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

Immunizations for Adults With HIV

Updates, Authorship, and Related Guidelines

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Highlights of changes, additions, and updates in the April 2, 2024 edition	After review of data presented at CROI 2024, the MCCC has withdrawn its 2023 recommendation for prevention of gonorrhea, which was based on data presented at CROI 2023. The MenB vaccine (Bexsero) is not recommended for gonorrhea prevention.
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Purpose of This Guideline

This compendium of immunization recommendations for adults (≥18 years) with HIV was compiled by the New York State Department of Health AIDS Institute (NYSDOH AI) to assist clinical practitioners in New York State who provide primary care to adults with HIV. The goal is to present a single compilation of all routine vaccinations for adults with HIV recommended by the Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), HIV Medicine Association (HIVMA) [DHHS 2022], and the Infectious Disease Society of America [Thompson, et al. 2021]. The European AIDS Clinical Society guidelines were also consulted [EACS 2021]. Where a recommendation differs from these source documents, the rationale is provided.

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

☑ 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. (A3)

The tables and accompanying discussion in this guideline compile recommendations, vaccination schedules, clinical comments, and sources from the Centers for Disease Control and Prevention (CDC), National Institutes of Health, and HIV Medicine Association guidelines [DHHS 2022], the Infectious Diseases Society of America [Thompson, et al. 2021], and the European AIDS Clinical Society [EACS 2021].

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 [Thompson, et al. 2021; Crum-Cianflone and Wallace 2014]. However, there is concern that individuals 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 adults with advanced HIV, especially those with CD4 counts <200 cells/mm^3 and/or HIV RNA levels (viral loads) ≥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.

Inactivated vaccines are generally considered safe, although data are insufficient to rule out rare adverse effects [ACIP 2022; Thompson, et al. 2021]. Live, attenuated vaccines are contraindicated for patients with CD4 counts <200 cells/mm^3, because of the risk of severe reactions in individuals who are immunosuppressed [CDC 1996; Redfield, et al. 1987; CDC 1985; Davis, et al. 1977]. For patients with HIV and CD4 counts ≥200 cells/mm^3, 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.

→ KEY POINTS: USE OF LIVE, ATTENUATED VACCINES

- **Individuals with CD4 count <200 cells/mm^3:** The following live, attenuated vaccines are **contraindicated:** Bacillus Calmette-Guérin; measles, mumps, rubella; oral typhoid; rotavirus; varicella; yellow fever; zoster.
- **Individuals with CD4 count ≥200 cells/mm^3:** Use live, attenuated vaccines only if an inactivated alternative is not available *and* the risk of disease is greater than the risk of vaccination.
- **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. Those who lack varicella immunity should avoid direct contact with people who develop rash.

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 [Kolber, et al. 2002; Rey, et al. 2000]. The changes are less likely to occur in patients taking antiretroviral therapy and have not been found to have long-term negative effects [Thompson, et al. 2021; Sullivan, et al. 2000]. 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/mm^3 for ≥6 months [McLean, et al. 2013]. Viral suppression is defined as an HIV RNA level (viral load) <200 copies/mL.

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 [Thompson, et al. 2021; Grohskopf, et al. 2019; Fiore, et al. 2011]. Live, attenuated virus vaccines may be safely administered to close contacts of individuals with HIV, with specific precautions for varicella and rotavirus vaccines. Transmission of live, attenuated virus after vaccination is rare [Thompson, et al. 2021]. However, patients with HIV who lack

varicella immunity are advised to avoid direct contact with people who develop a rash after varicella or zoster vaccination. [Thompson, et al. 2021; Fiore, et al. 2011; Cortese and Parashar 2009; Marin, et al. 2007].

The tables in this guideline (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.

◊ RESOURCE: HOW TO FILE A CLAIM WITH THE VACCINE INJURY COMPENSATION PROGRAM

- Tel: 1-800-338-2382
- Website: hrsa.gov/vaccinecompensation
- Address to file a claim: US Court of Federal Claims, 717 Madison Place NW, Washington, DC 20439

COVID-19

Table 1a: COVID-19 Vaccines	
Trade Names See FDA: COVID-19 Vaccines Authorized for Emergency Use or FDA-Approved	• Moderna COVID-19 Vaccine, Bivalent (mRNA vaccine) • Pfizer-BioNTech COVID-19 Vaccine, Bivalent (mRNA vaccine) • Novavax COVID-19 Vaccine, Adjuvanted (protein subunit vaccine) • Janssen (Johnson & Johnson) COVID-19 Vaccine (adenovirus vector vaccine) [a]
Indications	At least 1 bivalent mRNA COVID-19 vaccine for all individuals ≥6 months old
Administration	Administer according to CDC: COVID-19 Vaccination Schedule: • Table 1: Recommended COVID-19 vaccination schedule for people who are ***not*** moderately or severely immunocompromised by COVID-19 vaccination history, May 2023 • Table 2: Recommended COVID-19 vaccination schedule for people who are moderately or severely immunocompromised by COVID-19 vaccination history, May 2023
Comments	See CDC: COVID-19 Vaccination Schedule for the following additional information: • Description of moderate and severe immunocompromising conditions and treatments • Considerations for individuals ≥65 years old to receive an additional bivalent mRNA dose
Abbreviations: CDC, Centers for Disease Control and Prevention; FDA, U.S. Food and Drug Administration. **Note:** a. As of May 6, 2023, the J&J/Janssen viral vector COVID-19 vaccine is no longer available for use in the United States (see CDC: Overview of COVID-19 Vaccines).	

Universal vaccination: To reduce community transmission and protect individuals with HIV, this committee agrees with the CDC recommendations for universal vaccination against COVID-19 for adults (≥18 years old) with HIV, regardless of prior history of COVID-19 infection. This committee also agrees with the CDC's recommendation that people with HIV with active viremia or with a CD4 count <200 cells/mm^3 should be vaccinated as per the CDC's schedule for moderately or severely immunocompromised patients. Schedules for all patients include at least 1 bivalent vaccination dose, even if they have completed a monovalent vaccine dosing schedule.

