                                                                                                                 | I A N      |
| Hepatic panel:                               | • Aspartate aminotransferase  
• Alanine aminotransferase  
• Alkaline phosphatase  
• Total bilirubin  
• Check 3 months after initiation of ART, after initiating medication with risk for liver disease (e.g., statins, azoles), or if there is a history of viral hepatitis, and then at 12 months.  
• Check every year if patient is stable and without above risks.                                                                                                                                                  | I A N      |
<table>
<thead>
<tr>
<th>Laboratory Test</th>
<th>Comments</th>
<th>Frequency*</th>
</tr>
</thead>
</table>
| Random blood glucose (fasting or hemoglobin A1c if high) | - Check every 6 to 12 months if a patient has risk factors for diabetes (family history, obesity, use of protease inhibitors or INSTIs).  
  - If abnormal, repeat random glucose as a fasting glucose or A1C.  
  ☑ Results are used to diagnose diabetes. See Standards of Medical Care in Diabetes—2019 Abridged for Primary Care Providers. | I A N      |
| Tuberculosis screening                               | - Obtain IGRA TB test (such as T-SPOT or QuantiFERON-TB) or 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 or immigration).  
  ☑ Consider preventive therapy for patients with ≥5 mm reaction to PPD. See: CDC: Treatment of LTBI and TB for Persons with HIV and Clinical Info HIV.gov > Mycobacterium tuberculosis. | I A        |
| Hepatitis A                                          | • Anti-hepatitis A immunoglobulin  
  ☑ Repeat after vaccination to ensure immunity.  
  ☑ See the NYSDOH AI guideline Prevention and Management of HAV in Adults With HIV > Transmission and Prevention for testing and vaccination recommendations. | I N        |
| Hepatitis B                                          | • Surface antibody  
  • Surface antigen  
  • Core antibody  
  • If HBsAg-positive or if HbcAb-positive but HbcAb-negative, perform HBV DNA viral load test.  
  • Repeat HbcAb after vaccination to ensure immunity.  
  ☑ See the NYSDOH AI guideline HBV-HIV Coinfection > Baseline Evaluation and Screening for testing and vaccination recommendations. | I N        |
| Hepatitis C                                          | • HCV antibody  
  • HCV RNA quantitative viral load  
  • If patient was previously treated for HCV or is antibody-positive, perform HCV viral load test.  
  • Check at entry to care; repeat as clinically indicated for patients with exposure risk.  
  ☑ See the NYSDOH AI guideline Treatment of Chronic HCV with Direct-Acting Antivirals > Diagnosis of HCV Infection. | I N        |
| Measles titer                                        | • Vaccinate if patient is not immune and has a CD4 count >200 cells/mm³.                                                                                                                                  | I          |
| Varicella titer                                      | • For patients with no evidence of immunity and CD4 count >200 cells/mm³, 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.  
  • Live vaccines are contraindicated for patients with CD4 counts <200 cells/mm³.  
  • Above 50 years of age, regardless of varicella titer status or CD4 cell count, consider vaccination for Herpes zoster with recombinant zoster virus (RZV; SHINGRIX) two doses 2 to 6 months apart. | I          |
| Urinalysis                                           | • Evaluate for proteinuria.  
  • Check for symptoms of UTI or change in creatinine or other urinary symptoms (including glucosuria for patients on tenofovir).  
  ☑ See the NYSDOH AI guideline Antiretroviral Therapy > Laboratory Monitoring for Adverse Effects of ART. | I A N      |
| Urine pregnancy test                                 | • Perform for all individuals of childbearing potential who are sexually active.  
  • Repeat at patient request.                                                                                                                                                                         | I N        |
Table 3: Recommended Laboratory Testing for Adults With HIV  
*Frequency Key: I = initial (baseline) visit; A = annual visit; N = as needed

<table>
<thead>
<tr>
<th>Laboratory Test</th>
<th>Comments</th>
<th>Frequency*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lipid panel</td>
<td>• Perform at least every 3 years if patient has increased risk for CVD. • Consider annual screening if patient is taking protease inhibitors. • For adults &gt;75 years old, initiate discussion of possible benefits of age-appropriate preventive therapies in the context of comorbidities and life expectancy.   HIV is considered a risk-enhancing factor for CVD; clinicians may opt to perform more frequent lipid testing in patients with cardiovascular comorbidities.</td>
<td>I +/- N</td>
</tr>
<tr>
<td>Serum thyroid-stimulating hormone</td>
<td>• Insufficient evidence exists for routine screening of nonpregnant adults.   Adults with HIV have higher incidence of thyroid dysfunction than those without HIV. Discuss annual screening. See USPSTF Thyroid Dysfunction: Screening.</td>
<td>I +/-</td>
</tr>
<tr>
<td>Gonorrhea and chlamydia</td>
<td>• Perform baseline testing at oral, anal, urethral, and cervical sites for MSM and TGW and others as indicated by individual exposure. • Repeat based on risk factors and sites of exposure. • Repeat every 3 months for MSM and TGW.   See Update to the CDC’s Treatment Guidelines for Gonococcal Infection, 2020.</td>
<td>I A N</td>
</tr>
<tr>
<td>Syphilis</td>
<td>• Use same laboratory test consistently. • Repeat at least annually • Repeat every 3 months for patients with risk of exposure (e.g., MSM).   See the NYSDOH AI guideline Management of Syphilis in Patients with HIV.</td>
<td>I A N</td>
</tr>
<tr>
<td>Trichomonas</td>
<td>• Perform screening test if the patient has a vagina and is sexually active.</td>
<td>I A N</td>
</tr>
<tr>
<td>HLA-B*5701</td>
<td>• Must be performed before initiation of abacavir, otherwise not routine.</td>
<td>N</td>
</tr>
</tbody>
</table>

**Abbreviations:** ART, antiretroviral therapy; CDC, Centers for Disease Control and Prevention; MSM, men who have sex with men; CVD, cardiovascular disease; FDA, U.S. Food and Drug Administration; G6PD, glucose-6-phosphate dehydrogenase; HBcAb, hepatitis B core antibody; HBsAb, hepatitis B surface antibody; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; HCV, hepatitis C virus; IGRA, interferon gamma release assay; INSTI, integrase strand transfer inhibitor; PPD, purified protein derivative; TB, tuberculosis; TDF, tenofovir disoproxil fumarate; TGW, transgender women; USPSTF, United States Preventive Services Taskforce; UTI, urinary tract infection.
Routine Screening and Primary Prevention

RECOMMENDATIONS

Routine Screening and Primary Prevention

- For adults with HIV who are seen for primary care, clinicians should provide:
  - Risk-, age-, and sex-based screening as indicated and recommended in Table 4: Routine Screening for Adults With HIV. (A3)
  - Primary preventive care as recommended in Table 5: Primary Prevention for Adults With HIV. (A3)
- Clinicians and patients should engage 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)

Prevention is the cornerstone of primary care and is mostly the same for patients with and without HIV. Table 4: Routine Screening for Adults With HIV and Table 5: Primary Prevention for Adults With HIV, below, provide links to standard screening guidelines, some of which are specific to HIV.

Table 4: Routine Screening for Adults With HIV

<table>
<thead>
<tr>
<th>Type of Screening [a]</th>
<th>Recommended Guideline(s) [b]</th>
<th>Age of Screening Initiation, Frequency, and Comments</th>
</tr>
</thead>
</table>
USPSTF: BRCA-Related Cancer: Risk Assessment, Genetic Counseling, and Genetic Testing (2019) | Discuss screening with patients who are 50 to 75 years old every 2 years.  
Evidence of benefit is insufficient for patients who are >75 years old.  
Begin screening as early as age 40 for patients with family history of breast cancer (parent, sibling, or child).  
CDC Breast Cancer Screening Guidelines for Women provide a comparison of recommendations from various guidelines. |
| Colon cancer [c]     | USPSTF: Colorectal Cancer Screening (2016) [d] | Screen patients who are 45 to 75 years old: frequency depends on screening method. Confirm annually that appropriate testing has been completed.  
In patients who are >75 years old, the decision to perform screening should be individualized. |
| Cervical cancer [a, c] | NYSDOH AI: Cervical Screening for Dysplasia and Cancer (2018) | Begin screening at 21 years old or within 1 year of onset of sexual activity.  
No upper age limit for screening.  
Recommendations for cervical cancer screening in patients with HIV are not the same as those for people who do not have HIV. |
Recommendations for anal cancer screening in patients with HIV are not the same as those for people who do not have HIV. |
| Lung cancer [c]      | USPSTF: Lung Cancer Screening (2013) [d] | Screen patients who are 55 to 80 years old who have a 30 pack-year history.  
Screen patients who are current smokers or former smokers who quit <15 years ago. |
### Table 4: Routine Screening for Adults With HIV

<table>
<thead>
<tr>
<th>Type of Screening</th>
<th>Recommended Guideline(s) [b]</th>
<th>Age of Screening Initiation, Frequency, and Comments</th>
</tr>
</thead>
</table>
| Prostate cancer [a, c] | USPSTF: Prostate Cancer: Screening (2018) | • In patients who are 55 to 69 years old, the decision to perform screening should be individualized.  
• Engage in shared decision-making for patients who are ≥70 years old. |
| Bone density | USPSTF: Osteoporosis to Prevent Fractures: Screening (2018) | • Some experts recommend baseline bone densitometry screening for osteoporosis in postmenopausal cisgender women and in cisgender men and transgender women ≥50 years old who have HIV [Aberg, et al. 2014; Thompson, et al. 2020].  
☒ See NYSDOH AI: Selecting an Initial ART Regimen > Special Considerations for Comorbid Conditions. |
| Abdominal aortic aneurysm | USPSTF: Abdominal Aortic Aneurysm: Screening (2019) | • Perform screening in cisgender men and transgender women who are 65 to 75 years old who have ever smoked.  
• There is insufficient evidence for or against screening in cisgender women and transgender men who have ever smoked. |
| Routine vision [c] | USPSTF: Impaired Visual Acuity and Glaucoma in Adults: Screening (2020) | • Perform screening for patients of all ages every 2 years.  
• Recommend annual screening if CD4 count <200 cells/mm³. |

**Abbreviations:** CDC, Centers for Disease Control and Prevention; NYSDOH AI, New York State Department of Health AIDS Institute; USPSTF, U.S. Preventive Services Task Force.

- a. An anatomical inventory is necessary to identify appropriate sex-based screening.
- b. If no NYSDOH AI guideline is available, the relevant USPSTF guideline is included; the USPSTF guidelines are comprehensive and evidence-based.
- c. Screening recommendations are the same for individuals with HIV and without HIV.
- d. This guideline will be updated when the USPSTF guideline is updated.

### Table 5: Primary Prevention for Adults With HIV

<table>
<thead>
<tr>
<th>Type</th>
<th>Recommended Guideline(s)</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Tobacco smoking | USPSTF: Tobacco Smoking Cessation in Adults, Including Pregnant Women: Behavioral and Pharmacotherapy Interventions (2015) | • USPSTF:  
- Screen all adults for tobacco use.  
- Recommend cessation.  
- Provide behavioral and FDA-approved pharmacologic therapy.  
• Resources: Millionhearts.hhs.gov:  
  - Protocol for Identifying and Treating Patients Who Use Tobacco  
  - Identifying and Treating Patients Who Use Tobacco: Action Steps for Clinicians  
  - Tobacco Cessation Change Package |
### Table 5: Primary Prevention for Adults With HIV

<table>
<thead>
<tr>
<th>Type</th>
<th>Recommended Guideline(s)</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Unhealthy alcohol and drug use   | **NYSDOH AI: Substance Use Screening and Risk Assessment in Adults (2020)**              | - **NYSDOH AI:**  
  - Screen all adults for alcohol, tobacco, and drug use.  
  - Assess level of use and treat as indicated. Laboratory screening is not recommended.  
- **Resources:**  
  - **USPSTF:** Unhealthy Alcohol Use in Adolescents and Adults: Screening and Behavioral Counseling Interventions  
  - **NYSDOH AI:** Harm Reduction Approach to Treatment of All Substance Use Disorders, Treatment of Alcohol Use Disorder, and Treatment of Opioid Use Disorder |
| Cardiovascular disease           | **USPSTF:**  
  - Statin Use for the Primary Prevention of CVD in Adults: Preventive Medication (2016)  
  - Aspirin Use to Prevent CVD and Colorectal Cancer: Preventive Medication (2016)  
  - Healthful Diet and Physical Activity for CVD Prevention in Adults With Cardiovascular Risk Factors: Behavioral Counseling Interventions (2014) | - **Resources:**  
  - American College of Cardiology Atherosclerotic Cardiovascular Disease (ASCVD) Risk Estimator Plus  
  - Characteristics, Prevention, and Management of Cardiovascular Disease in People Living With HIV: A Scientific Statement From the American Heart Association |
| Depression                       | **USPSTF:** Depression in Adults: Screening                                            | - **USPSTF:** Screen for depression, with adequate systems in place to ensure accurate diagnosis, effective treatment, and appropriate follow-up.  
- **Resources:**  
  - Patient Health Questionnaire-2 (PHQ-2)  
  - PHQ-9  
  - Columbia-Suicide Severity Rating Scale (C-SSRS) |
| Domestic violence                | **USPSTF:** Intimate Partner Violence, Elder Abuse, and Abuse of Vulnerable Adults      | - Screen for domestic violence, including intimate partner violence, child abuse, and elder abuse. |
| Sexually transmitted infections  | **USPSTF:** Sexually Transmitted Infections: Behavioral Counseling                     | - **USPSTF:** Provide behavioral counseling for all sexually active adults and adolescents.  
- Include discussion of appropriate vaccinations. |
| Neural tube defects in pregnancy | **USPSTF:** Folic Acid for the Prevention of Neural Tube Defects: Preventive Medication  | - **USPSTF:** Folic acid supplementation is recommended for individuals who are planning or capable of pregnancy. |
Table 5: Primary Prevention for Adults With HIV

<table>
<thead>
<tr>
<th>Type</th>
<th>Recommended Guideline(s)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast cancer</td>
<td>USPSTF: <em>Breast Cancer: Medication Use to Reduce Risk</em></td>
<td>• USPSTF: Risk-reducing medications, such as tamoxifen, raloxifene, or aromatase inhibitors are recommended for women who are at increased risk for breast cancer and at low risk for medication-related adverse events.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Routine preventive medication is not recommended for women who are not at increased risk.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Note: <em>This committee</em> advises clinicians to screen for breast cancer in transgender and transfeminine men and cisgender females.</td>
</tr>
<tr>
<td>Skin cancer</td>
<td>USPSTF: <em>Skin Cancer Prevention: Behavioral Counseling</em></td>
<td>• USPSTF: Counsel patients to minimize ultraviolet radiation.</td>
</tr>
<tr>
<td>Falls</td>
<td>USPSTF: <em>Falls Prevention in Community-Dwelling Older Adults: Interventions</em></td>
<td>• USPSTF: Exercise interventions are recommended for adults ≥65 years old who are at increased risk for falls.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Note: <em>This committee</em> advises clinicians to include osteoporosis screening.</td>
</tr>
</tbody>
</table>

**Abbreviations:** CVD, cardiovascular disease; FDA, U.S. Food and Drug Administration; NYSDOH AI, New York State Department of Health AIDS Institute; USPSTF, U.S. Preventive Services Task Force.

