Immunizations for Adults With HIV

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Committee: Medical Care Criteria Committee
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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) [AIDSinfo 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.

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.

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 [Ezeanolue, et al. 2019; Rubin, et al. 2014]. 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 [CDC 1996; Redfield, et al. 1987; CDC 1985; Davis, et al. 1977]. 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.

→ KEY POINTS: USE OF LIVE, ATTENUATED VACCINES

- **Patients with CD4 count <200 cells/mm³**: The following live, attenuated vaccines are **contraindicated**: Bacillus Calmette-Guérin; measles, mumps, rubella; oral typhoid; rotavirus*; varicella; yellow fever; zoster.
- **Patients with CD4 count ≥200 cells/mm³**: 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.

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 (ART) and have not been found to have long-term negative effects [Rubin, et al. 2014; Sullivan, et al. 2000].

→ KEY POINTS

- 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].
- Viral suppression is defined as an HIV 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 [Grohskopf, et al. 2019; Rubin, et al. 2014; Fiore, et al. 2011]. 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 [Rubin, et al. 2014; Fiore, et al. 2011; Cortese and Parashar 2009; Marin, et al. 2007].

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](https://www.cdc.gov/vaccines/schedules/hcp/imz/index.html) and the vaccine manufacturers’ package inserts.

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**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 20005
COVID-19 Vaccine for Adults With HIV

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Committee: Medical Care Criteria Committee

RECOMMENDATIONS

• Clinicians should recommend COVID-19 vaccination for all people ≥5 years old, including those with HIV; vaccines to prevent COVID-19 have either been fully approved by the U.S. Food and Drug Administration (FDA) or approved through an FDA Emergency Use Authorization (EUA). (A1)

• Clinicians should provide supplemental vaccination ("third dose") to all people with HIV who are immunocompromised, including patients with active viremia or a CD4 count ≤200 cells/mm$^3$ and patients who met one of those criteria at the time of initial vaccination. (A2)

• Clinicians should provide a booster vaccination to all people ≥12 years old, including those with HIV. (A2)

The Pfizer-BioNTech COVID-19 vaccine received full FDA approval for use in adults on August 23, 2021. The Moderna and Johnson & Johnson (Janssen) vaccines are available through an FDA EUA; both companies have applied for full FDA approval. For more information, see:

- FDA full approval: Pfizer-BioNTech COVID-19 Vaccine (Comirnaty) for people ≥16 years old as a 2-dose primary series
- FDA EUA:
  - Pfizer-BioNTech COVID-19 Vaccine (for people 5–16 years old and certain other indications)
  - Moderna COVID-19 Vaccine (for people ≥18 years old)
  - Johnson & Johnson (Janssen) COVID-19 Vaccine (for people ≥18 years old)
- ClinicalInfo.HIV.gov: Interim Guidance for COVID-19 and Persons With HIV
- NIH COVID-19 guideline: Special Considerations in People With HIV

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 of infection and severe disease [Crum-Cianflone and Wallace 2014; Rubin, et al. 2014]. However, there is concern that patients with HIV-associated immunodeficiency may not 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/mm$^3$ 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 in this guideline (see Summary of Recommended Vaccines for Adults With HIV).

To reduce community transmission and protect those with HIV, this Committee recommends rapid and universal vaccination against COVID-19 for individuals with HIV, regardless of prior history of COVID-19 infection. The Committee also recommends a third primary dose for people who are immunocompromised as defined by the Centers for Disease Control and Prevention (CDC), which includes people with untreated and advanced HIV, and a single booster dose for all individuals with HIV.