The available vaccines against SARS-CoV-2 have strong evidence both for safety and efficacy in preventing severe disease and death [Grana, et al. 2022]. Additionally, many people with HIV have multiple risk factors for severe COVID-19 infection. For more information, see:

- **CDC:** COVID-19: Understanding Risk
- **NYC Health:** COVID-19: Prevention and Groups at Higher Risk > People at Increased Risk of Severe Illness
- **U.S. Department of Health and Human Services:** Guidance for COVID-19 and People With HIV
- **National Institutes of Health:** COVID-19 Treatment Guidelines: Special Considerations in People With HIV

Table 1b: Recommended COVID-19 Vaccination Schedule for Individuals ≥12 Years Old Who Are NOT Moderately or Severely Immunocompromised, May 2023 (Adapted from CDC: COVID-19 Vaccination Schedule Table 1)

COVID-19 Vaccination History	Recommendation [a]	Optional
Unvaccinated	1 dose of Moderna bivalent vaccine OR 1 dose of Pfizer-BioNTech bivalent vaccine	Individuals ≥65 years old have the option to receive 1 additional bivalent mRNA vaccine dose ≥4 months after first dose of a bivalent mRNA vaccine.
≥1 dose of monovalent mRNA vaccine; no previous doses of bivalent mRNA vaccine	• 1 dose of Moderna bivalent vaccine OR 1 dose of Pfizer-BioNTech bivalent vaccine • Administer bivalent vaccine ≥8 weeks [b] after last monovalent dose.	
Any previous dose(s) of bivalent mRNA vaccine, regardless of monovalent vaccine history	Vaccination is complete.	
≥1 dose of Novavax vaccine	• 1 dose of Moderna bivalent vaccine OR 1 dose of Pfizer-BioNTech bivalent vaccine • Administer bivalent vaccine ≥8 weeks [b] after last monovalent dose.	
≥1 dose of J&J/Janssen vaccine (individuals ≥18 years old) [c]	• 1 dose of Moderna bivalent vaccine OR 1 dose of Pfizer-BioNTech bivalent • **Note:** Administer bivalent vaccine ≥2 months after completion of the primary series dose (for people who have not previously received any booster doses) or ≥2 months after the last monovalent booster dose.	

Abbreviations: CDC, Centers for Disease Control and Prevention; J&J, Johnson & Johnson.

Notes:

a. COVID-19 vaccination is recommended regardless of history of SARS-CoV-2 infection. Defer any COVID-19 vaccination at least until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met. If SARS-CoV-2 infection was recent, may consider delaying a COVID-19 vaccine dose by 3 months from symptom onset or positive test result (if infection was asymptomatic). Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection is not recommended for the purpose of vaccine decision-making (see CDC: Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States > COVID-19 vaccination and SARS-CoV-2 infection).

b. An 8-week interval between the first and second doses of Moderna and Pfizer-BioNTech COVID-19 vaccines might be optimal for some people ages 6 months to 64 years, especially for males ages 12 to 39 years, as it might reduce the small risk of myocarditis and pericarditis associated with these vaccines.

c. As of May 6, 2023, the J&J/Janssen viral vector COVID-19 vaccine is no longer available for use in the United States (see CDC: Overview of COVID-19 Vaccines).

Table 1c: Recommended COVID-19 Vaccination Schedule for Individuals ≥12 Years Old Who ARE Moderately or Severely Immunocompromised [a], May 2023 (Adapted from CDC: COVID-19 Vaccination Schedule Table 2)

COVID-19 Vaccination History	Recommendation [b]	Interval Between Doses
Unvaccinated	3 doses of Moderna bivalent vaccine OR 3 doses of Pfizer-BioNTech bivalent vaccine	• Moderna: 4 weeks between dose 1 and dose 2; ≥4 weeks between dose 2 and dose 3 • Pfizer-BioNTech: 3 weeks between dose 1 and dose 2; ≥4 weeks between dose 2 and dose 3

Table 1c: Recommended COVID-19 Vaccination Schedule for Individuals ≥12 Years Old Who ARE Moderately or Severely Immunocompromised [a], May 2023 (Adapted from CDC: COVID-19 Vaccination Schedule Table 2)

COVID-19 Vaccination History	Recommendation [b]	Interval Between Doses
1 dose of monovalent Moderna vaccine	2 doses of Moderna bivalent vaccine	• Bivalent dose 1: 4 weeks after monovalent dose • Bivalent dose 2: ≥4 weeks after bivalent dose 1
2 doses of monovalent Moderna vaccine	1 dose of Moderna bivalent vaccine	≥4 weeks after last monovalent dose
3 doses of monovalent Moderna vaccine	1 dose of Moderna bivalent vaccine OR 1 dose of Pfizer-BioNTech bivalent vaccine	≥8 weeks after last monovalent dose
3 doses of monovalent Moderna vaccine and 1 dose of bivalent mRNA vaccine	Optional: 1 additional dose of Moderna bivalent vaccine OR Pfizer-BioNTech bivalent vaccine [c]	≥2 months after last bivalent mRNA vaccine dose
1 dose of monovalent Pfizer-BioNTech vaccine	2 doses of Pfizer-BioNTech bivalent vaccine	• Bivalent dose 1: 3 weeks after monovalent dose • Bivalent dose 2: ≥4 weeks after bivalent dose 1
2 doses of monovalent Pfizer-BioNTech vaccine	1 dose of Pfizer-BioNTech bivalent vaccine	≥4 weeks after last monovalent dose
3 doses of monovalent Pfizer-BioNTech vaccine	1 dose of Moderna bivalent vaccine OR 1 dose of Pfizer-BioNTech bivalent vaccine	≥8 weeks after last monovalent dose
3 doses of monovalent Pfizer-BioNTech vaccine and 1 dose of bivalent mRNA vaccine	Optional: 1 additional dose of Moderna bivalent vaccine OR Pfizer-BioNTech bivalent vaccine [c]	≥2 months after last bivalent mRNA vaccine dose
1 or 2 doses of Novavax vaccine	1 dose of Moderna bivalent vaccine OR 1 dose of Pfizer-BioNTech bivalent vaccine	≥8 weeks after last monovalent dose
1 dose of J&J/Janssen vaccine (individuals ≥18 years old) [d]	1 or 2 doses of Moderna bivalent vaccine OR Pfizer-BioNTech bivalent vaccine	• Dose 1: ≥4 weeks after last monovalent dose • Dose 2 (optional): ≥2 months after the recommended bivalent mRNA vaccine dose
1 dose of J&J/Janssen vaccine (individuals ≥18 years old) [d] and 1 dose of Moderna bivalent vaccine OR Pfizer-BioNTech bivalent vaccine	Optional: 1 dose of Moderna bivalent vaccine OR Pfizer-BioNTech bivalent vaccine [c]	≥2 months after the previous bivalent mRNA vaccine dose

Abbreviations: CDC, Centers for Disease Control and Prevention; J&J, Johnson & Johnson.

Notes:

a. See CDC: Description of moderate and severe immunocompromising conditions and treatment.

b. COVID-19 vaccination is recommended regardless of history of SARS-CoV-2 infection. Defer any COVID-19 vaccination at least until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met. If SARS-CoV-2 infection was recent, may consider delaying a COVID-19 vaccine dose by 3 months from symptom onset or positive test result (if infection was asymptomatic). Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection is not recommended for the purpose of vaccine decision-making (see CDC: Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States > COVID-19 vaccination and SARS-CoV-2 infection).

c. Further additional dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances of the patient. Any further additional doses should be administered ≥2 months after the last COVID-19 vaccine dose.

d. As of May 6, 2023, the J&J/Janssen viral vector COVID-19 vaccine is no longer available for use in the United States (see CDC: Overview of COVID-19 Vaccines).