### Prevention of Opportunistic Infections

**RECOMMENDATIONS**

**Prevention of Opportunistic Infections**

- Clinicians should initiate prophylaxis for specific opportunistic infections (OIs) and discontinue prophylaxis as indicated in *Table 6: Prophylaxis for Opportunistic Infections in Adults With HIV. (A*)*
  - Before initiating dapsone, clinicians should test patients for glucose-6-phosphate dehydrogenase (G6PD) deficiency. *(A*)
- Clinicians may discontinue primaryOI prophylaxis in patients who are taking effective ART and have evidence of immune recovery. *(A*)

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 newly diagnosed individuals 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 [Ransome, et al. 2015; Tominski, et al. 2017]. It is essential that clinicians who care for patients with HIV can identify common OIs and know when to provide and discontinue appropriate prophylaxis (see *Table 6: Prophylaxis for Opportunistic Infections in Adults With HIV*, below).
<table>
<thead>
<tr>
<th>Opportunistic Infection</th>
<th>Indications for Initiation and Discontinuation of Primary Prophylaxis</th>
<th>Preferred and Alternative Agent(s)</th>
<th>Indications for Discontinuation of Secondary Prophylaxis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cryptococcosis</td>
<td>• Primary prophylaxis is not routinely recommended.</td>
<td>N/A</td>
<td>• CD4 count &gt;100 to 200 cells/mm³ for ≥6 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Completed initial therapy, maintenance therapy for 1 year, and is asymptomatic for cryptococcosis</td>
</tr>
<tr>
<td>Cytomegalovirus</td>
<td>• Primary prophylaxis is not routinely recommended.</td>
<td>N/A</td>
<td>• CD4 count &gt;100 to 150 cells/mm³ for ≥6 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• No evidence of active disease</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Engaged in routine ophthalmologic examination</td>
</tr>
<tr>
<td><em>Mycobacterium avium</em></td>
<td>• <strong>Initiation:</strong> Not recommended for individuals on ART with an undetectable viral load or who are rapidly started on ART</td>
<td><em>Preferred:</em> Azithromycin; clarithromycin</td>
<td></td>
</tr>
<tr>
<td><em>complex</em></td>
<td>• <strong>Discontinuation:</strong> Taking ART and CD4 count &gt;100 cells/mm³ for ≥3 months</td>
<td><em>Alternative:</em> Rifabutin; azithromycin plus rifabutin</td>
<td>• Taking ART and CD4 count &gt;100 cells/mm³ for ≥6 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• At least 12 months of MAC treatment completed [a]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Asymptomatic for MAC</td>
</tr>
<tr>
<td>Pneumocystis jiroveci</td>
<td>• <strong>Initiation:</strong> CD4 count &lt;200 cells/mm³ (or &lt;14%) or history of oropharyngeal candidiasis</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>pneumonia</em> (formerly <em>Pneumocystis carinii</em> pneumonia)</td>
<td>• <strong>Discontinuation:</strong> Taking ART and CD4 count &gt;200 cells/mm³ for ≥3 months</td>
<td><em>Preferred:</em> TMP/SMX single strength once daily</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td><em>Alternatives:</em></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>- TMP/SMX double strength every other day</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Dapsone [b]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Dapsone plus pyrimethamine plus leucovorin</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Atovaquone</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Aerosolized pentamidine</td>
</tr>
<tr>
<td>Toxoplasma gondii</td>
<td>• <strong>Initiation:</strong> CD4 count &lt;100 cells/mm³ and positive serology for <em>Toxoplasma gondii</em> (IgG+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>encephalitis</em> [a, c]</td>
<td>• <strong>Discontinuation:</strong> Taking ART and CD4 count &gt;100 cells/mm³ for ≥3 months</td>
<td><em>Preferred:</em> TMP/SMX single strength once daily</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><em>Alternatives:</em></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>- Dapsone [b] plus pyrimethamine plus leucovorin</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Atovaquone with or without pyrimethamine plus leucovorin</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Taking ART and CD4 count &gt;200 cells/mm³ for ≥6 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Initial therapy completed</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Asymptomatic for TE</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Also see CDC, NIH, and IDSA Recommendations: Treating Opportunistic Infections Among HIV-Exposed and Infected Children</td>
</tr>
</tbody>
</table>
### Immunizations for Adults With HIV

*Medical Care Criteria Committee, December 2019, reviewed and updated February 2021*

☑ **RECOMMENDATION**

**Immunizations**

- Clinicians should follow the recommendations for routine vaccination of adults with HIV issued by the Centers for Disease Control and Prevention, the National Institutes of Health, the HIV Medicine Association, and the Infectious Disease Society of America, as presented here. (A2)

**Purpose**

This compendium of immunization recommendations for adults (≥18 years) with HIV was compiled by the New York State (NYS) Department of Health (DOH) AIDS Institute (AI) to assist clinical practitioners in NYS who provide primary care to adults with HIV. The goal is to present in one easy-to-use document all of the routine vaccinations recommended for adults with HIV by the Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), HIV Medicine Association (HIVMA) [AIDSpages 2019], and the Infectious Disease Society of America [Rubin, et al. 2014]. The European AIDS Clinical Society guidelines were also consulted [EACS 2019]. Where a recommendation differs from these source documents, the NYSDOH AI rationale is provided. This document integrates current evidence-based clinical recommendations into the healthcare-related implementation strategies of the *Ending the Epidemic initiative*, which seeks to end the AIDS epidemic in NYS by the end of 2020.

Immunizations against infectious diseases are a particularly important component of care for individuals with HIV. Immunodeficiency reduces natural defenses to vaccine-preventable diseases in people with HIV and places them at increased risk for disease and for severe disease [Crum-Cianflone NF and Wallace 2014; Rubin, et al. 2014]. However, there is concern that patients with HIV-associated immunodeficiency may not be able to mount and maintain an appropriate immune response to vaccines and may be harmed by live virus vaccines. The strength of the immune response may be lower in patients with more advanced HIV, especially among those with CD4 counts <200 cells/mm³ and/or HIV viral load >200 copies/mL, and shorter in duration than in adults without HIV [Crum-Cianflone NF and Wallace 2014]. Immunogenicity, vaccine response monitoring, and requirements for additional booster doses for patients with HIV are discussed on pages for individual vaccines.

**Development of this document:** This reference was compiled by the NYSDOH AI Clinical Guidelines Program, which is a collaborative effort between the NYSDOH AI Office of the Medical Director and the Johns Hopkins University School of Medicine, Division of Infectious Diseases.

The goal of the Clinical Guidelines Program, established in 1986, is to develop and disseminate evidence-based, state-of-the-art clinical practice guidelines to improve the quality of care throughout NYS for people with HIV, hepatitis C virus infections, or sexually transmitted infections; people with substance use issues; and members of the LGBTQ community. NYSDOH AI guidelines are developed by committees of clinical experts through a consensus-driven process.

The NYSDOH AI *Medical Care Criteria Committee* is charged with developing evidence-based clinical recommendations for clinicians in NYS who treat adults with HIV. The recommendations in this document, with the exception of one, are the
same as those of the CDC/NIH/HIVMA guidelines. This document also discusses published literature related to specific vaccines and the rationale for recommendations for which there is no consensus among the referenced guidelines, no evidence specific to patients with HIV, or new data have been published.

**Considerations and Contraindications**

The tables and accompanying discussion in this section compile recommendations from the Centers for Disease Control and Prevention (CDC), National Institutes of Health, and HIV Medicine Association guidelines on immunization of adults with HIV who are not pregnant, along with vaccination schedules, clinical comments, and sources. The only recommendation in this guideline that was developed by the HIV Clinical Guidelines Program Medical Care Criteria Committee is in the section on zoster vaccination. Table 21 compiles all immunization recommendations into one printable table.

Inactivated vaccines are generally considered safe, although data are insufficient to rule out rare adverse effects [Rubin, et al. 2014; Ezeanolue, et al. 2019]. Live, attenuated vaccines are contraindicated for patients with CD4 counts <200 cells/mm³, because of the risk of severe reactions in individuals who are immunosuppressed [Davis, et al. 1977; CDC 1985; Redfield, et al. 1987; CDC 1996]. For patients with HIV and CD4 counts ≥200 cells/mm³, inactivated forms of vaccines such as those for polio, influenza, typhoid, and zoster are preferred over the live vaccine options. Live, attenuated vaccines should be administered only when an inactivated version does not exist and the risk of the disease clearly outweighs the theoretical risk of vaccination.

<table>
<thead>
<tr>
<th>→ KEY POINTS: USE OF LIVE, ATTENUATED VACCINES</th>
</tr>
</thead>
<tbody>
<tr>
<td>• <strong>Patients with CD4 count &lt;200 cells/mm³</strong>: The following live, attenuated vaccines are contraindicated: Bacillus Calmette-Guérin; measles, mumps, rubella; oral typhoid; rotavirus*; varicella; yellow fever; zoster.</td>
</tr>
<tr>
<td>• <strong>Patients with CD4 count ≥200 cells/mm³</strong>: Use live, attenuated vaccines only if an inactivated alternative is not available and the risk of disease is greater than the risk of vaccination.</td>
</tr>
<tr>
<td>*Patient education: Patients with HIV should avoid handling diapers of infants vaccinated against rotavirus in the previous 4 weeks, and all household members should wash their hands after changing diapers of an infant recently vaccinated against rotavirus.</td>
</tr>
</tbody>
</table>

Transient increases in viral load and decreases in CD4 cell count caused by immune system activation have been described after vaccination in patients with HIV in some older studies [Rey, et al. 2000; Kolber, et al. 2002]. The changes are less likely to occur in patients taking antiretroviral therapy (ART) and have not been found to have long-term negative effects [Sullivan, et al. 2000; Rubin, et al. 2014].

<table>
<thead>
<tr>
<th>→ KEY POINTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>• In people older than 5 years with HIV, effective ART is defined as ART taken for ≥6 months, with a CD4 percentage ≥15% and a CD4 count ≥200 cells/mm³ for ≥6 months [McLean, et al. 2013].</td>
</tr>
<tr>
<td>• Viral suppression is defined as an HIV viral load &lt;200 copies/mL.</td>
</tr>
</tbody>
</table>

Clinicians should advise their patients with HIV that family members, close contacts, and other household members should receive all age-appropriate vaccinations, including an annual influenza vaccine, to reduce the patients’ exposure to vaccine-preventable diseases [Fiore, et al. 2011; Rubin, et al. 2014; Grohskopf, et al. 2019]. Live, attenuated virus vaccines may be safely administered to close contacts of persons with HIV, with specific precautions for varicella and rotavirus vaccines. Transmission of live, attenuated virus after vaccination is rare [Rubin, et al. 2014]. However, patients with HIV who lack varicella immunity are advised to avoid direct contact with persons who develop a rash after varicella or zoster vaccination and should not handle diapers of an infant recently vaccinated against rotavirus [Marin M, et al. 2007; Cortese and Parashar 2009; Fiore, et al. 2011; Rubin, et al. 2014].

Tables 7 through 20 (for each vaccine listed) present the recommended immunizations for adults with HIV, followed by discussion of each. For complete vaccination recommendations, see the CDC Immunization Schedules and the vaccine manufacturers’ package inserts.
COVID-19 Vaccine for Adults With HIV

Lead author: Christine Kerr, MD; July 13, 2021
Writing group: Joseph P. McGowan, MD, FACP, FIDSA; Steven M. Fine, MD, PhD; Rona Vail, MD; Samuel T. Merrick, MD; Asa Radix, MD, MPH, PhD; Christopher J. Hoffmann, MD, MPH; Charles J. Gonzalez, MD
Committee: Medical Care Criteria Committee

RECOMMENDATION

- Vaccines against SARS-CoV-2 to prevent COVID-19 have been approved under an FDA Emergency Use Authorization (EUA), and vaccination is recommended for all adults, including those living with HIV. For more information, see:
  - FDA EUAs: Pfizer-BioNTech COVID-19 Vaccine, Moderna COVID-19 Vaccine, Johnson & Johnson (Janssen) COVID-19 Vaccine
  - NIH COVID-19 Treatment Guidelines: Special Considerations in People With HIV

Immunodeficiency reduces natural defenses to vaccine-preventable diseases in people with HIV and places them at increased risk for disease and for severe disease [Crum-Cianflone and Wallace 2014; Rubin, et al. 2014]. However, there is concern that patients with HIV-associated immunodeficiency may not be able to mount and maintain an appropriate immune response to vaccines and may be harmed by live virus vaccines. The strength of the immune response may be lower in patients with more advanced HIV, especially among those with CD4 counts <200 cells/mm³ and/or HIV viral load >200 copies/mL, and shorter in duration than in adults without HIV [Crum-Cianflone and Wallace 2014]. Immunogenicity, vaccine response monitoring, and requirements for additional booster doses for patients with HIV are discussed on pages for individual vaccines.

To reduce community transmission and protect those living with HIV, this Committee recommends rapid and universal vaccination against COVID-19 for individuals with HIV.

Although safety and immunogenicity data on the newly available vaccines against SARS-CoV-2 are still evolving, many people with HIV have multiple risk factors for severe COVID-19 infection. For more information, see:
- CDC: COVID-19: People at Increased Risk
- NYC Health: COVID-19: Prevention and Groups at Higher Risk > People at Increased Risk of Severe illness

Table 7: COVID-19/SARS-CoV-2 Vaccine (July 2021)

<table>
<thead>
<tr>
<th>Trade name, vaccine type (approved under FDA EUAs)</th>
<th>Pfizer-BioNTech COVID-19 Vaccine: mRNA vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Moderna COVID-19 Vaccine: mRNA vaccine</td>
</tr>
<tr>
<td></td>
<td>Janssen COVID-19 Vaccine (Johnson &amp; Johnson): Viral vector vaccine</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Indications</th>
<th>Pfizer-BioNTech COVID-19 vaccine: ≥12 years old</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Moderna and Janssen COVID-19 vaccines: ≥18 years old</td>
</tr>
<tr>
<td></td>
<td>As determined by CDC guidelines; approved for use under FDA Emergency Use Authorizations.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Administration</th>
<th>Administer as per manufacturer’s instruction for each vaccine:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pfizer-BioNTech: 2 doses, given 3 weeks apart</td>
</tr>
<tr>
<td></td>
<td>Moderna: 2 doses, given 4 weeks apart</td>
</tr>
<tr>
<td></td>
<td>Johnson &amp; Johnson (Janssen): 1 dose</td>
</tr>
</tbody>
</table>

| Revaccination                                                   | Not yet determined                           |
Table 7: COVID-19/SARS-CoV-2 Vaccine (July 2021)

| Comments | Covered by the Countermeasures Injury Compensation Program |

Discussion: Beginning in late 2019, the novel coronavirus SARS-CoV-2 rapidly changed the face of medicine and daily life worldwide. COVID-19 morbidity and mortality are increased among individuals of older age and who have comorbidities that put them at higher risk of severe disease [Nandy, et al. 2020; Ssentongo, et al. 2020]. HIV infection alone, in the absence of significant immunosuppression, does not seem to confer an independently increased risk for severe COVID-19 disease or mortality, but patients with HIV are often living with multiple comorbidities and other risk factors for more severe disease. The relationship between the severity of COVID-19 infection and related mortality in HIV infection is unclear, but increased risk may be possible. Because there is increased risk, whether due to overlapping comorbidities or due to disease-specific factors, people living with HIV are a high-priority group for vaccination [Byrd, et al. 2020; Patel, et al. 2020; Mellor, et al. 2021; Ssentongo, et al. 2021].

To date, the clinical trials for all 3 vaccines approved under the FDA EUA included approximately 900 participants with HIV, a number too small to determine efficacy specifically in people with HIV [Polack, et al. 2020; Baden, et al. 2021; Sadoff, et al. 2021]. Nonetheless, to date, there has been no evidence of decreased vaccine efficacy and no reports of increased vaccine adverse effects in people with HIV. Research is ongoing to establish a complete safety and effectiveness profile and optimal dosing schedules for immunocompromised patients.