Discussion: COVID-19 morbidity and mortality are increased among individuals of older age and who have comorbidities that put them at high risk of severe disease [Bhaskaran, et al. 2021; Costenaro, et al. 2021; Mirzaei, et al. 2021; Patel, et al. 2021; Tesoriero, et al. 2021; Cooper, et al. 2020; Nandy, et al. 2020; Ssentongo, et al. 2020]. Although initial studies of HIV and COVID-19-related mortality found conflicting results, a World Health Organization report based on results from 37 countries found a 30% increased risk of severe illness at time of hospital admission and an in-hospital mortality rate of 23.1% for people with HIV [WHO 2021]. Because there is also an increased risk of COVID-19 infection, whether due to overlapping comorbidities or disease-specific factors, people with HIV are a high-priority group for vaccination [Mellor, et al. 2021; Patel, et al. 2021; Ssentongo, et al. 2021; Byrd, et al. 2020].

COVID-19 vaccines have been shown to be safe and highly effective at reducing severe illness, hospitalization, and mortality. Common mild adverse effects include injection site pain, headache, fatigue, myalgias, fever, and nausea. Rarely, more serious allergic reactions can occur. Myocarditis has been reported mostly among young men, mostly after the second dose of an mRNA vaccine, and has been mostly mild with spontaneous resolution (see CDC: Myocarditis and Pericarditis Considerations).

COVID-19 vaccines have been shown to be safe and effective in people with HIV [Yin, et al. 2022]. There has been no evidence of decreased vaccine efficacy and no reports of increased vaccine adverse effects in people with HIV, although antibody response may peak later and wane earlier [Fowokan, et al. 2023; Chambers, et al. 2022]. However, individuals with HIV and a CD4 count <350 cells/mm^3 are at high risk for breakthrough infection and should receive vaccination as per the schedule for patients who are immunocompromised [Lang, et al. 2022].

→ 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 are 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 (Hib)

Table 2: *Haemophilus influenzae* Type B Vaccine	
Trade Names	• Hiberix • ActHIB
Indications	Patients at risk of Hib infection
Administration	Administer according to CDC: Adult Immunization Schedule: • Recommendations for Ages 19 Years and Older, 2023: HTML | PDF (Table 1) • Recommendations by Medical Condition and Other Indication: HTML | PDF (Table 2)
Revaccination	None
Comments	Not routinely recommended for people with HIV in the absence of other risk factors
Abbreviations: CDC, Centers for Disease Control and Prevention; Hib, *Haemophilus influenzae* type B.	

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 Hib infection in adults with HIV [CDC 2023; Thompson, et al. 2021; Briere, et al. 2014]. 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 [MacLennan, et al. 2016; Dockrell, et al. 1999; Kroon, et al. 1997; Steinhoff, et al. 1991].

Hepatitis A Virus (HAV)

Table 3: Hepatitis A Virus Vaccine	
Trade Names	• HAV: Havrix; Vaqta • HAV inactivated + HBV: Twinrix
Indications	All adults with HIV [CDC(a) 2022]
Administration	• Administer according to CDC: Adult Immunization Schedule: – Recommendations for Ages 19 Years and Older, 2023: HTML | PDF (Table 1) – Recommendations by Medical Condition and Other Indication: HTML | PDF (Table 2) • Notes: – Obtain HAV IgG testing ≥1 month after final dose of vaccination series to confirm immune response. – If immune reconstitution appears likely, consider deferring until patient's CD4 count ≥200 cells/mm^3 [DHHS 2022].
Revaccination	Patients who do not respond to the primary HAV vaccination series should be revaccinated [Thompson, et al. 2021] and counseled to avoid exposure.
Comments	• See NYSDOH AI guideline Prevention and Management of Hepatitis A Virus Infection in Adults With HIV. • Covered by HRSA: Vaccine Injury Compensation Program
Abbreviations: CDC, Centers for Disease Control and Prevention; HAV, hepatitis A virus; HBV, hepatitis B virus; HRSA, Health Resources and Services Administration; IgG, immunoglobulin G.	

Discussion: The HAV vaccine is recommended for all adults with HIV who do not have immunity to HAV [CDC(a) 2022; Thompson, et al. 2021].

The reported rate of HAV antibody seroconversion after vaccination ranges from 49% to 96% [Mena, et al. 2015; Crum-Cianflone and Wallace 2014; Fiore, et al. 2006]. 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 [Cheng, et al. 2017; Crum-Cianflone(b), et al. 2011]. 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 [Mena, et al. 2015; Crum-Cianflone and Wallace 2014; Fiore, et al. 2006].

If a patient's CD4 count is <200 cells/mm^3 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 [DHHS 2022]. HAV vaccination should not be deferred in patients who are unlikely to achieve an increased CD4 cell count.

Care providers should perform HAV IgG testing at least 1 month after the final dose of the vaccination series to confirm immune response. HAV vaccination should be repeated in patients with no response to initial vaccination, [Thompson, et al. 2021], and they should be counseled to avoid exposure to HAV because they remain susceptible to infection, although a small study reported that 31% of participants who had not seroconverted at month 12 and before month 18 (n = 16) subsequently seroconverted after completing the 2-dose vaccination series [Cheng, et al. 2017]. If a patient is susceptible to both HAV and HBV, the combined HAV/HBV vaccine (given as 3 doses at 0, 1, and 6 months) can be used regardless of the patient's immune status [Thompson, et al. 2021].

Hepatitis B Virus (HBV)

Table 4: Hepatitis B Virus Vaccine	
Trade Names	• HBV 2-dose series: HEPLISAV-B (see comments) • HBV 3-dose series: Engerix-B; Recombivax HB; PreHevbrio (see comments) • HAV inactivated + HBV 3-dose series: Twinrix
Indications	Patients who are negative for anti-HBs and do not have chronic HBV infection

Table 4: Hepatitis B Virus Vaccine	
Administration	• Administer according to CDC: Adult Immunization Schedule: – Recommendations for Ages 19 Years and Older, 2023: HTML | PDF (Table 1) – Recommendations by Medical Condition and Other Indication: HTML | PDF (Table 2) • Notes: – 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 [DHHS 2022]. – Test for anti-HBs 4 to 16 weeks after administration of the last dose of the vaccination series.
Revaccination	Patients who do not respond to the primary HBV vaccination series (anti-HBs <10 IU/L) should be revaccinated with Heplisav-B or a double dose of the vaccine series previously administered.
Comments	• In patients at risk for HBV infection, initial vaccination should not be deferred if the CD4 count is <200 cells/mm^3 [DHHS 2022]. • If an accelerated schedule is used, a fourth booster dose should be administered ≥6 months after initiation of the series; the accelerated schedule is not recommended for patients with CD4 counts <500 cells/mm^3. • The HAV/HBV combined vaccine is not recommended for the double-dose or 4-injection HBV vaccination strategy. • PreHevbrio, a 3-antigen recombinant HBV vaccine, was approved in 2021 by the FDA for use for individuals ≥18 years old [FDA 2021], but experience regarding its use in patients with HIV is lacking at this time. • Heplisav-B and PreHevbrio are not recommended in pregnancy because of lack of safety data [CDC 2023]. • See NYSDOH AI guideline Prevention and Management of Hepatitis B Virus Infection in Adults With HIV. • Covered by HRSA: Vaccine Injury Compensation Program
Abbreviations: anti-HBs, hepatitis B surface antibody; CDC, Centers for Disease Control and Prevention; FDA, U.S. Food and Drug Administration; HAV, hepatitis A virus; HBV, hepatitis B virus; HRSA, Health Resources and Services Administration.	

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 2023]. The antibody response to the HBV vaccine is reduced in individuals 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% [Mena, et al. 2015; Mast, et al. 2006], with diminishing response with lower CD4 cell counts [Pollack, et al. 2016; Pettit, et al. 2010; Kim, et al. 2008; Overton, et al. 2005]. Undetectable or very low viral load is associated with increased response to HBV vaccination [Mena, et al. 2015; Kim, et al. 2008; Overton, et al. 2005]. Initial vaccination should not be deferred in patients with low CD4 cell counts; some patients with HIV and CD4 counts ≤200 cells/mm^3 may have an immune response [DHHS 2022; Whitaker, et al. 2012].

The 3 single-antigen HBV vaccines currently approved by the FDA for individuals ≥18 years old are Engerix-B, Recombivax HB, and Heplisav-B. PreHevbrio, a 3-antigen recombinant HBV vaccine, was approved in 2021 by the FDA for use for individuals ≥18 years old [FDA 2021], but experience regarding its use in patients with HIV is lacking at this time.

In 3 randomized controlled trials among individuals without HIV, administration of 2 doses of Heplisav-B was associated with a higher seroprotection rate than 3 doses of Engerix-B [FDA(b) 2020]. However, the 3 formulations have not yet been established to be equally effective in patients with HIV. A retrospective cohort study among individuals with HIV found seroprotection rates were increased with the Heplisav-B vaccine compared with other previously used HBV vaccines [Schnittman, et al. 2021]. In addition, a recent modeling study determined that use of Heplisav-B among individuals with HIV results in lower costs and increased benefits compared with Engerix-B [Rosenthal, et al. 2020]. The 2-dose option may facilitate completion rates for the vaccination series.

Improved immune response has been reported using a 4-injection double-dose (40 µg) regimen [Chaiklang, et al. 2013; Launay, et al. 2011]. Studies of a 3-injection double-dose regimen reported increased seroconversion rates compared with standard dose only among adults with HIV with CD4 counts >350 cells/mm^3 and low or undetectable HIV viral load [Potsch, et al. 2012; Fonseca, et al. 2005]. 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/mm^3 because of the increased likelihood of nonresponse [de Vries-Sluijs, et al. 2011]. Patients with HIV should be tested for anti-HBs 4 to 16 weeks after completing the vaccination series [DHHS 2022; Thompson, et al. 2021]. Other strategies to improve immune response have demonstrated

some success, including intradermal administration [Launay, et al. 2011] and addition of adjuvants [Overton, et al. 2010; Cooper, et al. 2005; Sasaki, et al. 2003], but the evidence is not sufficient to make a recommendation.

Patients who do not respond to primary vaccination should be revaccinated with Heplisav-B or a double dose of the vaccine series previously administered. In a recent retrospective, cross-sectional study among individuals with HIV who failed to seroconvert after vaccination (anti-HBs negative and hepatitis B surface antigen negative) with Engerix-B or Recombivax HB, revaccination with Heplisav-B was highly effective in achieving seroprotection [Khaimova, et al. 2021]. If Heplisav-B is not administered as the initial HBV vaccination series, revaccination with the 2-dose series may be considered. Several studies have reported increased response rates from double-dose revaccination [Psevdos, et al. 2010; Cardell, et al. 2008; de Vries-Sluijs, et al. 2008], 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]. In patients who do not have an immune response to HBV vaccination and are initiating antiretroviral therapy, revaccination can be deferred until the CD4 count increases to ≥200 cells/mm^3 [DHHS 2022]. Revaccination should not be delayed in patients who are unlikely to achieve an increased CD4 cell count.

For people 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 individuals with HIV, the combined vaccine is not recommended for the double-dose or 4-injection HBV vaccination strategy.

Human Papillomavirus (HPV)

Table 5: Human Papillomavirus Vaccine	
Trade Name	Gardasil 9
Indications	All patients 9 to 45 years old who were not previously vaccinated or did not receive a complete 3-dose series
Administration	Administer through age 45 years as a 3-dose series according to CDC: Adult Immunization Schedule: • Recommendations for Ages 19 Years and Older, 2023: HTML | PDF (Table 1) • Recommendations by Medical Condition and Other Indication: HTML | PDF (Table 2)
Revaccination	None
Comments	• A 2-dose schedule is not recommended [CDC(a) 2021]. • 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 quadrivalent vaccine. • Follow recommendations for cervical and anal cancer screening in NYSDOH AI guidelines Screening for Cervical Dysplasia and Cancer in Adults With HIV and Screening for Anal Dysplasia and Cancer in Adults With HIV. • Covered by HRSA: Vaccine Injury Compensation Program
Abbreviations: CDC, Centers for Disease Control and Prevention; HPV, human papillomavirus; HRSA, Health Resources and Services Administration.	

Discussion: In 2006, the U.S. Food and Drug Administration (FDA) approved a 9-valent vaccine that protects against nononcogenic HPV types 6 and 11 and oncogenic HPV types 16, 18, 31, 33, 45, 52, and 58 (Gardasil 9). Because it offers broader coverage of HPV types than other vaccines, the 9-valent vaccine is the only HPV vaccine available in the United States (see CDC: Supplemental information and guidance for vaccination providers regarding use of 9-valent HPV for more information). The HPV vaccine is approved by the FDA for preventive but not therapeutic use.

Extrapolating data from the demonstrated effectiveness of the quadrivalent HPV vaccine in older individuals [Wilkin, et al. 2018], the FDA expanded the age range for approved use of the HPV vaccine in the United States from ages 9 to 26 years to ages 9 to 45 years [FDA(a) 2020]. There is no specific mention of HIV infection in the updated FDA approval. Although 1 study

demonstrated lower efficacy of the quadrivalent vaccine in individuals with HIV [Wilkin, et al. 2018], other research linked HIV viral suppression to vaccine efficacy [Money, et al. 2016].

When to vaccinate: HPV vaccination may be scheduled at the same time as standard adolescent vaccines offered at ages 9 to 12 years [CDC(a) 2021]. If possible, the HPV vaccine series should begin at 9 years old. The 3-dose vaccine is recommended for all patients with HIV who are 9 to 45 years old. The 9-valent HPV vaccine should be administered according to the CDC standard schedule for immunocompromised adults, children, and adolescents (a 3-dose regimen over a 6-month period at 0, 2, and 6 months) and should be offered regardless of CD4 cell count.

HPV vaccination provides high levels of neutralizing antibodies for at least 5 years and is protective in individuals ≤26 years old who do not have HIV, regardless of history of sexual activity; however, the full length of its protection has not been established. In an observational study conducted in England that examined the effectiveness of a national HPV immunization program, the reduction in cervical cancer was greatest in individuals who received the vaccine at ages 12 to 13 years [Falcaro, et al. 2021]. Although data are limited, the immunogenicity of the quadrivalent HPV vaccine has been demonstrated in individuals with HIV [Wilkin, et al. 2018; Kojic, et al. 2014].