→ KEY POINTS

- Medical mistrust may prevent people in high vaccine priority groups from seeking or agreeing to vaccination [Bogart, et al. 2021]; heightened awareness and open discussion of medical mistrust is essential to encouraging vaccination of people with HIV.
- The effects of systemic racism and associated health inequities made apparent by the U.S. COVID-19 pandemic may create barriers to vaccine access among some people with HIV. Clinicians who provide medical care for people with HIV are strongly encouraged to discuss and advocate for vaccination with all of their patients.

**Haemophilus Influenzae Type B Conjugate (Hib)**

Table 8: Hib Vaccine

<table>
<thead>
<tr>
<th>Trade Names</th>
<th>Hiberix; ActHIB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications</td>
<td>Patients at risk of Hib infection (see CDC: Recommended Immunization Schedule for Adults Aged 19 Years or Older, United States 2018)</td>
</tr>
<tr>
<td>Administration</td>
<td>Administer according to the CDC Immunization Schedule for all adults at risk</td>
</tr>
<tr>
<td>Revaccination</td>
<td>None</td>
</tr>
<tr>
<td>Comments</td>
<td>Not routinely recommended for people with HIV in the absence of other risk factors (see the CDC Immunization Schedule)</td>
</tr>
</tbody>
</table>

Discussion: Hib vaccination is not routinely recommended for patients with HIV in the absence of other risk factors, such as anatomic or functional asplenia, sickle cell disease, or hematopoietic stem cell transplant, because there is a low risk of *H. influenzae* type b infection in adults with HIV [Briere, et al. 2014; Rubin, et al. 2014; CDC 2019c]. Data on the safety and efficacy of the Hib vaccine among adults with HIV indicate a strong immune response, similar to that in adults without HIV, except among those with severe immunosuppression [Steinhoff, et al. 1991; Kroon, et al. 1997; Dockrell, et al. 1999; MacLennan, et al. 2016].
Hepatitis A Virus (HAV)

Table 9: HAV Vaccine

<table>
<thead>
<tr>
<th>Trade Names</th>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAV: Havrix; Vaqta</td>
<td>Patients aged ≥1 year with HIV [CDC 2019a]</td>
</tr>
<tr>
<td>HAV inactivated + hepatitis B virus (HBV): Twinrix</td>
<td></td>
</tr>
</tbody>
</table>

Administration

- Administer according to the CDC Immunization Schedule
- Obtain HAV IgG at least 1 month after final dose of vaccination series to identify nonresponders
- If immune reconstitution appears likely, then consider deferring until patient’s CD4 count >200 cells/mm³ [AIDSinfo 2019]

Revaccination

Nonresponders to primary HAV vaccination series should be revaccinated [Aberg, et al. 2014] and counseled to avoid exposure

Comments

- See the New York State Department of Health AIDS Institute guideline HAV-HIV Coinfection
- Covered by the Vaccine Injury Compensation Program

Discussion: The HAV vaccine is recommended for all adults with HIV who do not have immunity to HAV [CDC 2019a]. The reported rate of HAV antibody seroconversion after vaccination ranges from 49% to 96% [Fiore, et al. 2006; Crum-Cianflone NF and Wallace 2014; Mena, et al. 2015]. A long-term follow-up study reported that more than 85% of individuals who seroconverted after vaccination had a sustained antibody response for 5 to 10 years [Crum-Cianflone NF, et al. 2011b; Cheng A, et al. 2017]. Although immunocompetent individuals with HIV respond to the HAV vaccine nearly as well as individuals without HIV, individuals with lower CD4 cell counts are less likely to acquire protective levels of antibody [Fiore, et al. 2006; Crum-Cianflone NF and Wallace 2014; Mena, et al. 2015].

If a patient’s CD4 count is <200 cells/mm³ or the patient has symptomatic HIV, it is preferable to defer vaccination until several months after initiation of antiretroviral therapy to maximize the antibody response to the vaccine [AIDSinfo 2019]. HAV vaccination should not be deferred in patients who are unlikely to achieve an increased CD4 cell count (see NYSDOH AI guideline Prevention and Management of HAV in Adults With HIV).

Care providers should perform HAV IgG at least 1 month after final dose of vaccination series to identify nonresponders. Nonresponders to HAV vaccination should be revaccinated [Aberg, et al. 2014] and counseled to avoid exposure to HAV because they remain susceptible to infection, although a small study reported that 31% of primary nonresponders (n = 16) subsequently seroconverted after completing the 2-dose vaccination series [Cheng A, et al. 2017]. If patients are susceptible to both HAV and HBV, the combined HAV/HBV vaccine (3 doses at 0, 1, and 6 months) can be used regardless of the patient’s immune status [Aberg, et al. 2014].

Hepatitis B Virus (HBV)

Table 10: HBV Vaccine

<table>
<thead>
<tr>
<th>Trade Names</th>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBV 2-dose series: HEPLISAV-B (see note in comments)</td>
<td>Patients who are negative for hepatitis B surface antibody (anti-HBs) and do not have chronic HBV infection (see CDC: Recommended Immunization Schedule for Adults Aged 19 Years or Older, United States 2018 and the New York State Department of Health AIDS Institute (NYSDOH AI) guideline HBV-HIV Coinfection &gt; Figure 3).</td>
</tr>
<tr>
<td>HBV 3-dose series: Engerix-B; Recombivax HB</td>
<td></td>
</tr>
<tr>
<td>Hepatitis A virus (HAV) inactivated + HBV: Twinrix</td>
<td></td>
</tr>
</tbody>
</table>

Administration

- Administer according to the CDC Immunization Schedule for all adults [Schillie, et al. 2018]
- Alternative administration strategies, such as a 3- or 4-injection double-dose vaccination series or an accelerated schedule of 0, 1, and 3 weeks, may be considered [AIDSinfo 2019]
- Test for anti-HBs 1 to 2 months after administration of the last dose of the vaccination series [Rubin, et al. 2014]
### Table 10: HBV Vaccine

<table>
<thead>
<tr>
<th>Revaccination</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nonresponders to the primary HBV vaccination series (anti-HBs &lt;10 IU/L) should receive a double-dose revaccination series; a 4-dose schedule should be considered</td>
<td></td>
</tr>
</tbody>
</table>

- In patients at risk for HBV infection, initial vaccination should not be deferred if CD4 count is <200 cells/mm³ [AIDSinfo 2019]
- If an accelerated schedule is used, a fourth dose booster should be administered at least 6 months after initiation of the series; the accelerated schedule is not recommended for patients with CD4 counts <500 cells/mm³
- The HAV/HBV combined vaccine is not recommended for the double-dose or 4-injection HBV vaccination strategy
- HEPLISAV-B, a 2-dose (1 month apart) recombinant HBV surface antigen vaccine with a novel adjuvant is now available [Dynavax 2017]. There are no data available on use among people with HIV. There were no autoimmune adverse events among people with HIV exposed to the adjuvant [FDA 2017]
- See the NYSDOH AI guideline HBV-HIV Coinfection
- Covered by the Vaccine Injury Compensation Program

### Discussion:

The HBV vaccine is recommended for all adults with HIV who do not have immunity to HBV and who do not have chronic HBV infection [CDC 2019c]. The antibody response to the HBV vaccine is reduced in persons with HIV compared with those who do not have HIV; the reported immune response to the standard dose (20 µg) ranges from 34% to 89% [Mast, et al. 2006; Mena, et al. 2015], with diminishing response with lower CD4 cell counts [Overton, et al. 2005; Kim, et al. 2008; Pettit, et al. 2010; Pollack, et al. 2016]. Undetectable or very low viral load is associated with increased response to HBV vaccination [Overton, et al. 2005; Kim, et al. 2008; Mena, et al. 2012]. Initial vaccination should not be deferred in patients with low CD4 cell counts; some patients with HIV and CD4 counts <200 cells/mm³ may have an immune response [Whitaker, et al. 2012; AIDSinfo 2019]. Improved immune response has been reported using a 4-injection double-dose (40 µg) regimen [Launay, et al. 2011; Chaiklang, et al. 2013]. Studies of a 3-injection double-dose regimen reported increased seroconversion rates compared to standard dose only among adults with HIV with CD4 counts >350 cells/mm³ and low or undetectable HIV viral load [Fonseca, et al. 2005; Potsch, et al. 2012]. Accelerated schedules (0, 1, and 3 weeks) may increase adherence to the full vaccination series but are not recommended for patients with CD4 counts ≤500 cells/mm³ due to the increased likelihood of nonresponse [de Vries-Sluijs, et al. 2011]. Patients with HIV should be tested for anti-HBs 1 to 2 months after completing the vaccination series [Aberg, et al. 2014; AIDSinfo 2019]. Other strategies to improve immune response have demonstrated some success, including intradermal administration [Launay, et al. 2011] and addition of adjuvants [Sasaki, et al. 2003; Cooper CL, et al. 2005; Overton, et al. 2010], but the evidence is not sufficient to make a recommendation.

Nonresponders to primary vaccination should be revaccinated using a double-dose regimen with consideration of a 4-dose schedule. Several studies have reported increased response rates from double-dose revaccination among nonresponders [Cardell, et al. 2008; de Vries-Sluijs, et al. 2008; Psevdos, et al. 2010], although the only randomized controlled trial comparing a 3-injection standard dose (20 µg) to a 3-injection, double-dose (40 µg) regimen for revaccination found no difference in response rates. However, the double-dose regimen resulted in a greater and more durable immune response [Rey, et al. 2015]. HBV revaccination can be deferred among nonresponders who are initiating antiretroviral therapy until CD4 counts increase to ≥200 cells/mm³ [AIDSinfo 2019]. Revaccination should not be delayed in patients who are unlikely to achieve an increased CD4 cell count. For more detailed information, see NYSDOH AI guideline HBV-HIV Coinfection.

Three HBV vaccination formulations are available in the United States. The efficacy of these vaccines has been reported to be equivalent when used in patients who do not have HIV; however, the 3 formulations have not yet been established to be equally effective in patients with HIV. For persons who are susceptible to both HAV and HBV, the combined HAV/HBV vaccine can be used regardless of immune status, with 3 doses, administered at 0, 1, and 6 months. Because no data are available regarding double-dose or 4-injection HBV vaccination with the combined HAV/HBV vaccine in the presence of HIV, the combined vaccine is not recommended for the double-dose or 4-injection HBV vaccination strategy. A 2-dose (1 month apart) recombinant hepatitis B surface antigen vaccine with a novel adjuvant is available. There are no data available on use in people with HIV, but seroprotective rates were superior to comparator 3-dose series among older adults and adults with diabetes [Schillie, et al. 2018]. No autoimmune adverse events were reported among people with HIV exposed to the adjuvant [FDA 2017]. The 2-dose option may facilitate completion rates for the vaccination series. For more information, see NYSDOH AI guideline HBV-HIV Coinfection > Prevention.
Human Papillomavirus (HPV)

Table 11: HPV Vaccine

<table>
<thead>
<tr>
<th>Trade Names</th>
<th>Gardasil 9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications</td>
<td>All patients aged 9 to 26 years who were not previously vaccinated or did not receive a complete 3-dose series (see CDC: Recommended Immunization Schedule for Adults Aged 19 Years or Older, United States 2018).</td>
</tr>
<tr>
<td>Administration</td>
<td>Administer through age 26 years as a 3-dose series according to the CDC Immunization Schedule for adults with immunocompromising conditions.</td>
</tr>
<tr>
<td>Revaccination</td>
<td>None</td>
</tr>
</tbody>
</table>
| Comments | • A 2-dose schedule is not recommended [CDC 2019b]  
• Because of the broader coverage offered by the 9-valent HPV vaccine, it is the only HPV vaccine currently available in the United States (see CDC HPV Home > Information for Healthcare Professionals for more information)  
• Although the 9-valent vaccine has not been specifically studied in people with HIV, it is expected that the response will be the same in this population as with the 4-valent vaccine  
• Follow recommendations for cervical and anal cancer screening in women with HIV and men who have received the HPV vaccine [AIDSinfo 2019]  
• Covered by the Vaccine Injury Compensation Program |

Discussion: The HPV vaccine is safe and immunogenic among individuals with HIV [Giacomet, et al. 2014; Kojic, et al. 2014; Markowitz, et al. 2014; Toft, et al. 2014; Faust, et al. 2016] and is recommended for women and men aged 9 to 26 years who did not already receive a complete 3-dose series [CDC 2019c]. Routine HPV vaccination is recommended for all adolescents at age 11 to 12 years [CDC 2018]. Available data do not support HPV vaccination in all adults older than 26 years, including those with HIV [Wilkin, et al. 2016]. Mathematical modeling based on the quadrivalent vaccine has demonstrated that offering HPV vaccination up to age 40 years to MSM with HIV likely would be cost-effective [Lin, et al. 2017]; however, this study did not account for lower vaccine response rates with increased age. Other analyses demonstrate 1) efficacy in adults older than 26 years, although at rates lower than in adolescents; 2) a comparable immune response for HPV type 16; and 3) a slightly lower immune response for HPV types 6, 11, and 18 among women aged 25 to 45 years [Munoz, et al. 2009; Westra, et al. 2011].

The HPV vaccine is U.S. Food and Drug Administration-approved for preventive but not therapeutic use; there are no data to support the use of the HPV vaccine to ameliorate existing disease. In individuals who have had an abnormal Pap test result before being vaccinated, the HPV vaccine may protect against infection from HPV types other than those that caused earlier or existing cervical abnormalities. HPV vaccination should be offered regardless of CD4 cell count [AIDSinfo 2019]. Lower seroconversion rates after HPV vaccination have been reported among women with HIV who are not taking antiretroviral therapy [Kahn, et al. 2013] or who have CD4 counts <200 cells/mm³ and/or HIV viral load >10,000 copies/mL than among women who do not have HIV [Kojic, et al. 2014]. In another study, women with HIV and a suppressed viral load had a 1.74 to 3.03 times higher peak antibody response than those who did not have viral suppression at the time of first injection; the clinical significance of this finding is not known [Money, et al. 2016].

In individuals who have had an abnormal Pap test result before being vaccinated, the HPV vaccine may protect against infection from HPV subtypes other than those that caused earlier or existing cervical abnormalities. However, the vaccine does not cover all HPV serotypes that increase risk of cancer, and the vaccine may be less effective in individuals with HIV. In women and men with HIV who have received the HPV vaccine, clinicians should continue to follow recommendations for cervical and anal cytologic screening, including visual inspection of the anogenital area during annual examinations [AIDSinfo 2019]. (See the New York State Department of Health AIDS Institute guidelines on Cervical Screening for Dysplasia and Cancer and Screening for Anal Dysplasia and Cancer in Adults with HIV).

HPV testing is not required before administration of the vaccine [Markowitz, et al. 2014]. The 2-dose schedule is not recommended for immunocompromised adults, including those with HIV [Meites, et al. 2016]. There is no recommendation for obtaining follow-up antibody titers because the minimum protective titers have not been established and the immune response rate is high [Markowitz, et al. 2014]. Although the 9-valent vaccine has not been
specifically studied in people with HIV, it is the preferred vaccine because of the broader range of HPV subtypes seen in this population [AIDSinfo 2019].