Vaccination is not expected to change the course of established HPV infections but may prevent infection from other strains that are part of a polyvalent vaccine.

HPV testing and vaccination: HPV testing is not recommended before vaccine administration. It is unlikely that an individual will have been infected with all the HPV types covered by the 9-valent vaccine; therefore, it is expected that the 9-valent HPV vaccine will be effective against any of the 9 HPV types or any HPV types to which the individual has not been exposed. There also may be beneficial prevention due to cross-reactivity with other HPV types not included in the 9-valent vaccine [Wheeler, et al. 2012].

Revaccination with the 9-valent HPV vaccine is not currently recommended for individuals who previously received the bivalent or quadrivalent HPV vaccine [Petrosky, et al. 2015]. Vaccination with the quadrivalent HPV vaccine has demonstrated cross-protection against other oncogenic HPV types [Kemp, et al. 2011]. There is no maximum interval between vaccine doses as long as 3 doses are given, so there is no need to repeat doses if a scheduled vaccination is missed [CDC(a) 2021].

Influenza

Table 6: Influenza Vaccine	
Trade Names	See CDC influenza vaccines table
Indications	All adults with HIV
Administration	Administer annually during flu season (October through May) according to CDC: Adult Immunization Schedule: • Recommendations for Ages 19 Years and Older, 2023: HTML | PDF (Table 1) • Recommendations by Medical Condition and Other Indication: HTML | PDF (Table 2)
Revaccination	None
Comments	Covered by HRSA: Vaccine Injury Compensation Program
Abbreviation: CDC, Centers for Disease Control and Prevention; HRSA, Health Resources and Services Administration.	

Discussion: People with HIV are at greater risk of severe morbidity from an influenza infection [Grohskopf, et al. 2019; Kunisaki and Janoff 2009] 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 [Thompson, et al. 2021; Grohskopf, et al. 2019]. Inactivated influenza vaccine offers protective immunity in adults with HIV [Grohskopf, et al. 2019; Remschmidt, et al. 2014; Beck, et al. 2012]. 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 ≥35 years old, have low CD4 cell counts, and have detectable viremia [Garg, et al. 2016; Crum-Cianflone(a), et al. 2011; Evison, et al. 2009; Yamanaka, et al. 2005; Kroon, et al. 2000]. 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 ≥18 years old who are given a double-

dose vaccine than for those given the standard dose vaccine, but the clinical significance of this remains unknown [McKittrick, et al. 2013; Cooper, et al. 2011]. A study among children and young adults (3 to 21 years old) found no increased immunity among participants with HIV who received the double-dose vaccine [Hakim, et al. 2016].

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 [Glinka, et al. 2016; Werker, et al. 2014]. 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 7: Measles, Mumps, Rubella Vaccine	
Trade Name	M-M-R II
Indications	For patients with CD4 counts ≥200 cells/mm^3 for ≥6 months who do not have evidence of MMR immunity
Administration	Administer according to the CDC: Adult Immunization Schedule: • Recommendations for Ages 19 Years and Older, 2023: HTML | PDF (Table 1) • Recommendations by Medical Condition and Other Indication: HTML | PDF (Table 2)
Revaccination	Recommended only in the setting of an outbreak
Comments	• **Contraindicated** for patients with CD4 counts <200 cells/mm^3 • The MMR + varicella vaccine (ProQuad) should not be substituted for the MMR vaccine [McLean, et al. 2013]. • 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, et al. 2018]. • Covered by HRSA: Vaccine Injury Compensation Program
Abbreviations: CDC, Centers for Disease Control and Prevention; HRSA, Health Resources and Services Administration; MMR, measles, mumps, rubella.	

Discussion: Immunocompromised individuals 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/mm^3 for ≥6 months and who do not have evidence of immunity to MMR should be vaccinated with 2 doses of MMR vaccine ≥4 weeks 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, individuals with perinatally acquired HIV who received childhood vaccination with MMR before establishment of effective antiretroviral therapy (ART) should be revaccinated (2 doses) after effective 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 MMR vaccination. 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 [Abzug, et al. 2012; Aurpibul, et al. 2007]. If individuals previously vaccinated with 2 doses of a mumps-containing vaccine are identified as having 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, et al. 2018].

MMR vaccination contains live virus and is contraindicated for patients with CD4 counts <200 cells/mm^3 because of reports of adverse events, such as measles pneumonitis, in severely immunocompromised patients [Angel, et al. 1998; CDC 1996]. Serious adverse effects have not been reported in adults who were not severely immunocompromised [Chaiwarith, et al. 2016; McLean, et al. 2013; Belaunzaran-Zamudio, et al. 2009]. The MMR + varicella vaccine has not been adequately studied in individuals with HIV and is not recommended as a substitute for the MMR vaccine in this population [McLean, et al. 2013].

Meningococcal Serotypes A, C, W, and Y (MenACWY)

Table 8: Meningococcal Serotypes A, C, W, and Y Vaccine	
Trade Names	• Menactra (MenACWY-D) • Menveo (MenACWY-CRM) • MenQuadfi (MenACWY-TT)
Indications	All patients with HIV
Administration	• Administer 2 doses of MenACWY vaccine ≥8 weeks apart in those not previously vaccinated. • For those previously vaccinated with 1 dose of MenACWY vaccine, administer the second dose at the earliest opportunity ≥8 weeks after the previous dose. • See CDC: Adult Immunization Schedule: – Recommendations for Ages 19 Years and Older, 2023: HTML | PDF (Table 1) – Recommendations by Medical Condition and Other Indication: HTML | PDF (Table 2)
Revaccination	Administer 1 booster dose of MenACWY vaccine every 5 years.
Comments	• MenACWY-D should not be administered until ≥4 weeks after pneumococcal conjugate vaccine. • See Meningococcal Disease: NYSDOH Health Advisory and Vaccine Recommendations • Covered by HRSA: Vaccine Injury Compensation Program
Abbreviations: CDC, Centers for Disease Control and Prevention; HRSA, Health Resources and Services Administration; MenACWY, meningococcal serotypes A, C, W, and Y.	

Discussion: Adults with HIV are at increased risk of invasive meningococcal disease due to serogroups C, W, and Y [Mbaeyi, et al. 2020; Folaranmi, et al. 2017]. A 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/mm^3 [Miller, et al. 2014]. As of 2020, the CDC recommends vaccinating all previously unvaccinated adults with HIV with a 2-dose primary series of MenACWY vaccine (MenACWY-CRM, MenACWY-D, or MenACWY-TT) administered ≥8 weeks apart [Mbaeyi, et al. 2020].

Data on meningococcal vaccine efficacy among adults with HIV are not currently available [Mbaeyi, et al. 2020]. 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 [Lujan-Zilbermann, et al. 2012; Siberry, et al. 2010]. 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. There is no recommendation for post-vaccination serologic testing to determine immune response [Mbaeyi, et al. 2020].

Meningococcal Serotype B (MenB)

Table 9: MenB Vaccine for Prevention of MenB Infection	
Trade Names	• Bexsero (4CMenB) • Trumenba (MenB-FHbp)
Indications	Patients at risk of MenB infection
Administration	Administer according to CDC: Adult Immunization Schedule, 2023: HTML | PDF
Revaccination	None

Table 9: MenB Vaccine for Prevention of MenB Infection	
Comments	• Bexsero (4CMenB) and Trumenba (MenB-FHbp) are not interchangeable • Not routinely recommended for people with HIV in the absence of other risk factors • Covered by HRSA: Vaccine Injury Compensation Program
Abbreviations: CDC, Centers for Disease Control and Prevention; HRSA, Health Resources and Services Administration; MenB, meningococcal serotype B.	

Discussion: The MenB vaccine offers protection against MenB infection. 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 2023].

Mpox

☑ RECOMMENDATIONS

Mpox Vaccine

- Clinicians should recommend vaccination against mpox (formerly "monkeypox") for individuals ≥18 years old with HIV who are at high risk of or who have been exposed to mpox within the past 14 days and for whom vaccination may reduce the risk of infection or decrease symptoms if infection has occurred. (A2)
- Clinicians should use only the JYNNEOS (Imvamune or Imvanex) mpox vaccine for individuals with HIV, as it is the only available vaccine that is considered safe for administration in this population. (A*)
- Clinicians should recommend vaccination for adults with HIV, regardless of their CD4 cell count and degree of viral suppression. (A3)

Table 10: Mpox Vaccine [a]	
Trade name	JYNNEOS (also called Imvamune or Imvanex)
Type of vaccine	Live virus that does not replicate efficiently in human cells
Administration	Two subcutaneous injections 4 weeks apart
Indication	Individuals with HIV ≥18 years old who are at high risk of or who have been exposed to mpox within the past 14 days
Adverse reactions	Injection site reactions such as pain, swelling, and redness. Vaccination with JYNNEOS will not cause mpox infection.
Contraindications	Severe allergy to any component of the vaccine (gentamicin, ciprofloxacin, or egg protein)
Immune response	Maximal development of the immune response takes 2 weeks after second dose.
Pregnancy/ breastfeeding	No evidence of reproductive harm from animal data. Pregnancy and breastfeeding are not contraindications for vaccination.
Abbreviation: CDC, Centers for Disease Control and Prevention. **Note:** a. See package insert and CDC: Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines During the 2022 U.S. Monkeypox Outbreak.	

Immunization: The CDC considers people with HIV to be at risk for severe mpox disease and recommends prioritization of those at risk for receipt of the JYNNEOS mpox vaccine [CDC(b) 2022]. Vaccination is used to prevent mpox and as post-exposure prophylaxis; it protects against disease when administered before exposure. If administered after exposure, the vaccine may prevent development or decrease the severity of mpox disease (see CDC: Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines During the 2022 U.S. Monkeypox Outbreak).

Two vaccines against mpox are currently approved by the U.S. Food and Drug Administration: JYNNEOS (Imvamune or Imvanex) and ACAM2000. Only JYNNEOS is safe for people with HIV. The ACAM2000 vaccine is contraindicated in adults with HIV and their household contacts.

JYNNEOS contains live vaccinia virus, but the virus does not replicate in humans. JYNNEOS is considered safe to use in adults with HIV regardless of viral load or CD4 cell count. No data are available on the effectiveness of available mpox vaccines in this current outbreak.

The safety and immunogenicity of the JYNNEOS vaccine have been evaluated in adults with HIV; however, the immunogenicity is unknown in individuals who are not virally suppressed or who have with CD4 counts ≤200 cells/mm^3. Vaccine efficacy may be lower in patients with low CD4 cell counts. However, given the risk of severe illness in immunosuppressed individuals, vaccination is recommended regardless of CD4 cell count and degree of viral suppression.

Vaccine dosing: The CDC recommends the mpox vaccine be given within 4 days of exposure to prevent disease. If given 4 to 14 days after exposure, vaccination may not prevent disease but may reduce symptoms [CDC(b) 2022]. Peak immunogenicity is achieved 2 weeks after the second JYNNEOS dose [Rao, et al. 2022].

→ KEY POINTS

- JYNNEOS (Imvamune or Imvanex) is the only mpox vaccination safe for adults with HIV.
- Care should be taken to avoid language and behavior that marginalizes and stigmatizes communities at risk.

Presentation: A high index of suspicion is required because the clinical presentation of mpox disease can vary from a few scattered papules and mild constitutional symptoms to severe illness. Symptoms of mpox may include fever, headache, muscle aches, backache, swollen lymph nodes, moderate to severe pain, exhaustion, and rash that may include painful oral, anal, or genital lesions.

Mortality: Studies of mpox in remote, medically underserved areas of Central Africa have reported mortality of 11% in unvaccinated individuals [Durski, et al. 2018]. People with advanced HIV or who are not virally suppressed may be at risk of severe disease. To date, no deaths have been reported in the United States during the current outbreak, but a fulminant form of mpox has been reported in people with advanced immunosuppression due to HIV [Mitja, et al. 2023].

Transmission: Although many of those affected in the current global outbreaks are men who have sex with men, the virus can be acquired by anyone who has been in close contact with someone with mpox. The virus that causes mpox is transmitted via the following:

- Direct skin-to-skin contact with an infectious rash, scabs, or body fluids
- Exposure to respiratory secretions during prolonged face-to-face contact or intimate physical contact, such as kissing, cuddling, or sex
- Touching objects or fabrics (e.g., clothing or linens) that have been in contact with the rash or body fluids of someone with mpox
- Being scratched or bitten by an infected animal

Pneumococcal

Table 11: Pneumococcal Vaccine
(see also CDC: Adult Immunization Schedules: By Age [Table 1] and Medical Condition [Table 2] and CDC: PneumoRecs VaxAdvisor)

Trade Names	• Vaxneuvance (PCV15; 15-valent pneumococcal conjugate vaccine) • Prevnar 20 (PCV20; 20-valent pneumococcal conjugate vaccine) • Pneumovax 23 (PPSV23; 23-valent pneumococcal polysaccharide vaccine)
Indications	All patients with HIV
Administration	**For patients who have not received a pneumococcal vaccine or whose vaccination status is unknown:** Vaccinate with 1 dose of PCV15 *or* 1 dose of PCV20. If PCV15 is used, follow with 1 dose of PPSV23, with a minimum interval of 8 weeks between the doses.
Revaccination	Consult CDC: PneumoRecs VaxAdvisor

Table 11: Pneumococcal Vaccine (see also CDC: Adult Immunization Schedules: By Age [Table 1] and Medical Condition [Table 2] and CDC: PneumoRecs VaxAdvisor)	
Comments	• Pneumococcal vaccination should be not be deferred for patients with CD4 count <200 cells/mm^3 and/or detectable viral load; however, the follow-up secondary administration of the PPSV23 vaccine may be deferred until the patient's CD4 count is ≥200 cells/mm^3 and/or viral load is undetectable. • The Menactra (MenACWY-D) vaccine for meningococcal serotype groups A,C, W, and Y (MenACWY) should not be administered until ≥4 weeks after pneumococcal conjugate vaccine.
Abbreviation: CDC, Centers for Disease Control and Prevention.	