**Influenza**

<table>
<thead>
<tr>
<th>Table 12: Influenza Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trade Names</strong></td>
</tr>
<tr>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td><strong>Administration</strong></td>
</tr>
<tr>
<td><strong>Revaccination</strong></td>
</tr>
<tr>
<td><strong>Comments</strong></td>
</tr>
</tbody>
</table>

**Discussion:** People with HIV are at greater risk of severe morbidity from an influenza infection [Kunisaki and Janoff 2009; Grohskopf, et al. 2019] than people who do not have HIV and should be vaccinated annually during flu season (October through May) according to *standard (CDC) guidelines* for all adults [Aberg, et al. 2014; Grohskopf, et al. 2019]. Inactivated influenza vaccine offers protective immunity in adults with HIV [Beck, et al. 2012; Remschmidt, et al. 2014; Grohskopf, et al. 2019]. Live, attenuated influenza vaccine should not be used for individuals with HIV. Antibody titers lower than those observed in the general population have been reported among adults with HIV, especially among those with advanced HIV disease who are older than 35 years, have low CD4 cell counts, and have detectable viremia [Kroon, et al. 2000; Yamanaka, et al. 2005; Evison, et al. 2009; Crum-Cianflone NF, et al. 2011a; Garg, et al. 2016]. Studies comparing intradermal and intramuscular vaccines report no difference in immunogenicity, but intradermal vaccination is associated with increased likelihood of redness, swelling, and tenderness at the injection site [Garg, et al. 2016; Seo, et al. 2016]. The CDC does not recommend a second vaccination in individuals with HIV [Grohskopf, et al. 2019], although one study reported that a second dose of an adjuvanted vaccine significantly increased the rate of seroprotective responses [Bickel, et al. 2011]. There is some evidence that influenza seroprotection is higher for people aged 18 years or older who are given a double-dose vaccine than for those given the standard dose vaccine, but the clinical significance of this remains unknown [Cooper C, et al. 2011; McKittrick, et al. 2013]. Another study among children and young adults (aged 3 to 21 years) found no increased immunity among participants with HIV who received the double-dose vaccine [Hakim, et al. 2016]. The high-dose vaccine is not licensed for people older than 65 years. Results of 2 studies suggest a possible benefit to delaying influenza vaccination to after mid-November; patients vaccinated later in the flu season had lower rates of laboratory-confirmed influenza and influenza-like illnesses than those vaccinated earlier in the season [Werker, et al. 2014; Glinka, et al. 2016]. Monitoring regional influenza activity will help ensure appropriate timing of influenza vaccination. There is no recommendation for post-vaccination serologic testing to determine immune response [Grohskopf, et al. 2019].

**Measles, Mumps, Rubella (MMR)**

<table>
<thead>
<tr>
<th>Table 13: MMR Vaccine</th>
</tr>
</thead>
</table>
| **Trade Names** | • M-M-R II  
• MMR + varicella: ProQuad |
| **Indications** | For patients with CD4 counts ≥200 cells/mm³ who do not have evidence of MMR immunity, as determined by the CDC’s *Recommended Immunization Schedule for Adults Aged 19 Years or Older, United States 2018* |
| **Administration** | Two doses at least 28 days apart (see the *CDC Immunization Schedule*) |
| **Revaccination** | Recommended only in the setting of an outbreak (see the *CDC Immunization Schedule*) |
Table 13: MMR Vaccine

<table>
<thead>
<tr>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Contraindicated</strong> for patients with CD4 counts &lt;200 cells/mm³ (see the <a href="https://www.cdc.gov/vaccines/schedules/hcp/childadolescent.html">CDC Immunization Schedule</a>)</td>
</tr>
<tr>
<td>Those who previously received 2 doses of a mumps-containing vaccine and are at increased risk for mumps in the setting of an outbreak should receive a third dose to improve protection against mumps disease and related complications [Marin M, et al. 2018]</td>
</tr>
<tr>
<td>Covered by the <a href="https://www.hrsa.gov/vaccineinjuryprogram">Vaccine Injury Compensation Program</a></td>
</tr>
</tbody>
</table>

Discussion: Immunocompromised persons are at increased risk of serious and life-threatening complications if infected with measles [McLean, et al. 2013]. Patients with HIV who have CD4 counts ≥200 cells/mm³ and who do not have evidence of immunity to MMR should be vaccinated with 2 doses of MMR vaccine at least 28 days apart. Documentation of previous age-appropriate vaccination or laboratory confirmation of prior disease is acceptable evidence of immunity. Serologic screening is required if other acceptable evidence of immunity is not available and to determine rubella immunity among individuals of childbearing potential. In the absence of other evidence of immunity, persons with perinatally acquired HIV who received childhood vaccination with MMR before establishment of effective ART should be revaccinated (2 doses) after effective antiretroviral therapy (ART) is established [McLean, et al. 2013]. There is no recommendation for post-vaccination serologic testing to determine immune response [McLean, et al. 2013].

Two studies that examined the antibody response after MMR vaccination in adults with HIV taking ART reported high levels of protective antibodies post-vaccination, although the levels were lower than in adults without HIV. A study conducted in Mexico among adults with HIV who were seronegative for measles reported no significant difference in initial antibody response to measles vaccination between adults with and without HIV (81% vs 85%). However, at 1 year, the observed decline in antibody response was faster in adults with HIV than in those without HIV [Belaunzaran-Zamudio, et al. 2009]. A study in Thailand reported protective antibodies to measles (74.1%), mumps (65.7%), and rubella (93.3%) among adults with HIV 8 to 12 weeks after vaccination with MMR. Compared with adults without HIV, the seroconversion rates were lower but reached statistical significance only for mumps [Chaiwarith, et al. 2016].

No data are available on revaccination in adults with HIV. Revaccination has improved measles antibody response in children with HIV on ART who had an inadequate initial response to vaccination [Aurpibul, et al. 2007; Abzug, et al. 2012]. If persons previously vaccinated with 2 doses of a mumps-containing vaccine are identified as at increased risk for mumps by public health authorities because of an outbreak, these at-risk individuals should receive a third dose of a mumps-containing vaccine to improve protection against mumps disease and related complications [Marin M, et al. 2018].

MMR vaccination contains live virus and is contraindicated for patients with CD4 counts <200 cells/mm³ due to reports of adverse events, such as measles pneumonitis, in severely compromised patients [CDC 1996; Angel, et al. 1998]. Serious adverse effects have not been reported in adults who were not severely immunocompromised [Belaunzaran-Zamudio, et al. 2009; McLean, et al. 2013; Chaiwarith, et al. 2016]. MMRV has not been adequately studied in individuals with HIV and is not recommended as a substitute for MMR in this population [McLean, et al. 2013; Rubin, et al. 2014].

Meningococcal Serotype Non-B (MenACWY)

Table 14: MenACWY Vaccine

<table>
<thead>
<tr>
<th>Trade Names</th>
</tr>
</thead>
<tbody>
<tr>
<td>MenACWY: Menactra</td>
</tr>
<tr>
<td>MCV4: Menveo</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients with HIV (see the CDC’s <a href="https://www.cdc.gov/vaccines/schedules/hcp/childadolescent.html">Recommended Immunization Schedule for Adults Aged 19 Years or Older, United States 2018</a>)</td>
</tr>
<tr>
<td>See <a href="https://www.health.ny.gov/disease_control/communicable/diseases/medical_advisories/meningococcal_2013.pdf">NYSDOH Meningococcal Disease Health Advisories</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administer 2 doses of MenACWY at least 8 weeks apart in those not previously vaccinated (see the CDC Immunization Schedule)</td>
</tr>
<tr>
<td>For those previously vaccinated with 1 dose of MenACWY, administer the second dose at the earliest opportunity at least 8 weeks after the previous dose (see the CDC Immunization Schedule)</td>
</tr>
</tbody>
</table>
Table 14: MenACWY Vaccine

<table>
<thead>
<tr>
<th>Revaccination</th>
<th>Administer 1 booster dose of MenACWY every 5 years (see the CDC Immunization Schedule)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comments</td>
<td>• MenACWY is preferred over MPSV4 in adults with HIV &gt;55 years of age</td>
</tr>
<tr>
<td></td>
<td>• Covered by the Vaccine Injury Compensation Program</td>
</tr>
</tbody>
</table>

Discussion: Adults with HIV are at increased risk of invasive meningococcal disease due to serogroups C, W, and Y. [MacNeil, et al. 2016; Folaranmi, et al. 2017]. A recent study in New York City reported a 10-fold increased risk of invasive meningococcal disease in patients with HIV, with the highest risk among those with CD4 counts <200 cells/mm³ [Miller L, et al. 2014]. As of 2017, the CDC recommends vaccinating all previously unvaccinated adults with HIV with a 2-dose primary series of MenACWY (MenACWY-CRM or MenACWY-D) administered at least 8 weeks apart [MacNeil, et al. 2016].

Data on meningococcal vaccine efficacy among adults with HIV are not currently available [MacNeil, et al. 2016]. Among adolescents with HIV, available evidence indicates that the vaccine is immunogenic and serious adverse events are rare, but adolescents with HIV (and especially those with lower CD4 cell counts and higher viral loads) had reduced antibody levels compared with adolescents without HIV [Siberry, et al. 2010; Lujan-Zilbermann, et al. 2012]. Adding a second vaccine dose significantly improved antibody levels 28 and 72 weeks after immunization, particularly among adolescents with CD4% ≥15 [Lujan-Zilbermann, et al. 2012].

Booster doses every 5 years are needed to maintain immunity. Although MPSV4 is the only meningococcal vaccine licensed for persons aged 56 years or older, MenACWY is preferred among older adults because of the need for revaccination. Limited data among adults without HIV suggest a greater immune response after a booster dose of MenACWY than with MPSV4; however, no data are available for adults with HIV. There is no recommendation for post-vaccination serologic testing to determine immune response [MacNeil, et al. 2016].

Meningococcal Serotype B (MenB)

Table 15: MenB Vaccine

<table>
<thead>
<tr>
<th>Trade Names</th>
<th>Bexsero; Trumenba</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications</td>
<td>Patients at risk of MenB infection, as determined by the CDC’s Recommended Immunization Schedule for Adults Aged 19 Years or Older, United States 2018</td>
</tr>
<tr>
<td>Administration</td>
<td>Administer according to the CDC Immunization Schedule for patients at risk</td>
</tr>
<tr>
<td>Revaccination</td>
<td>None</td>
</tr>
<tr>
<td>Comments</td>
<td>• Not routinely recommended for people with HIV in the absence of other risk factors (see the CDC Immunizations Schedule)</td>
</tr>
<tr>
<td></td>
<td>• Covered by the Vaccine Injury Compensation Program</td>
</tr>
</tbody>
</table>

Discussion: MenB vaccine is not routinely recommended for adults with HIV unless they have another indication for immunization. No increased risk of serogroup B meningococcal disease among individuals with HIV has been reported [CDC 2019c].

Pneumococcal

Table 16: Pneumococcal Vaccine: 13-Valent and 23-Valent (PCV13, PPSV23)

<table>
<thead>
<tr>
<th>Trade Names</th>
<th>Prevnar 13 (PCV130); Pneumovax 23 (PPSV23)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications</td>
<td>All patients with HIV (see the CDC’s Recommended Immunization Schedule for Adults Aged 19 Years or Older, United States 2018)</td>
</tr>
</tbody>
</table>
Table 16: Pneumococcal Vaccine: 13-Valent and 23-Valent (PCV13, PPSV23)

**Administration**
- The complete series of vaccinations is 1 dose of PCV13 and 2 doses of PPSV23 before age 65 years, followed by 1 additional dose of PPSV23 after age 65 years (see the CDC Immunization Schedule)
- See Table 17, below, for detailed administration guidelines based on age and previous vaccination history

**Revaccination**
See Table 17, below

**Comments**
The PCV13 vaccine should not be deferred for patients with CD4 count <200 cells mm\(^{-3}\) and/or detectable viral load; however, the follow-up secondary administration of PPSV23 vaccine may be deferred until the patient’s CD4 count is >200 cells mm\(^{-3}\) and/or viral load is undetectable

**Discussion:** Individuals with HIV are at increased risk of serious disease due to *Streptococcus pneumoniae*, including bacteremia, meningitis, and pneumonia. Pneumococcal vaccination is recommended for all adults with HIV as soon as possible after HIV diagnosis [CDC 2019c; Matanock, et al. 2019]. The complete series is 1 dose of PCV13 as a priming vaccine, followed by 2 doses of PPSV23 before age 65 years and 1 additional dose of PPSV23 after age 65 years. Because only 1 dose of PPSV23 is recommended after a patient reaches age 65 years, those who begin vaccination at age 65 years or older should receive 1 dose of PCV13 and 1 dose of PPSV23 [Tomczyk, et al. 2014]. There is no recommendation for post-vaccination serologic testing to determine immune response [CDC 2019c; Matanock, et al. 2019]. See Table 17 for vaccination recommendations by previous pneumococcal immunization history and age at time of initial evaluation.


Patients with CD4 counts <200 cells/mm\(^3\) are at the highest risk of pneumococcal disease. Because immunogenicity has been demonstrated for individuals with HIV with CD4 counts <200 cells/mm\(^3\) who received PCV7 [French, et al. 2010], use of PCV13 may be considered in severely immunocompromised patients. Patients with HIV who have not previously received any pneumococcal vaccine should receive a dose of PCV13, regardless of CD4 cell count. Although there is evidence of the effectiveness of PPSV23 among patients with CD4 counts <200 cells/mm\(^3\), the benefit appears to be greatest among patients with viral loads <100,000 copies/mL and among those who are on antiretroviral therapy.

If zoster vaccine is also being administered, it should be separated from the pneumococcal vaccine by at least 4 weeks [Merck 2017].

Table 17: Pneumococcal Vaccination Recommendations for Adults with HIV, by Previous Pneumococcal Immunization History and Age at Time of Initial Evaluation (see CDC Immunization Schedule)

<table>
<thead>
<tr>
<th>Previous Immunization History</th>
<th>Aged 18-64 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>No previous PCV13/PPSV23* or unknown status</td>
<td>1 dose of PCV13, then</td>
</tr>
<tr>
<td>by clinical documentation or patient self-report</td>
<td>1st dose of PPSV23 ≥8 weeks later, then</td>
</tr>
<tr>
<td>2nd dose of PPSV23 ≥5 years after 1st dose of PPSV23, then</td>
<td>3rd dose of PPSV23 if 65 years or older and ≥5 years since 2nd dose of PPSV23 and 2nd dose of PPSV23 given before age 65 years</td>
</tr>
</tbody>
</table>

| No PCV13 + 1 dose of PPSV23 | 1 dose of PCV13 ≥1 year after 1st dose of PPSV23, then |
| 2nd dose of PPSV23 if both ≥8 weeks after PCV13 dose and ≥5 years after 1st dose of PPSV23, then | 3rd dose of PPSV23 if 65 years or older and ≥5 years since 2nd dose of PPSV23 and 2nd dose of PPSV23 given before age 65 years |

<table>
<thead>
<tr>
<th>Aged 65 Years or Older</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 dose of PCV13, then</td>
</tr>
<tr>
<td>1 dose of PPSV23 ≥8 weeks later</td>
</tr>
<tr>
<td>1 dose of PCV13 ≥1 year after 1st dose of PPSV23, then</td>
</tr>
<tr>
<td>2nd dose of PPSV23 if both ≥8 weeks after PCV13 dose and ≥5 years after 1st dose of PPSV23 and 1st dose of PPSV23 was given before age 65 years</td>
</tr>
</tbody>
</table>
Table 17: Pneumococcal Vaccination Recommendations for Adults with HIV, by Previous Pneumococcal Immunization History and Age at Time of Initial Evaluation (see CDC Immunization Schedule)

<table>
<thead>
<tr>
<th>Previous Immunization History</th>
<th>Aged 18-64 Years</th>
<th>Aged 65 Years or Older</th>
</tr>
</thead>
<tbody>
<tr>
<td>No PCV13 + 2 doses of PPSV23</td>
<td>• 1 dose of PCV13 ≥1 year after most recent dose of PPSV23 and 3rd dose of PPSV23 if 65 years or older and ≥5 years after 2nd dose of PPSV23 and 2nd dose of PPSV23 given before age 65 years and ≥8 weeks after PCV13 dose</td>
<td>• 1 dose of PCV13 ≥1 year after most recent dose of PPSV23, then 3rd dose of PPSV23 if ≥5 years after 2nd dose of PPSV23 and 2nd dose of PPSV23 given before age 65 years and ≥8 weeks after PCV13 dose</td>
</tr>
<tr>
<td>1 dose of PCV13 + No PPSV23</td>
<td>• 1st dose of PPSV23 ≥8 weeks after PCV13 dose, then 2nd dose of PPSV23 ≥5 years later, then 3rd dose of PPSV23 if 65 years or older and ≥5 years since 2nd dose of PPSV23 and 2nd dose of PPSV23 given before age 65 years</td>
<td>• 1 dose of PPSV23 ≥8 weeks after PCV13 dose</td>
</tr>
<tr>
<td>1 dose of PCV13 + 1 dose of PPSV23</td>
<td>• 2nd dose of PPSV23 if ≥8 weeks after PCV13 dose and ≥5 years since 1st dose of PPSV23, then 3rd dose of PPSV23 if both 65 years or older and ≥5 years since 2nd dose of PPSV23 and 2nd dose of PPSV23 given before age 65 years</td>
<td>• If 1st dose of PPSV23 given before age 65 years: 2nd dose of PPSV23 ≥8 weeks after PCV13 dose and ≥5 years after 1st dose of PPSV23 If 1st dose of PPSV23 given at 65 years or older: No further doses of PPSV23 required</td>
</tr>
<tr>
<td>1 dose of PCV13 + 2 doses of PPSV23</td>
<td>• If 2nd dose of PPSV23 given before age 65 years: 3rd dose of PPSV23 if 65 years or older and ≥5 years since 2nd dose of PPSV23</td>
<td>• If 2nd dose of PPSV23 given before age 65 years: 3rd dose of PPSV23 ≥8 weeks after PCV13 dose and ≥5 years since 2nd dose of PPSV23 If 2nd dose of PPSV23 given at 65 years or older: No 3rd dose of PPSV23 required</td>
</tr>
</tbody>
</table>

Table 18: Tdap and Td Vaccines

<table>
<thead>
<tr>
<th>Trade Names</th>
<th>Tdap: Adacel; Boostrix Td: Tenivac; Decavac (generic 9Td)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications</td>
<td>For all patients, as determined by the CDC’s Recommended Immunization Schedule for Adults Aged 19 Years or Older, United States 2018 for all adults</td>
</tr>
<tr>
<td>Administration</td>
<td>Administer according to the CDC Immunization Schedule for all adults</td>
</tr>
<tr>
<td>Revaccination</td>
<td>Td is usually given as a booster dose every 10 years, but it can also be given earlier after a severe and dirty wound or burn</td>
</tr>
<tr>
<td>Comments</td>
<td>Covered by the Vaccine Injury Compensation Program</td>
</tr>
</tbody>
</table>

Discussion: The recommendations for Tdap and Td vaccination of adults with HIV are the same as for all adults [CDC 2019c]. The safety and efficacy of vaccination with Tdap has not been studied in this population [Rubin, et al. 2014].
Varicella

Table 19: Varicella Vaccine

| Trade Names | • Varicella: Varivax  
• Measles, mumps, and rubella (MMR) + varicella (MMRV): ProQuad |
| Indications | • For patients with CD4 counts ≥200 cells/mm³ who do not have evidence of immunity to varicella, as determined by the CDC’s Recommended Immunization Schedule for Adults Aged 19 Years or Older, United States 2018  
• HIV-infected children ≥12 months old with CD4+ T-lymphocyte percentages ≥15% |
| Administration | Administer according to the CDC Immunization Schedule for all adults |
| Revaccination | None |
| Comments | • Contraindicated for patients with CD4 counts <200 cells/mm³ (see the CDC Immunization Schedule)  
• Anti-varicella IgG screening should be performed in patients with no known history of chickenpox or shingles [Marin M, et al. 2007]  
• MMRV should not be used [Rubin, et al. 2014]  
• Antitherapeutic agents should be avoided at least 24 hours before and 14 days after administration [Ezeanolue, et al. 2019]  
• An interval of at least 3 months is recommended between administration of post-exposure varicella IgG (VariZIG) and varicella vaccination [Cohn, et al. 2013]  
• Clinical disease due to varicella after vaccination, a very rare event, should be treated with acyclovir [AIDSinfo 2019]  
• Covered by the Vaccine Injury Compensation Program |

Discussion: Patients with HIV who have CD4 counts ≥200 cells/mm³ and do not have immunity to varicella should be vaccinated according to CDC guidelines for all adults, with 2 doses of single-antigen varicella vaccine 4 to 8 weeks apart or a second dose if they have received only 1 dose. Varicella vaccination contains live virus and is contraindicated for patients with CD4 counts <200 cells/mm³ because of the risk of disseminated disease [Kramer, et al. 2001; Marin M, et al. 2007; CDC 2019c]. Data on the effectiveness of varicella vaccination among adults with HIV are lacking, but vaccination has been shown to be effective among children with HIV [Marin M, et al. 2007; CDC 2012; Crum-Cianflone NF and Wallace 2014]. Clinicians should verify varicella immunity due to the possibility of severe disease in individuals with HIV. Birth before 1980 is not accepted as evidence of immunity in immunocompromised persons; anti-varicella IgG screening should be performed in patients with HIV who have no known history of chickenpox or shingles [Marin M, et al. 2007]. Post-vaccination serologic testing to determine immune response is not recommended because commercially available assays lack sensitivity and may give false-negative results [Marin M, et al. 2007]. Clinical disease due to varicella after vaccination, a very rare event, should be treated with acyclovir [Marin M, et al. 2007; AIDSinfo 2019]. If household members or close contacts develop a rash after vaccination, individuals with HIV should avoid contact with the affected person until after the rash resolves [Marin M, et al. 2007; Rubin, et al. 2014; Ezeanolue, et al. 2019]. Because they can interfere with vaccine virus replication and decrease vaccine effectiveness, all antitherapeutic agents should be avoided for at least 72 hours before varicella vaccination through 14 days after [CDC 2016]. If post-exposure varicella immune globulin is given, clinicians should wait at least 5 months before vaccination [Ezeanolue, et al. 2019].

Zoster

Table 20: Zoster Vaccine

| Trade Names | Shingrix: Recombinant zoster vaccine (RZV), adjuvanted—PREFERRED |
| Indications | Medical Care Criteria Committee recommendation: Patients with HIV ≥50 years of age (A2) |
### Table 20: Zoster Vaccine

<table>
<thead>
<tr>
<th>Administration</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two IM doses, spaced 2 to 6 months apart, regardless of past receipt of zoster live vaccine (ZVL)</td>
<td>• RZV provides strong protection against shingles and post-herpetic neuralgia. Currently, there are no data on immunogenicity specific to people with HIV; however, superior efficacy and longer duration of protection have been demonstrated among the elderly, and a recombinant vaccine is preferred people with HIV</td>
</tr>
<tr>
<td>RZV is preferred over ZVL [Dooling, et al. 2018] (A2)</td>
<td>• ZVL (brand name Zostavax) is also available but is not recommended for people with HIV and is <em>contraindicated</em> in patients with CD4 count &lt;200 cells/mm³ (see <a href="https://www.cdc.gov/vaccines/hcp/Immunization-Algorithms/default.htm">Centers for Disease Control and Prevention (CDC) guidelines</a>). If RZV is not available and ZVL must be administered:</td>
</tr>
<tr>
<td>Perform anti-varicella immunoglobulin G (IgG) screening in patients with no known history of chickenpox or shingles</td>
<td>- Perform anti-varicella IgG screening in patients with no known history of chickenpox or shingles</td>
</tr>
<tr>
<td></td>
<td>- Instruct patients to avoid antitherpetic agents for 1 to 2 days before vaccination through 14 days after [Marin M, et al. 2007]</td>
</tr>
<tr>
<td></td>
<td>- Separate administration of ZVL from administration of pneumococcal vaccine by at least 4 weeks [Merck 2017]</td>
</tr>
</tbody>
</table>

**Discussion:** Patients with HIV are at increased risk of zoster (initial episodes and recurrences) at all stages of HIV disease; the risk is greater among those with severe immunodeficiency and lower CD4 cell counts [Harpaz, et al. 2008; Blank, et al. 2012]. Zoster vaccination may reduce disease burden in individuals with HIV; however, data on the use of zoster vaccine among adults with HIV are limited. The Advisory Committee on Immunization Practices recommends RZV for use in immunocompetent adults aged ≥50 years; as noted above, the [Medical Care Criteria Committee](https://www.hivguidelines.org) recommends 2 doses of RZV, administered 2 to 6 months apart, for adults with HIV ≥50 years of age. RZV provides strong protection against shingles and post-herpetic neuralgia. There is no specific data on immunogenicity in people with HIV; however, superior efficacy and longer duration of seroprotection have been demonstrated in the elderly, and a recombinant vaccine is preferred over a live, attenuated vaccine in this population [Dooling, et al. 2018].

Limited data are available on the immunogenicity of live, attenuated zoster vaccine in people with HIV (ZVL). The Committee does not recommend use of ZVL in people with HIV because of the potential for adverse effects and for interference by co-administered antiviral and immunoglobulin therapy [Benson, et al. 2012; Shafran 2016]. If ZVL is used due to lack of access to RZV, [CDC guidelines](https://www.cdc.gov/vaccines/hcp/Immunization-Algorithms/default.htm) recommend that, if possible, antitherpetic agents should be avoided 1 to 2 days before through 14 days after administration of the zoster vaccine [Harpaz, et al. 2008]. In addition, zoster vaccine should be separated from pneumococcal vaccine by at least 4 weeks [Merck 2017]. Anti-varicella IgG screening should be performed in patients with no known history of chickenpox or shingles. Zoster vaccination is contraindicated for patients with CD4 counts <200 cells/mm³ [Harpaz, et al. 2008]. There is no recommendation for post-vaccination serologic testing to determine immune response [Harpaz, et al. 2008].
### Summary of Recommended Vaccines for Adults With HIV

#### Table 21: Summary of Recommended Vaccines for Adults With HIV

<table>
<thead>
<tr>
<th>Vaccine Trade Name</th>
<th>Indications</th>
<th>Administration and Revaccination</th>
<th>Comments</th>
</tr>
</thead>
</table>
| **COVID-19/SARS-CoV-2** | • Pfizer-BioNTech COVID-19 vaccine: ≥12 years old  
• Moderna and Janssen COVID-19 vaccines: ≥18 years old  
• As determined by CDC guidelines; approved for use under FDA Emergency Use Authorizations. | • Administer as per manufacturer’s instruction for each vaccine:  
– Pfizer-BioNTech: 2 doses, given 3 weeks apart  
– Moderna: 2 doses, given 4 weeks apart  
– Johnson & Johnson (Janssen): 1 dose  
• **Revaccination:** Not yet determined | Covered by the Countermeasures Injury Compensation Program |
| **Haemophilus Influenzae Type B Conjugate (Hib)** | Patients at risk of Hib infection; see CDC guidelines for all adults | • Administer according to CDC guidelines for all adults  
• **Revaccination:** None | Not routinely recommended for people with HIV in the absence of other risk factors |
| **Hepatitis A (HAV)** | All patients aged ≥1 year with HIV | • Administer according to CDC guidelines  
• Obtain HAV IgG at least 1 month after final dose of vaccination series to identify nonresponders  
• If immune reconstitution appears likely, then consider deferring until patient’s CD4 count >200 cells/mm³  
• **Revaccination:** Nonresponders to primary HAV vaccination series should be revaccinated and counseled to avoid exposure | • Covered by the Vaccine Injury Compensation Program*  
• See NYSDOH AI guideline *Prevention and Management of Hepatitis A Virus in Adults With HIV* |
| **Hepatitis B (HBV)** | Patients who are negative for anti-HBs and do not have chronic HBV infection; see NYSDOH AI guideline *HBV-HIV Coinfection*, Figure 3 | • Administer according to CDC guidelines for all adults  
• Alternative administration strategies, such as a 3- or 4-injection double-dose vaccination series or an accelerated schedule of 0, 1, and 3 weeks, may be considered  
• Test for anti-HBs 1 to 2 months after administration of the last dose of the vaccination series  
• In patients at risk for HBV infection, initial vaccination should not be deferred if CD4 cell count is <200 cells/mm³  
• If an accelerated schedule is used, a 4th dose booster should be administered at least 6 months after initiation of the series; the accelerated schedule is not recommended for patients with CD4 counts <500 cells/mm³  
• The HAV/HBV combined vaccine is not recommended for the double-dose or 4-injection HBV vaccination strategy |
<table>
<thead>
<tr>
<th>Vaccine Trade Name</th>
<th>Indications</th>
<th>Administration and Revaccination</th>
<th>Comments</th>
</tr>
</thead>
</table>
| **Human Papillomavirus (HPV)**   | • Gardasil 9                                                                | • Administer through age 26 years as a 3-dose series according to CDC guidelines for adults with immuno-compromising conditions  
  **Revaccination:** None                                          | • A 2-dose schedule is not recommended  
  • Because of the broader coverage offered by the 9-valent HPV vaccine, it is the only HPV vaccine currently available in the United States (see CDC HPV Home > Information for Healthcare Professionals for more information)  
  • Although the 9-valent vaccine has not been specifically studied in people with HIV, it is expected that the response will be the same in this population as with the 4-valent vaccine  
  • Follow recommendations for cervical and anal cancer screening in women with HIV and men who have received the HPV vaccine  
  • Covered by the Vaccine Injury Compensation Program* |
| **Influenza**                    | • For brand names, see CDC flu vaccines table                               | • Administer annually during flu season (October through May) according to CDC guidelines for all adults  
  **Revaccination:** None                                          | Covered by the Vaccine Injury Compensation Program*                                                                                                  |
| **Measles, Mumps, and Rubella (MMR)** | • M-M-R II  
  • MMR + varicella: ProQuad                                                | • Two doses at least 28 days apart  
  **Revaccination:** Recommended only in the setting of an outbreak                                                                 | Contraindicated for patients with CD4 counts <200 cells/mm³  
  • MMRV should not be substituted for MMR  
  • Those who previously received 2 doses of a mumps-containing vaccine and are at increased risk for mumps in the setting of an outbreak should receive a third dose to improve protection against mumps disease and related complications |