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 2023; Kobayashi, et al. 2022]. Patients who have not previously been vaccinated or whose vaccination status is unknown should receive 1 dose of PCV15 or 1 dose of PCV20; if PCV15 is used, it should be followed with 1 dose of PPSV23, with a minimum interval of 8 weeks between the doses. There is no recommendation for post-vaccination serologic testing to determine immune response [CDC 2023; Kobayashi, et al. 2022]. See the CDC: PneumoRecs VaxAdvisor for vaccination recommendations by age and pneumococcal immunization history.

Pneumococcal vaccination has been shown to reduce pneumococcal bacteremia and mortality among adults with HIV [Chowers, et al. 2017; Rodriguez-Barradas, et al. 2008; Grau, et al. 2005; Hung, et al. 2004]. Both polysaccharide and conjugate pneumococcal vaccines appear to be safe and immunogenic among adults with HIV who have CD4 counts ≥200 cells/mm^3 [Lombardi, et al. 2016; Bhorat, et al. 2015; Rodriguez-Barradas, et al. 2015; Ho, et al. 2013].

Patients with CD4 counts <200 cells/mm^3 are at the highest risk of pneumococcal disease. Immunogenicity was demonstrated for individuals with HIV with CD4 counts <200 cells/mm^3 who received PCV7 [French, et al. 2010]. Patients with HIV who have not previously received any pneumococcal vaccine should receive a dose of PCV15 or PCV20, 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 HIV RNA levels <100,000 copies/mL and among those who are on antiretroviral therapy [French, et al. 2010].

Contraindications to pneumococcal vaccination include a history of anaphylaxis caused by any vaccine component. Patients with a history of an anaphylactic reaction to any conjugate vaccines or diphtheria toxoid should not receive conjugate vaccine [CDC 2023].

Tetanus, Diphtheria, and Pertussis (Tdap) and Tetanus-Diphtheria (Td)

Table 12: Tdap and Td Vaccines	
Trade Names	• Tdap: Adacel; Boostrix • Td: Tenivac; TDVax
Indications	All adult patients
Administration	Administer according to CDC: Adult Immunization Schedule: • Recommendations for Ages 19 Years and Older, 2023: HTML | PDF (Table 1) • Recommendations by Medical Condition and Other Indication: HTML | PDF (Table 2)
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.
Comments	Covered by HRSA: Vaccine Injury Compensation Program
Abbreviations: CDC, Centers for Disease Control and Prevention; HRSA, Health Resources and Services Administration; Tdap, tetanus, diphtheria, and pertussis; Td, tetanus-diphtheria.	

Discussion: The recommendations for Tdap and Td vaccination of adults with HIV are the same as for those in the general population [CDC 2023; Thompson, et al. 2021]. The safety and efficacy of vaccination with Tdap has not been studied in this population [Crum-Cianflone and Wallace 2014].

Varicella

Table 13: Varicella Vaccine	
Trade Name	Varivax
Indications	For patients with CD4 counts ≥200 cells/mm^3 who do not have evidence of immunity to varicella
Administration	Administer according to CDC: Adult Immunization Schedule: • Recommendations for Ages 19 Years and Older, 2023: HTML | PDF (Table 1) • Recommendations by Medical Condition and Other Indication: HTML | PDF (Table 2)
Revaccination	None
Comments	• **Contraindicated** for patients with CD4 counts <200 cells/mm^3 (see CDC: Adult Immunization Schedule) • Anti-varicella IgG screening should be performed in patients with no known history of chickenpox or shingles [Marin, et al. 2007]. • MMR + varicella (ProQuad) vaccine should not be used [McLean, et al. 2013]. • Antiherpetic agents should be avoided ≥24 hours before and for 14 days after administration [ACIP 2022; CDC(b) 2021]. • An interval of ≥5 months is recommended between administration of post-exposure VariZIG and varicella vaccination [ACIP 2022; DHHS 2022; CDC 2006]. • Clinical disease due to varicella after vaccination, a very rare event, should be treated with acyclovir [DHHS 2022]. • Covered by HRSA: Vaccine Injury Compensation Program
Abbreviations: CDC, Centers for Disease Control and Prevention; HRSA, Health Resources and Services Administration; IgG, immunoglobulin G; MMR, measles, mumps, rubella; VariZIG, varicella zoster immune globulin.	

Discussion: Patients with HIV who have CD4 counts ≥200 cells/mm^3 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 administered 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/mm^3 because of the risk of disseminated disease [CDC 2023; Marin, et al. 2007; Kramer, et al. 2001]. 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 [Crum-Cianflone and Wallace 2014; CDC 2012; Marin, et al. 2007].

Because of the possibility of severe disease in individuals with HIV, clinicians should verify varicella immunity. Birth before 1980 is not accepted as evidence of immunity in immunocompromised individuals; anti-varicella immunoglobulin G screening should be performed in patients with HIV who have no known history of chickenpox or shingles [Marin, 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, et al. 2007]. Clinical disease due to varicella after vaccination, a very rare event, should be treated with acyclovir [DHHS 2022; Marin, et al. 2007]. If household members or close contacts develop a rash after vaccination, people with HIV should avoid contact with the affected individual until after the rash resolves [ACIP 2022; Marin, et al. 2007]. Because they can interfere with vaccine virus replication and decrease vaccine effectiveness, all antiherpetic agents should be avoided for at least 24 hours before varicella vaccination through 14 days after [ACIP 2022; CDC(b) 2021]. If post-exposure varicella zoster immune globulin is given, clinicians should wait ≥5 months before varicella vaccination [ACIP 2022; DHHS 2022; CDC 2006].

Zoster

Table 14: Zoster Vaccine	
Trade Names	Shingrix: RZV, adjuvanted
Indications	MCCC recommendation: Patients with HIV ≥18 years old (A2)
Administration	• Two intramuscular doses, given 2 to 6 months apart, regardless of past receipt of ZVL (brand name Zostavax) • Perform anti-varicella IgG screening in patients with no known history of chickenpox or shingles [Marin, et al. 2007]. • See CDC: Adult Immunization Schedule: – Recommendations for Ages 19 Years and Older, 2023: HTML | PDF (Table 1) – Recommendations by Medical Condition and Other Indication: HTML | PDF (Table 2)

Table 14: Zoster Vaccine	
Comments	• 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 for people with HIV [Anderson, et al. 2022; Dooling, et al. 2018]. • As of November 2020, ZVL is no longer available for use in the United States.
Abbreviations: CDC, Centers for Disease Control and Prevention; IgG, immunoglobulin G; MCCC, Medical Care Criteria Committee; RZV, recombinant zoster vaccine; ZVL, zoster vaccine live.	