**Table 21: Summary of Recommended Vaccines for Adults With HIV**
<table>
<thead>
<tr>
<th>Vaccine Trade Name</th>
<th>Indications</th>
<th>Administration and Revaccination</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meningococcal Serotype Non-B (MenACWY)</td>
<td>• All patients with HIV</td>
<td>• Administer 2 doses of MenACWY at least 8 weeks apart in those not previously vaccinated</td>
<td>• Covered by the Vaccine Injury Compensation Program*</td>
</tr>
<tr>
<td></td>
<td>• MenACWY: Menactra</td>
<td>• For those previously vaccinated with 1 dose of MenACWY, administer the 2nd dose at the earliest opportunity at least 8 weeks after the previous dose</td>
<td>• MenACWY is preferred over MPSV4 in adults with HIV &gt;55 years of age</td>
</tr>
<tr>
<td></td>
<td>• MCV4: Menveo</td>
<td>• Revaccination: Administer 1 booster dose of MenACWY every 5 years</td>
<td>• Covered by the Vaccine Injury Compensation Program*</td>
</tr>
<tr>
<td>Meningococcal Serotype B (MenB)</td>
<td>Patients at risk of MenB infection, as determined by CDC guidelines</td>
<td>• Administer according to CDC guidelines for patients at risk</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Revaccination: None</td>
<td>Not routinely recommended for people with HIV in the absence of other risk factors</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Covered by the Vaccine Injury Compensation Program*</td>
</tr>
<tr>
<td>Pneumococcal</td>
<td>All patients with HIV</td>
<td>• The complete series of vaccinations is 1 dose of PCV13 and 2 doses of PPSV23 before age 65 years, followed by 1 additional dose of PPSV23 after age 65 years</td>
<td>The PCV13 vaccine should not be deferred for patients with CD4 count &lt;200 cells/mm³ and/or detectable viral load; however, the follow-up secondary administration of PPSV23 vaccine may be deferred until the patient’s CD4 count is &gt;200 cells/mm³ and/or viral load is undetectable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• See Table 17 for detailed administration guidelines based on age and previous vaccination history</td>
<td></td>
</tr>
<tr>
<td>Tetanus, Diphtheria, and Pertussis (Tdap)</td>
<td>For all patients, as determined by CDC guidelines for all adults</td>
<td>• Administer according to CDC guidelines for all adults</td>
<td>Covered by the Vaccine Injury Compensation Program*</td>
</tr>
<tr>
<td>and Tetanus-Diphtheria (Td)</td>
<td></td>
<td>• Revaccination: Td is usually given as a booster dose every 10 years, but it can also be given earlier after a severe and dirty wound or burn</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Varicella</td>
<td>• For patients with CD4 cell counts ≥200 cells/mm³ who do not have evidence of immunity to varicella, as determined by CDC guidelines for all adults</td>
<td>• Administer according to CDC guidelines for all adults</td>
<td>Contraindicated for patients with CD4 counts &lt;200 cells/mm³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Revaccination: None</td>
<td>Anti-varicella IgG screening should be performed in patients with no known history of chickenpox or shingles</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>MMRV should not be used</td>
</tr>
</tbody>
</table>
### Table 21: Summary of Recommended Vaccines for Adults With HIV

<table>
<thead>
<tr>
<th>Vaccine Trade Name</th>
<th>Indications</th>
<th>Administration and Revaccination</th>
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<tbody>
<tr>
<td>Zoster</td>
<td>MCCC recommendation: Patients aged ≥50 years with HIV (A2)</td>
<td>Two IM doses, spaced 2 to 6 months apart, regardless of past receipt of ZVL</td>
<td>RZV is preferred over ZVL (A2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• See CDC information on administering Shingrix</td>
<td>RZV provides strong protection against shingles and post-herpetic neuralgia. Currently, there are no data on efficacy specific to people with HIV; however, superior efficacy and longer duration of protection have been demonstrated among the elderly, and a recombinant vaccine is preferred people with HIV</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Perform anti-varicella IgG screening in patients with no known history of chickenpox or shingles</td>
<td>In addition, immunogenicity and safety following a 3-dose schedule has been demonstrated among people with HIV infection. Note: RZV is administered IM in distinction to ZVL which is delivered by SQ injection.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Revaccination:</strong> None</td>
<td></td>
</tr>
</tbody>
</table>

**Abbreviations:** CDC: Centers for Disease Control and Prevention; MMR: measles, mumps, and rubella; NYSDOH AI: New York State Department of Health AIDS Institute; RZV: recombinant zoster vaccine; ZVL: zoster vaccine live.

*Vaccine injury compensation program: Tel: 1-800-338-2382; U.S. Court of Federal Claims, 717 Madison Place, NW, Washington DC 20005

### Aging in Patients With HIV

**Lead author: Eugenia L. Siegler, MD, with the Medical Care Criteria Committee; July 2020**

**Purpose**

Although the effects of HIV on aging have been studied for years, HIV care has been acknowledged only recently as a domain of geriatrics [Guaraldi and Rockwood 2017]. Geriatric assessment provides a complete view of a patient’s function, cognition, and health, and improves prognostication and treatment decisions [Singh HK, et al. 2017a]. As the population with HIV grows older, application of the principles of geriatrics can enhance quality of care.

The purpose of this guidance is to:

- Raise clinicians’ awareness of the needs and concerns of patients with HIV who are ≥50 years old.
- Inform clinicians about an aging-related approach to older patients with HIV.
- Offer recommendations to help clinicians provide optimal care for this population.
- Provide resources about aging with HIV for healthcare providers and their patients.
Suggest steps to guide medical settings in implementing geriatric care into HIV clinical practice.

Because published evidence to support clinical recommendations is not currently available, this guidance presents good practices to help clinicians recognize and address the needs of older patients with HIV.

**Definition of “older”:** Published studies differ in their definitions of older patients with HIV (e.g., ≥50 years, ≥55 years, ≥60 years), and the needs of individuals within different age groups may differ markedly. This guidance defines older patients as those ≥50 years old, which is the same definition used by the United States Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV [AIDSinfo 2019].

**Demographics:** At the end of 2017, according to the Centers for Disease Control and Prevention (CDC), more than 49% of people with HIV in the United States were ≥50 years old [CDC 2020]. As of the end of 2018 in New York State (NYS), 54.9% of people with HIV were ≥50 years old, and nearly 24% were at least 60 years old [NYCDHMH 2018]. That same year, almost 19% of new HIV diagnoses in NYS occurred in people ≥50 years old, and one-third of them had progressed to AIDS at the time of diagnosis [NYCDHMH 2018]. In light of these NYS demographics, the AIDS Institute has developed this guidance to help care providers expand services for older people with HIV.

### COVID-19: Resources and Guidance

For treatment guidelines on COVID-19 and other information for healthcare providers in New York State, the New York State Department of Health AIDS Institute Clinical Guidelines Program advises clinicians to consult the following resources:

- **New York State Department of Health:** NYSDOH Information on Novel Coronavirus
- **AIDSinfo:** Interim Guidance for COVID-19 and Persons with HIV
- **U.S. Centers for Disease Control and Prevention (CDC):** Information for Healthcare Professionals about Coronavirus (COVID-19)
- **National Institutes of Health (NIH):** Coronavirus Disease (COVID-19) Treatment Guidelines

### Recognizing and Addressing Effects of Aging in Older Patients With HIV

#### GOOD PRACTICES

- With patients who have HIV and are ≥50 years old, discussing the effects of aging can help identify medical priorities and evaluate physical function. Such conversations may also prompt consideration of advance directives and help patients recognize effects of ageism stigma.
- Use of a framework such as the “Geriatric 5 Ms: Mind, Mobility, Medications, Multimorbidity, and Matters Most,” can help address issues of aging in patients with HIV.
- Becoming familiar with the many available screening tools and local and national services will help meet the needs of older patients with HIV.
- In older patients with HIV who are being treated for multiple comorbidities, prioritization of treatment plans may help reduce the potential for polypharmacy.
- Evaluation of medication lists at every clinical visit to identify and mitigate potentially harmful drug-drug interactions will help minimize the effects of polypharmacy in older patients with HIV.
- Familiarity with the benefits and local sources of palliative care will help clinicians recognize and meet the needs of older patients who have HIV and other serious illnesses.
- Referral to a social worker or care coordinator can help older patients with HIV to transition from commercial insurance or Special Needs Plans (SNPs) to Medicare without experiencing a loss of services or medication coverage.

### Effects of Aging

Long-term survivors, defined as those who have had HIV for more than 2 decades, and especially those who were diagnosed with HIV before the era of effective antiretroviral therapy, appear to have physiologic changes consistent with advanced aging, even at the level of gene expression and modification [De Francesco, et al. 2019]. When compared with age-matched controls who do not have HIV, older patients with HIV have more comorbidities and polypharmacy.
As a consequence, older individuals with HIV may not recognize concerns as aging-related or may feel survivor’s guilt [Machado 2012]. These age-related concerns are not limited to long-term survivors. Although individuals aged 50 years and older with newly diagnosed HIV are not likely to exhibit the same degree of age advancement as those who have lived a long time with HIV, they may have a delayed diagnosis, lower CD4 counts, and AIDS at the time of diagnosis [Tavoschi, et al. 2017]. And late initiation of antiretroviral therapy increases their long-term risk of complications [Molina, et al. 2018].

Sex differences in the effect of HIV on aging remain an area of controversy. Studies in several countries have found that women with HIV have life expectancies closer to their HIV-negative counterparts than do men with HIV, but this finding has not been supported by studies in North America [Samji, et al. 2013; Wandeler, et al. 2016]. A Canadian study showed shortened life expectancy among women with HIV compared to men with HIV [Hogg, et al. 2017]. Women with HIV in resource-rich countries appear to have a heightened risk of cardiovascular disease [Stone, et al. 2017], cognitive loss [Maki, et al. 2018], and more rapid declines in bone mineral density [Erlandson, et al. 2018].

### Approach to Aging in HIV Care

It is essential to discuss aging-related concerns with patients with HIV who are ≥50 years old. Some HIV healthcare providers and their patients have enduring relationships. Such longstanding ties promote high levels of trust, but they can also inhibit exploration of new concerns and promote too tight a focus on keeping viral load undetectable and treating common comorbidities. As a consequence, older individuals with HIV may not recognize concerns as aging-related or may feel it inappropriate to discuss aging; HIV care providers may have never addressed aging-related needs with patients or developed facility with geriatric assessment.

Care of older patients with HIV begins with recognizing that aging-related issues are a fundamental part of primary care. Geriatric concerns do not supplant other medical conditions; they reframe them in light of a multiplicity of problems and a finite lifespan. A geriatric approach, even for people in their 50s, can improve quality of care.

Older people with HIV may range from age 50 to age 80 and beyond and are a heterogeneous group. Providing care for older patients requires balance to avoid ageism and neglect of essential care and prevent excessive, dangerous, or unnecessary treatments. Determining what is appropriate for patients begins with an assessment of their health and their priorities. At its most basic, the geriatric approach can be described as attention to the “5Ms”: Mind, Mobility, Multimorbidty, Medications, and Matters Most [Tinetti M, et al. 2017]. Although certain aging-related syndromes (e.g., dizziness, incontinence) may not easily fit into one of these categories, the 5Ms have been useful as a way to understand how geriatricians help patients reframe and discuss their problems and their needs.

**Mind:** This category includes all domains of behavioral health, including cognition, mood, and other disorders. General assessment questions about instrumental activities of daily living (e.g., using transportation, managing medications, and handling finances) can provide information about practical concerns and offer clues about cognitive or emotional barriers to self-care. Healthcare providers can also use specific tools to screen patients for disorders such as cognitive impairment, which may be caused by factors both related to and independent of HIV, [Winston and Spudich 2020], or depression (see Resource: The “5M” Assessment Domains for Older People With HIV and Associated Resources).

**Mobility:** Healthcare providers can begin to address mobility with a general assessment of activities of daily living to determine if patients have difficulty dressing or bathing. Discussion of a patient’s fall risk can begin with a question such as, “Have you fallen in the past year?” or healthcare providers can use a comprehensive fall-risk screening tool (see Resource: The “5M” Assessment Domains for Older People With HIV and Associated Resources).

Many aging-related syndromes, such as frailty and gait disorders, fall into the mobility category. Frailty, often defined as an increased vulnerability to stressors [Bloch 2018], is more prevalent in individuals with HIV compared with age-matched controls [Levett, et al. 2016]. There are many ways to measure frailty, and some can be easily adapted to the clinical setting [Morley, et al. 2013]. Physical activity is an important way to prevent age-related mobility syndromes and evidence-based guidelines for individuals with HIV are available [Montoya, et al. 2019].
Multimorbidity: Care for older patients with HIV usually involves management of multiple comorbidities, each of which may require treatment with multiple medications. Nonpharmacologic management (e.g., smoking cessation, dietary modification, exercise) can also improve symptoms associated with multiple comorbidities [Fitch 2019].

A geriatric perspective recognizes that, in patients with multimorbidities, strict adherence to multiple disease-based treatment guidelines may not be possible or may jeopardize a patient’s health. A recent review promotes a “6th M” to suggest that clinicians and patients should focus on problems that are “modifiable” [Erlandson and Karris 2019]. Simultaneous management of multiple chronic conditions necessitates establishing treatment priorities [Yarnall, et al. 2017], which requires understanding a patient’s priorities [Tinetti ME, et al. 2019].

Medications: Many older individuals with HIV take antiretroviral medications to suppress the virus and take other medications to treat comorbidities, which can make medication management especially challenging. Medication evaluation should include a review of all medications, potential drug-drug interactions [Livio and Marzolini 2019], and short- and long-term toxicities. It may be beneficial to simplify antiretro viral and other medication regimens to ensure that harms from drug-drug interactions and other adverse effects of treatment are avoided [del Carmen 2019]. Caution is required when adjusting or simplifying antiretrovirals if regimen changes involve either initiating or discontinuing a medication with pharmacologic inhibitive or induction actions; these changes may have an impact on levels of co-administered medications.

Consultation with a pharmacist can help clinicians manage the complexities of polypharmacy and medication adjustments in older patients. Online resources to are available as well; see:

- University of Liverpool HIV Drug Interactions Checker
- UCSF HIV InSite Database of Antiretroviral Drug Interactions
- NYSDOH AI: ART Drug-Drug Interactions Resource

Matters Most: This is the broadest category and includes medical and social priorities, sexual health, and advance directives. Asking questions such as, “Have you thought about aging?” or “What would you like to know about aging with HIV?” creates opportunities to learn about patient’s concerns about the future and to discuss survivorship, guilt, ageism, financial worries, and other concerns [del Carmen 2019].

Many consider sexuality an essential part of health at any age. There is no age limit at which clinicians should stop taking a sexual history or discussing HIV pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) for partners (see NYSDOH AI guidelines PrEP to Prevent HIV and Promote Sexual Health and PEP to Prevent HIV Infection). Initiating discussions of sexual health, including topics such as erectile dysfunction and loss of libido in men, and menopause and post-menopausal sex in women, and screening for sexually transmitted infections as needed may also provide insights into relationships and the strength of a patient’s social network. For more information, see:

- Management of Gonorrhea and Chlamydia in Patients with HIV > Screening (NYSDOH AI)
- Management of Syphilis in Patients with HIV > Screening (NYSDOH AI)
- Sexually Transmitted Infections Treatment Guidelines, 2021 > Screening (CDC)

Overall, patient health and priorities, rather than age, direct the frequency of cancer screening in individuals with HIV. The literature on adherence to cancer screening guidelines among individuals with HIV is mixed with most [Corrigan, et al. 2019], but not all [Barnes, et al. 2018], studies failing to find that older individuals were screened less frequently. In patients with a good prognosis, clinicians should continue to follow screening guidelines (see Routine Screening and Primary Prevention section). Screening can be re-evaluated when it conflicts with patient priorities, or patient prognosis is poor.

Addressing aging-related concerns directly can help older patients with HIV discuss financial concerns and prepare for the future when more personal assistance may be needed. Discussion of insurance coverage can provide an opportunity to help patients prepare for the transition from commercial insurance or SNPs to Medicare-based plans. Planning is essential because these often offer far more comprehensive care coordination, medication coverage, and health-maintenance services than Medicare-based plans.

“Matters-most” topics may also include discussion of palliative care and frank discussion of long-term care needs and end-of-life plans. Advance directives should be addressed and, if an advance directive is in place, revisited. It is preferable for the patient to designate a specific agent or agents who can speak for them when they are incapacitated. Those patients who cannot or will not identify a trusted individual to be their agent can complete the New York State Medical Orders for Life-Sustaining Treatment (MOLST) to describe their wishes regarding medical treatment.
Geriatric Assessment

The gold standard for geriatric evaluation is the Comprehensive Geriatric Assessment (CGA), which assesses multiple domains of health and function [Singh HK, et al. 2017a]. Because it is comprehensive, the CGA is lengthy, and its use may not be feasible in many clinical settings (administration can take longer than one hour). Resource: The “5M” Assessment Domains for Older People With HIV and Associated Resources lists domains of geriatric assessment and relevant available resources for older patients with HIV, organized according to the geriatric 5Ms. Clinicians can perform a global assessment such as the one used in the Medicare Annual Wellness Visit [CMS 2020] or choose one or several specific areas for focus.

It may be difficult to implement needed aging-related assessments when access to expertise or funding is limited, but every attempt should be made to assess aging-related issues to the degree possible.

“5M” Assessment Domains for Older People with HIV and Selected Tools and Resources

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Source</th>
<th>Tools and Resources</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MIND</strong></td>
<td></td>
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</tr>
<tr>
<td>Cognition</td>
<td>Hartford Institute for Geriatric Nursing</td>
<td>The Lawton Instrumental Activities of Daily Living (IADL) Scale</td>
</tr>
<tr>
<td></td>
<td>Montreal Cognitive Assessment (MoCA)</td>
<td>MoCA® Test (Note: As of September 2020, registration and training will be required)</td>
</tr>
<tr>
<td></td>
<td>Alzheimer’s Association</td>
<td>Alzheimer’s Disease Pocketcard app: Available for download through the Apple App Store or Google Play</td>
</tr>
<tr>
<td></td>
<td>Mini-Cog®</td>
<td>Mini-Cog® Screening for Cognitive Impairment in Older Adults</td>
</tr>
</tbody>
</table>
| Social isolation, loneliness | Campaign to End Loneliness | • Report: The Psychology of Loneliness  
• Information and Research on Loneliness  
• Resources |
| | University of California San Francisco (UCSF) Stress Measurement Network | Stress Measurement Toolbox |
| Mental health | Calculate by QxMD | Patient Health Questionnaire (PHQ-4): Ultra-Brief Screening for Anxiety and Depression |
| | Substance Abuse and Mental Health Services Administration (SAMHSA) | Growing Older: Providing Integrated Care for an Aging Population |
| | CDC > HIV Basics | Facts about HIV Stigma |
| **MOBILITY** | | |
| Gait, balance, activity level, fall risk, exercise | Alzheimer’s Association | Katz Index of Independence in Activities of Daily Living (ADL) |
| | CDC > STEADI: Stopping Elderly Accidents, Deaths, and Injuries | • Algorithm for Fall Risk Screening, Assessment, and Intervention  
• Preventing Falls in Older Patients: Provider Pocket Guide  
• Functional Assessments |
<p>| | Article [Phelan, et al. 2015] | Assessment and Management of Fall Risk in Primary Care Settings |
| | American College of Sports Medicine | Exercise is Medicine® Health Care Providers’ Action Guide |</p>
<table>
<thead>
<tr>
<th>Assessment</th>
<th>Source</th>
<th>Tools and Resources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fraility</td>
<td>Comprehensive Geriatric Assessment</td>
<td>Tool Kit, including Fraility Assessment</td>
</tr>
<tr>
<td>MULTIMORBIDITY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Management of multiple chronic conditions</td>
<td>Article [Boyd, et al. 2019]</td>
<td>Decision Making for Older Adults With Multiple Chronic Conditions: Executive Summary for the American Geriatrics Society Guiding Principles on the Care of Older Adults With Multimorbidity</td>
</tr>
<tr>
<td>Bone health</td>
<td>Article [Brown TT, et al. 2015]</td>
<td>Recommendations for Evaluation and Management of Bone Disease In HIV</td>
</tr>
<tr>
<td></td>
<td>Article [Biver, et al. 2019]</td>
<td>Diagnosis, Prevention, and Treatment of Bone Fragility in People Living With HIV: A Position Statement From The Swiss Association Against Osteoporosis</td>
</tr>
<tr>
<td></td>
<td>Systematic review and meta-analysis</td>
<td>Management of Osteoporosis in Patients Living With HIV–A Systematic Review and Meta-Analysis</td>
</tr>
<tr>
<td>Continence</td>
<td>National Association for Continence</td>
<td>Resources for Healthcare Providers</td>
</tr>
<tr>
<td>Food insecurity</td>
<td>United States Department of Agriculture (USDA) &gt; Food Insecurity in the U.S.</td>
<td>Survey Tools</td>
</tr>
<tr>
<td>Obesity and lipohypertrophy</td>
<td>Article [Lake, et al. 2017]</td>
<td>Practical Review of Recognition and Management of Obesity and Lipohypertrophy in Human Immunodeficiency Virus Infection</td>
</tr>
<tr>
<td>MEDICATIONS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Polypharmacy and drug-drug interactions</td>
<td>Article [O’Mahony, et al. 2015]</td>
<td>STOPP/START criteria for potentially inappropriate prescribing in older people: version 2</td>
</tr>
<tr>
<td></td>
<td>University of Liverpool &gt; HIV Drug Interactions</td>
<td>HIV Drug Interactions Checker</td>
</tr>
<tr>
<td></td>
<td>NYSDOH AI Clinical Guidelines Program</td>
<td>• ART Drug-Drug Interactions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• ARV Dose Adjustments for Hepatic and Renal Impairment</td>
</tr>
<tr>
<td></td>
<td>Article [AGS 2019]</td>
<td>American Geriatrics Society 2019 Updated AGS Beers Criteria* for Potentially Inappropriate Medication Use in Older Adults</td>
</tr>
<tr>
<td>MATTERS MOST</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sexual health</td>
<td>NYSDOH AI Clinical Guidelines Program</td>
<td>GOALS Framework for Sexual History Taking in Primary Care</td>
</tr>
<tr>
<td>Advance directives</td>
<td>NYSDOH</td>
<td>• Appointing Your Health Care Agent in New York State (with fillable Health Care Proxy form)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Medical Orders for Life-Sustaining Treatment (MOLST)</td>
</tr>
<tr>
<td>Working with family caregivers</td>
<td>United Hospital Fund &gt; Next Step in Care</td>
<td>Toolkits, Guides, and More for Health Care Providers</td>
</tr>
<tr>
<td>Elder abuse</td>
<td>New York State Coalition on Elder Abuse</td>
<td>• Understanding Elder Abuse</td>
</tr>
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<td></td>
<td>National Center on Elder Abuse</td>
<td>• Research &amp; Education</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Suspect Abuse &gt; Get Help</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Reporting Abuse</td>
</tr>
<tr>
<td>Quality of life</td>
<td>CDC: Health-Related Quality of Life</td>
<td>CDC HRQOL-14 “Healthy Days Measure”</td>
</tr>
</tbody>
</table>
### Resource: The “5M” Assessment Domains for Older People With HIV and Selected Tools and Resources

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Source</th>
<th>Tools and Resources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Palliative care</td>
<td>Article [Harding 2018]</td>
<td>Palliative Care as an Essential Component of the HIV Care Continuum</td>
</tr>
<tr>
<td>Prognosis</td>
<td>Yale School of Medicine &gt; Veterans Aging Cohort Study (VACS)</td>
<td>VACS Index Calculator</td>
</tr>
<tr>
<td></td>
<td>UCSF</td>
<td>ePrognosis Calculator</td>
</tr>
</tbody>
</table>

### Integrating the Needs of Older Patients With HIV Into Medical Settings

This guidance is designed to foster a shift in the practitioner’s perspective when caring for older patients with HIV. However, the clinician cannot provide optimal care in the absence of support. Clinical practices can also begin to address HIV-related aging issues by taking the steps outlined below.

1. **Assess the clinic’s ability to meet the needs of older patients with HIV:**
   - Review the demographics of the patient population to identify the number of patients in need of aging-related services at present and in the near- and long-term.
   - Track patient requests for aging-related services and identify options for responding to those requests.
   - Identify resources needed to address any aging-related priorities identified by a community or clinic advisory board.
   - Identify clinic care providers who are experienced in geriatrics or the care of older patients.
   - If the clinic is not able to provide multidisciplinary, comprehensive services, identify how the clinic can assist patients in accessing needed services.
   - Anticipate problems with finances and insurance coverage for those approaching 65 (earlier, for those on disability) who are transitioning to Medicare.

2. **Engage older patients with HIV in program planning:**
   - Provide ample opportunities for patients and clinical care providers and staff to identify needs to be addressed. This is an essential step for programs of any size. The University of California San Francisco (UCSF) used extensive patient input to develop its **Golden Compass program** for older individuals with HIV [Greene, et al. 2015].
   - Provide opportunities for discussion of ageism and stigma, so patients and clinical care providers and staff can understand and identify its effects and how to address them.
   - Develop a wish list of services and be realistic about what is possible. Set goals and a timeline for program development.

3. **Consider options and develop protocols for identifying patients in need of aging-related care and services.**
   - Patients may be identified based on:
     - Age, such that all patients with HIV who are ≥50 years old should be assessed.
     - Prognosis, such that a prognostic threshold for referral is established based on measures such as the Veterans Aging Cohort Study (VACS) Index Calculator.
     - Clinical criteria, such as a recent history of falls, deteriorating memory, polypharmacy, or frailty.
     - Patient request.

4. **Develop an assessment strategy:**
   - Identify who will perform assessments and how results will be communicated to patients and other care providers involved with the patient.
   - Determine the scope of assessment: Will it focus on one particular problem (e.g., gait disorders, cognition), or will assessment address a broad array of problems? Examples of assessment types include the following:
     - **Global geriatric screening tools**: Global geriatric screening tools are available for administration by clinical staff or patient self-administration, at home or in the clinic. Dedicated time for assessment may be scheduled as part of primary care, following a model such as the Medicare Annual Wellness Visit [CMS 2020]. Some clinics may collaborate with aging specialists, such as geriatricians or nurse practitioners who specialize in gerontology and can perform a comprehensive geriatric assessment.
Specific screening tools: If a clinic has decided to focus on one or several specific assessments, these can be built into the workflow. For example, a clinic could determine that all patients ≥50 years old will be screened for fall risk and cognitive impairment. In this case, patients could be asked to complete a fall-risk evaluation, such as the Stopping Elderly Accidents, Deaths, and Injuries (STEADI), before the visit, or a nurse could administer a timed walk test while the patient is walking from the waiting room to the exam room.

Any of the domains listed in Resource: The “5M” Assessment Domains for Older People With HIV and Selected Tools and Resources would be appropriate for inclusion in a program to enhance care of older individuals with HIV.

5. Develop protocols for referral:

- Identify aging-related care and services that can be provided on-site and care and services that require referral to an external source. Referral protocols can be problem-specific. For example, if a patient is assessed as being at high risk for falls, the clinic should take a standard approach to address that risk, which could include referral to physical therapy, podiatry, or neurology; medication review by a pharmacist; home safety assessment; and/or an exercise program.

- Identify local specialty care providers to whom patients can be referred.

### ONLINE CLINICAL RESOURCES FOR AGING AND GERIATRIC CARE

<table>
<thead>
<tr>
<th>Online Resource</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIDS Education and Training Center National Coordinating Resource Center</td>
<td>Care of People Aging with HIV: Northeast/ Caribbean Toolkit</td>
</tr>
<tr>
<td>American Academy of HIV Medicine &gt; HIV &amp; Aging</td>
<td>Recommended Treatment Strategies for Clinicians Managing Older Patients with HIV</td>
</tr>
<tr>
<td>American Geriatrics Society &gt; Geriatrics Healthcare Professionals</td>
<td>Geriatrics Workforce Enhancement Program Coordinating Center:</td>
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<td></td>
<td>- National Coordinating Center</td>
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<tr>
<td></td>
<td>- Finger Lakes Geriatric Education Center: Rochester, Ithaca</td>
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<td></td>
<td>- New York City: Hartford Institute for Geriatric Nursing</td>
</tr>
<tr>
<td></td>
<td>- Johns Hopkins School of Medicine</td>
</tr>
<tr>
<td>World Health Organization &gt; Ageing and Life Course</td>
<td>Integrated care for older people (ICOPE): guidance for</td>
</tr>
<tr>
<td></td>
<td>person-centered assessment and pathways in primary care</td>
</tr>
</tbody>
</table>

Linking to the Aging Services Network

An essential part of care for individuals with HIV who are ≥60 years old is connecting to the aging services network, which was initiated through the Older Americans Act of 1965 [O'Shaughnessy 2012]. Social work and care coordination staff should become familiar with the services that are offered locally and should assist clients in preparing for the transition to Medicare when medication benefits and care coordination change.

### ONLINE RESOURCES FOR AGING SERVICES AND ENTITLEMENTS

- Aging and Disability Resource Centers
- Eldercare Locator
- Medicare Rights Center
- National Association of Area Agencies on Aging
- National Council on Aging: BenefitsCheckUp
- New York State Office for the Aging, provides links to local agencies on aging and other resources like the state Aging and Disability Resource Center.
- SAGE: Advocacy for LGBT Elders
All Recommendations

<table>
<thead>
<tr>
<th>All RECOMMENDATIONS: Comprehensive Primary Care for Adults With HIV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>History, Assessment, and Evaluation</strong></td>
</tr>
<tr>
<td>• For all adults with HIV who present for primary care, clinicians should perform the baseline assessments detailed in the following tables (A3):</td>
</tr>
<tr>
<td>- Table 1: HIV, Medications, and General Medical Status and History for Adults With HIV</td>
</tr>
<tr>
<td>- Table 2: Psychosocial, Behavioral Health, Sexual Health, and Well-Being Assessment of Adults With HIV</td>
</tr>
<tr>
<td>- Table 3: Recommended Laboratory Testing for Adults With HIV</td>
</tr>
<tr>
<td>• Clinicians should repeat these assessments as indicated in Tables 1, 2, and 3. (A3)</td>
</tr>
<tr>
<td><strong>Immunizations</strong></td>
</tr>
<tr>
<td>• Clinicians should follow the recommendations for routine vaccination of adults with HIV issued by the Centers for Disease Control and Prevention, the National Institutes of Health, the HIV Medicine Association, and the Infectious Disease Society of America, as presented here. (A2)</td>
</tr>
<tr>
<td><strong>Anti-COVID-19 Vaccine for Adults With HIV</strong></td>
</tr>
<tr>
<td>• Clinicians should follow the recommendations for routine vaccination of adults with HIV issued by the Centers for Disease Control and Prevention, the National Institutes of Health, the HIV Medicine Association, and the Infectious Disease Society of America, as presented here. (A2)</td>
</tr>
<tr>
<td>• Vaccines against SARS-CoV-2 to prevent COVID-19 have been approved under an FDA Emergency Use Authorization (EUA), and vaccination is recommended for all adults, including those living with HIV. For more information, see:</td>
</tr>
<tr>
<td>- FDA EUAs: Pfizer-BioNTech COVID-19 Vaccine, Moderna COVID-19 Vaccine, Johnson &amp; Johnson (Janssen) COVID-19 Vaccine</td>
</tr>
<tr>
<td>- NIH COVID-19 Treatment Guidelines: Special Considerations in People With HIV</td>
</tr>
<tr>
<td><strong>Routine Screening and Primary Prevention</strong></td>
</tr>
<tr>
<td>• For adults with HIV who are seen for primary care, clinicians should provide:</td>
</tr>
<tr>
<td>- Risk-, age-, and sex-based screening as indicated and recommended in Table 4: Routine Screening for Adults With HIV. (A3)</td>
</tr>
<tr>
<td>- Primary preventive care as recommended in Table 5: Primary Prevention for Adults With HIV. (A3)</td>
</tr>
<tr>
<td>• Clinicians and patients should engage 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)</td>
</tr>
<tr>
<td><strong>Prevention of Opportunistic Infections</strong></td>
</tr>
<tr>
<td>• Clinicians should initiate prophylaxis for specific opportunistic infections (OIs) and discontinue prophylaxis as indicated in Table 6: Prophylaxis for Opportunistic Infections in Adults With HIV. (A*)</td>
</tr>
<tr>
<td>- Before initiating dapsone, clinicians should test patients for glucose-6-phosphate dehydrogenase (G6PD) deficiency. (A*)</td>
</tr>
<tr>
<td>• Clinicians may discontinue primaryOI prophylaxis in patients who are taking effective ART and have evidence of immune recovery. (A*)</td>
</tr>
</tbody>
</table>
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Dynavax. HEPLISAV-B: Highlights of prescribing information. 2017 Nov. [https://www.heplisavb.com/assets/pdfs/HEPLISAV-B-Prescribing-Information.pdf](https://www.heplisavb.com/assets/pdfs/HEPLISAV-B-Prescribing-Information.pdf) [accessed 2019 Dec 2]


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[http://programme.aids2020.org/Abstract/Abstract/11300](http://programme.aids2020.org/Abstract/Abstract/11300)


How This Guideline Was Developed

This guideline was developed by the New York State (NYS) Department of Health (DOH) AIDS Institute (AI) Clinical Guidelines Program, which is a collaborative effort between the NYSDOH AI Office of the Medical Director and the Johns Hopkins University School of Medicine, Division of Infectious Diseases.