Discussion: People 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 [Blank, et al. 2012; Harpaz, et al. 2008]. 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 2 doses of recombinant zoster vaccine (RZV; brand name Shingrix) to prevent herpes zoster in adults ≥19 years old who are immunosuppressed [Anderson, et al. 2022]; the previous recommendation was for vaccination of adults ≥50 years old [Dooling, et al. 2018]. On December 1, 2021, the MCCC updated its recommendation as well: Adults with HIV ≥18 years old should receive 2 doses of RZV, administered 2 to 6 months apart. 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 [Anderson, et al. 2022; Dooling, et al. 2018]. As of November 2020, the live, attenuated zoster vaccine (ZVL; brand name Zostavax) is no longer available for use in the United States.

Anti-varicella IgG screening should be performed in patients with no known history of chickenpox or shingles [Marin, et al. 2007] , and patients with a negative titer should be vaccinated for varicella if their CD4 count is >200 cells/mm^3 as an initial step, and the series should be completed before zoster vaccination. There is no recommendation for post-vaccination serologic testing to determine immune response [Harpaz, et al. 2008].

All Recommendations

☑ ALL RECOMMENDATIONS: IMMUNIZATIONS FOR ADULTS WITH HIV

Immunizations

- Clinicians should follow the recommendations for routine vaccination of adults with HIV issued by the CDC, the National Institutes of Health, the HIV Medicine Association, and the Infectious Disease Society of America, as presented here. (A3)

Mpox Vaccine

- Clinicians should recommend vaccination against mpox (formerly "monkeypox") for individuals ≥18 years old with HIV who are at high risk of or who have been exposed to mpox within the past 14 days and for whom vaccination may reduce the risk of infection or decrease symptoms if infection has occurred. (A2)
- Clinicians should use only the JYNNEOS (Imvamune or Imvanex) mpox vaccine for individuals with HIV, as it is the only available vaccine that is considered safe for administration in this population. (A*)
- Clinicians should recommend vaccination for adults with HIV, regardless of their CD4 cell count and degree of viral suppression. (A3)

Abbreviations: CDC, Centers for Disease Control and Prevention; EUA, emergency use authorization; FDA, U.S. Food and Drug Administration.

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Supplement: Guideline Development and Recommendation Ratings

Table S1: Guideline Development: New York State Department of Health AIDS Institute Clinical Guidelines Program	
Developer	New York State Department of Health AIDS Institute (NYSDOH AI) Clinical Guidelines Program
Funding source	NYSDOH AI
Program manager	Clinical Guidelines Program, Johns Hopkins University School of Medicine, Division of Infectious Diseases. See Program Leadership and Staff.
Mission	To produce and disseminate evidence-based, state-of-the-art clinical practice guidelines that establish uniform standards of care for practitioners who provide prevention or treatment of HIV, viral hepatitis, other sexually transmitted infections, and substance use disorders for adults throughout New York State in the wide array of settings in which those services are delivered.
Expert committees	The NYSDOH AI Medical Director invites and appoints committees of clinical and public health experts from throughout New York State to ensure that the guidelines are practical, immediately applicable, and meet the needs of care providers and stakeholders in all major regions of New York State, all relevant clinical practice settings, key New York State agencies, and community service organizations.
Committee structure	• Leadership: AI-appointed chair, vice chair(s), chair emeritus, clinical specialist(s), JHU Guidelines Program Director, AI Medical Director, AI Clinical Consultant, AVAC community advisor • Contributing members • Guideline writing groups: Lead author, coauthors if applicable, and all committee leaders
Disclosure and management of conflicts of interest	• Annual disclosure of financial relationships with commercial entities for the 12 months prior and upcoming is required of all individuals who work with the guidelines program, and includes disclosure for partners or spouses and primary professional affiliation. • The NYSDOH AI assesses all reported financial relationships to determine the potential for undue influence on guideline recommendations and, when indicated, denies participation in the program or formulates a plan to manage potential conflicts. Disclosures are listed for each committee member.
Evidence collection and review	• Literature search and review strategy is defined by the guideline lead author based on the defined scope of a new guideline or update. • A comprehensive literature search and review is conducted for a new guideline or an extensive update using PubMed, other pertinent databases of peer-reviewed literature, and relevant conference abstracts to establish the evidence base for guideline recommendations. • A targeted search and review to identify recently published evidence is conducted for guidelines published within the previous 3 years. • Title, abstract, and article reviews are performed by the lead author. The JHU editorial team collates evidence and creates and maintains an evidence table for each guideline.

Table S1: Guideline Development: New York State Department of Health AIDS Institute Clinical Guidelines Program	
Recommendation development	• The lead author drafts recommendations to address the defined scope of the guideline based on available published data. • Writing group members review the draft recommendations and evidence and deliberate to revise, refine, and reach consensus on all recommendations. • When published data are not available, support for a recommendation may be based on the committee's expert opinion. • The writing group assigns a 2-part rating to each recommendation to indicate the strength of the recommendation and quality of the supporting evidence. The group reviews the evidence, deliberates, and may revise recommendations when required to reach consensus.
Review and approval process	• Following writing group approval, draft guidelines are reviewed by all contributors, program liaisons, and a volunteer reviewer from the AI Community Advisory Committee. • Recommendations must be approved by two-thirds of the full committee. If necessary to achieve consensus, the full committee is invited to deliberate, review the evidence, and revise recommendations. • Final approval by the committee chair and the NYSDOH AI Medical Director is required for publication.
External reviews	• External review of each guideline is invited at the developer's discretion. • External reviewers recognized for their experience and expertise review guidelines for accuracy, balance, clarity, and practicality and provide feedback.
Update process	• JHU editorial staff ensure that each guideline is reviewed and determined to be current upon the 3-year anniversary of publication; guidelines that provide clinical recommendations in rapidly changing areas of practice may be reviewed annually. Published literature is surveilled to identify new evidence that may prompt changes to existing recommendations or development of new recommendations. • If changes in the standard of care, newly published studies, new drug approval, new drug-related warning, or a public health emergency indicate the need for immediate change to published guidelines, committee leadership will make recommendations and immediate updates and will invite full committee review as indicated.

Table S2: Recommendation Ratings and Definitions		
Strength	**Quality of Evidence**	
A: Strong B. Moderate C: Optional	1	Based on published results of at least 1 randomized clinical trial with clinical outcomes or validated laboratory endpoints.
	*	Based on either a self-evident conclusion; conclusive, published, in vitro data; or well-established practice that cannot be tested because ethics would preclude a clinical trial.
	2	Based on published results of at least 1 well-designed, nonrandomized clinical trial or observational cohort study with long-term clinical outcomes.
	2†	Extrapolated from published results of well-designed studies (including nonrandomized clinical trials) conducted in populations other than those specifically addressed by a recommendation. The source(s) of the extrapolated evidence and the rationale for the extrapolation are provided in the guideline text. One example would be results of studies conducted predominantly in a subpopulation (e.g., one gender) that the committee determines to be generalizable to the population under consideration in the guideline.
	3	Based on committee expert opinion, with rationale provided in the guideline text.