Established in 1986, the goal of the Clinical Guidelines Program is to develop and disseminate evidence-based, state-of-the-art clinical practice guidelines to improve the quality of care provided to people with HIV, hepatitis C virus, or sexually transmitted infections; people with substance use issues; and members of the LGBTQ community. NYSDOH AI guidelines are developed by committees of clinical experts through a consensus-driven process.

Medical Care Criteria Committee (MCCC) for adult HIV care guidelines: The NYSDOH AI charged the MCCC (adult HIV and related guidelines) with developing evidence-based recommendations for clinicians in NYS who provide care to individuals with HIV. The purpose of the Comprehensive Primary Care for Adults with HIV clinical practice guideline is to provide NYS clinicians with evidence-based clinical recommendations for provision of comprehensive primary care to patients who have HIV, whether care is provided in an HIV specialty or primary care setting. The goal is to ensure that individuals with HIV in NYS can access optimal primary care in multiple outpatient clinical settings.

Committee makeup: Members of the MCCC (see Box A1: MCCC Leaders and Members, below) were appointed by the NYSDOH AI to ensure representation of clinical practice in all major regions of the state, relevant medical disciplines and subspecialties, key NYS agencies, community stakeholders, and patient advocates. Individuals confirmed as MCCC members are required to disclose any potential conflicts of interest; disclosures are reviewed and approved by the NYSDOH AI Office of the Medical Director (see Funding and Disclosure of Potential Conflicts of Interest, below).

Committee role: Committee members actively participate in guideline development, including evidence review, drafting of recommendations and text, manuscript review, consensus approval of all recommendations, and rating of recommendations.

Committee leadership: Working with the lead author, the MCCC Writing Group reviewed and refined the manuscript, facilitated consensus approval of all recommendations, and addressed feedback from the Committee at large.

Johns Hopkins University (JHU) Editorial Role: The JHU editorial team coordinated, guided, and documented all Committee activities and edited the guideline material for clarity, flow, and style.

MCCC Writing Group (all Committee members and reviewers are listed in Box A1, below)

- Joseph P. McGowan, MD, FACP, FIDSA, Chair
- Steven Fine, MD, PhD, Co-Vice-Chair (effective December 2020)
- Rona Vail, MD, Co-Vice-Chair (effective December 2020)
- Samuel T. Merrick, MD, Chair Emeritus
- Charles J. Gonzalez, MD, AI Medical Director
- Lyn C. Stevens, MS, NP, ACRN, AI Deputy Director
- Asa Radix, MD, MPH, FACP, AAHIVS
- Christopher J. Hoffmann, MD, MPH, Director, JHU-NYSDOH Guidelines Program

AIDS Institute and JHU Editorial and Program Management Team

- Laura Duggan Russell, MPH, AI Guidelines Program Manager
- Mary Beth Hansen, MA, JHU Guidelines Project Director
- Johanna Gribble, MA, JHU Medical Editor
- Jen Ham, MPH, JHU Medical Editor
- Rachel Lastra, JHU Medical Editor
- Jesse Ciekot, JHU Program Coordinator
Box A1: MCCC Leaders and Members (when this guideline was developed)

Unless noted otherwise, Committee members had no disclosures of financial relationships with commercial entities

Leadership
- **Chair** (effective March 2018): Joseph P. McGowan, MD, FACP, FIDSA, North Shore University Hospital, Manhasset, NY
- **Co-Vice-Chair** (Vice-Chair effective March 2018; Co-Vice-Chair effective December 2020): Steven M. Fine, MD, PhD, University of Rochester Medical Center, Rochester, NY
- **Co-Vice-Chair** (effective December 2020): Rona M. Vail, MD, Callen-Lorde Community Health Center, New York, NY
- **Chair Emeritus** (effective March 2018): Samuel T. Merrick, MD, New York-Presbyterian-Weill Cornell, New York, NY
- **Medical Director**: Charles J. Gonzalez, MD, New York State Department of Health (NYSDOH) AIDS Institute (AI), New York, NY (May 2018)
- **Deputy Medical Director**: Lyn Stevens, MS, NP, ACRN, NYSDOH AI, Albany, NY
- **Director, JHU-NYSDOH AI Guidelines Program**: Christopher J. Hoffmann, MD, MPH, Johns Hopkins University School of Medicine, Baltimore, MD

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- James C. M. Brust, MD, Albert Einstein College of Medicine/Montefiore Medical Center, Bronx, NY
- John M. Conry, PharmD, AAHIVP, FNAP, St. John’s University, Queens, NY
- Elliot DeHaan, MD, New York-Presbyterian Hospital/Weill Cornell Medical Center, New York, NY
- Mary Dyer, MD, Hudson River Healthcare, Monticello, NY
- Daniel Egan, MD, Columbia University Vagelos College of Physicians and Surgeons, New York, NY
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- Jeremiah Johnson, Community Advisor, TAG, New York, NY
- Christine A. Kerr, MD, Galileo Health
- Jeremy D. Kidd, MD, MPH, New York-Presbyterian Hospital, Columbia University, New York, NY
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- Hector Ojeda-Martinez, MD, SUNY Downstate Medical Center, Brooklyn, NY
- Asa E. Radix, MD, MPH, FACP, AAHIVS, Callen-Lorde Community Health Center, New York, NY
- Sanjiv S. Shah, MD, MPH, AAHIVM, AAHIVS, Icahn School of Medicine at Mount Sinai, New York, NY
- Noga Shalev, MD, Columbia University Medical Center, New York, NY
- Eugenia L. Siegler, MD, Weill Cornell Medical College, New York, NY
- Maria Teresa (Tess) Timoney, MS, RN, CNM, Bronx Lebanon Hospital Center, Bronx, NY
- Marguerite A. Urban, MD, University of Rochester School of Medicine and Dentistry, Rochester, NY
- Antonio E. Urbina, MD, The Mount Sinai Hospital, Comprehensive Health Program-Downtown, New York, NY
- Scientific Advisor: Gilead, Viiv, Merck
- Geoffrey A. Weinberg, MD, University of Rochester School of Medicine and Dentistry, Rochester, NY

External Reviewers
- Victor Alvarez, NYSDOH AI Community Advisory Committee
- Joseph Conigliaro, MD, MPH, Professor, Institute of Health Innovations & Outcomes Research, Feinstein Institutes for Medical Research; Chief, General Internal Medicine, Northwell Health; Professor, Medicine, Donald and Barbara Zucker School of Medicine at Hofst/Hofst
- William Hall, MD, Professor Emeritus, Department of Medicine, Highland Hospital, University of Rochester Medical Center

Funding and disclosure of potential conflicts of interest (COIs): NYS funds supported the development of this guideline through a grant awarded to the JHU School of Medicine, Division of Infectious Diseases, from the NYSDOH AI.

All active MCCC members, invited consultants and coauthors, peer reviewers, and program staff are required to disclose financial relationships with commercial entities, including gifts that may be actual conflicts of interest or may be perceived as conflicts. These individuals must disclose financial relationships annually, for themselves, their partners/spouses, and their organization/institution. On their annual disclosures, MCCC members are asked to report for the previous 12 months and the upcoming 12 months.

All reported financial relationships with commercial entities are reviewed by the NYSDOH AI guidelines program to assess the potential for undue influence on guideline recommendations made by the Committee.
All guideline recommendations received consensus approval of the full MCCC, and the final review and approval of the recommendations were performed by the Committee Chair and the NYSDOH AI Medical Director and Deputy Medical Director, none of whom reported conflicts of interest.

**Evidence collection and review:** The NYSDOH AI guideline development process is based on a strategic search and analysis of the published evidence. Box A2 illustrates the evidence review and selection process.

<table>
<thead>
<tr>
<th>Box A2: Evidence Collection and Review Processes</th>
</tr>
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<tbody>
<tr>
<td>• NYSDOH AI and MCCC defined the goal of the guideline: To provide evidence-based clinical recommendations to guide practitioners in delivering comprehensive primary care to adults with HIV.</td>
</tr>
<tr>
<td>• MCCC appointed a lead author who conducted a systematic literature search in PubMed using MeSH terms; all searches were limited to studies that 1) were published within the previous 5 years; 2) involved only human subjects; and 3) were published in English.</td>
</tr>
<tr>
<td>• Lead authors reviewed studies identified through searches and excluded based on the following criteria: Publication type, study design, participants, and clinical relevance to the guideline.</td>
</tr>
<tr>
<td>• Author and editorial staff conducted additional searches using PubMed and online databases to identify:</td>
</tr>
<tr>
<td>- Studies published prior to the 5-year search limit.</td>
</tr>
<tr>
<td>- Studies published during the guideline development process.</td>
</tr>
<tr>
<td>- Recent conference abstracts.</td>
</tr>
<tr>
<td>- Older studies known to provide strong evidence in support of specific recommendations or to undergird expert opinion.</td>
</tr>
<tr>
<td>• Lead authors developed and the Writing Group and then all MCCC members reviewed and approved evidence-based guideline recommendations:</td>
</tr>
<tr>
<td>- Writing Group reviewed, deliberated, refined, and approved draft recommendations.</td>
</tr>
<tr>
<td>- MCCC members reviewed, provided written comment on, deliberated, and reached consensus on recommendations.</td>
</tr>
<tr>
<td>- Members of the Writing Group reviewed the cited evidence and assigned a 2-part rating to each recommendation to indicate the strength of the recommendation and the quality of the supporting evidence; consensus reached on ratings.</td>
</tr>
<tr>
<td>- Additional evidence identified and cited during the rating process (see below).</td>
</tr>
<tr>
<td>• Ongoing update process:</td>
</tr>
<tr>
<td>- JHU editorial staff will surveil published literature on an ongoing basis to identify new evidence that may prompt changes to existing recommendations or development of new recommendations.</td>
</tr>
<tr>
<td>- JHU editorial staff will ensure that the MCCC reviews new studies at least 4 times per year, and more often if newly published studies, new drug approval, or drug-related warning indicate the need for an immediate change to the published guideline.</td>
</tr>
<tr>
<td>- JHU editorial staff will track, summarize, and publish ongoing changes to the guideline.</td>
</tr>
<tr>
<td>- MCCC will review and approve substantive changes to, additions to, or deletions of recommendations.</td>
</tr>
<tr>
<td>- MCCC will initiate a full review of the guideline 4 years after the original publication date.</td>
</tr>
<tr>
<td>- NYSDOH AI will publish a comprehensive update 5 years after the original publication date.</td>
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</tbody>
</table>

**Recommendation development and rating process:** The clinical recommendations presented in this guideline were developed by consensus based on a synthesis of the current evidence collected through the systematic search described above. If no data were available, the recommendations are based on expert opinion, and this status is indicated in the rating and the text.

The Writing Group met via teleconferences over approximately 2 years to finalize the guideline and reach consensus on recommendations and rationale. Once consensus among the Writing Group members was reached, the guideline was reviewed by the full MCCC, and consensus was reached on all recommendations. Writing Group review discussions were recorded, and recordings were reviewed carefully to ensure that all decisions and changes were captured and integrated into the manuscript.

Members of the Writing Group then individually reviewed the evidence for each recommendation and assigned a 2-part rating (see below). The individual ratings were compiled into a report distributed to all raters, and conference call discussions were held to deliberate ratings for which consensus was needed. Once all raters agreed on the interpretation of evidence and ratings for all recommendations, the guideline was sent to the NYSDOH AI for review and approval.
AIDS Institute Clinical Guidelines Program: Recommendations Ratings
(updated June 2019 [a])

<table>
<thead>
<tr>
<th>Strength of Recommendation Ratings</th>
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<tbody>
<tr>
<td>A  Strong recommendation</td>
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<tr>
<td>B  Moderate recommendation</td>
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<tr>
<td>C  Optional</td>
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</table>

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<tr>
<th>Quality of Supporting Evidence Ratings</th>
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<tbody>
<tr>
<td>1  Evidence is derived from published results of at least one randomized trial with clinical outcomes or validated laboratory endpoints.</td>
</tr>
<tr>
<td>* Evidence is strong because it is based on a self-evident conclusion(s); conclusive, published, in vitro data; or well-established practice that cannot be tested because ethics would preclude a clinical trial.</td>
</tr>
<tr>
<td>2  Evidence is derived from published results of at least one well-designed, nonrandomized clinical trial or observational cohort study with long-term clinical outcomes.</td>
</tr>
<tr>
<td>2† Evidence has been extrapolated from published results of well-designed studies (including non-randomized 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.</td>
</tr>
<tr>
<td>3  Recommendation is based on the expert opinion of the committee members, with rationale provided in the guideline text.</td>
</tr>
</tbody>
</table>

With the June 2019 update, the ratings for quality of supporting evidence were expanded to add the * rating and the 2† rating.

Guideline updates: Members of the MCCC will monitor developments in an ongoing structured manner to maintain guideline currency. Once the guidelines are published on the program website: www.hivguidelines.org, any updates will be made to the HTML document as needed as new, peer-reviewed literature is published if evidence is made available that changes best practices.

Notification of newly published studies will be automated, and the Writing Group will review new data as it is available. Newly published data that provide support for existing recommendations will be cited in the text, and the studies will be added to the reference list(s).

If newly published data prompt a revision to recommendations or rationale, the lead author and the Writing Group will propose appropriate edits and determine whether the changes warrant review and approval by the entire MCCC. If MCCC review is required, JHU will distribute updates via email, and a conference call will be convened if required. Deletion of existing recommendations, addition of any new recommendations, or substantive changes to existing recommendations will prompt MCCC review and consensus.

The full guideline will be reviewed and updated on the 4th anniversary of original publication to prepare for publication of an updated guideline on or before the 5th anniversary of original publication.