Although safety and immunogenicity data on the 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 Information for Specific Groups of People > At Increased Risk for Severe Illness
- 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 (January 2022)
As determined by *CDC guidelines*, approved for use under FDA Emergency Use Authorizations [a,b]

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Pfizer-BioNTech COVID-19 Vaccine (Comirnaty)</th>
<th>Moderna COVID-19 Vaccine</th>
<th>Johnson &amp; Johnson (Janssen) COVID-19 Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of vaccine</td>
<td>mRNA</td>
<td>mRNA</td>
<td>Viral vector</td>
</tr>
<tr>
<td>Authorized use</td>
<td>≥5 years old</td>
<td>≥18 years old</td>
<td>≥18 years old</td>
</tr>
<tr>
<td>Primary series administration</td>
<td>• 2 doses&lt;br&gt;• Administer 3 weeks apart&lt;br&gt;• Dose for children &lt;12 years old is lower than dose for children ≥12 years old</td>
<td>• 2 doses&lt;br&gt;• Administer 4 weeks apart</td>
<td>• 1 dose</td>
</tr>
<tr>
<td>Supplemental vaccine administration: Recommended for <em>immunocompromised</em> patients as defined by the CDC; includes those with untreated or advanced HIV (viral load ≥200 copies/mL or CD4 count ≤200 cells/mm³) at any time during the initial vaccination period, even if no longer immunocompromised at time of supplemental dose</td>
<td>• For patients ≥5 years old&lt;br&gt;• Administer at least 28 days after dose 2 of initial series&lt;br&gt;• Dose is the same as initial dose</td>
<td>• For patients ≥18 years old&lt;br&gt;• Administer at least 28 days after dose 2 of initial series&lt;br&gt;• Dose is the same as initial dose</td>
<td>• No additional vaccine administration</td>
</tr>
<tr>
<td>Booster vaccine administration (revaccination); see Figure below</td>
<td>• For patients ≥18 years old: Pfizer-BioNTech, Moderna, or J&amp;J (Janssen) vaccines may be used for booster&lt;br&gt;• For patients between 12 and 17 years old who completed initial Pfizer-BioNTech vaccine series: Pfizer-BioNTech vaccine may be used for booster&lt;br&gt;• Administer ≥5 months after dose 2 of initial series&lt;br&gt;• Dose is the same as initial dose</td>
<td>• For patients ≥18 years old: Moderna, Pfizer-BioNTech, or J&amp;J (Janssen) vaccines may be used for booster&lt;br&gt;• Administer ≥5 months after dose 2 of initial series&lt;br&gt;• Moderna booster dose of 50 mcg is not the same as the primary dose of 100 mcg</td>
<td>• For patients ≥18 years old: J&amp;J (Janssen), Pfizer-BioNTech, or Moderna vaccines may be used for booster&lt;br&gt;• Administer ≥2 months after primary vaccination&lt;br&gt;• Dose is the same as initial dose</td>
</tr>
</tbody>
</table>

**Abbreviation:** CDC, Centers for Disease Control and Prevention.

**Notes:**
- a. See also: [CDC > Considerations for COVID-19 vaccination in moderately or severely immunocompromised people.](#)
- b. Covered by the [Countermeasures Injury Compensation Program.](#)

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(23.1%) for people with HIV [WHO 2021]. Because there is 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].

The data are not clear regarding whether mixing vaccines confers greater protection than using the same brand and vaccine type for all doses. However, vaccinations should not be delayed in pursuit of a particular vaccine.

For purposes of exposure, contact tracing, and quarantine, and regardless of HIV status, people are considered fully vaccinated after completion of a primary series, but breakthrough infections are possible. People with HIV who are immunocompromised, either from advanced HIV or another cause, such as hematologic malignancy, should receive a third (supplemental) dose of the primary vaccine if they originally received the Pfizer-BioNTech or Moderna vaccine series. This supplemental dose is recommended under the FDA EUA for immunocompromised patients, including those with untreated or advanced HIV (viral load ≥200 copies/mL or CD4 count ≤200 cells/mm³) [CDC 2022c]. If patients met those criteria at any point during their primary vaccination series, they should be offered a supplemental dose, even if they are no longer immunocompromised at the time of supplemental dose administration.

As of early 2022, booster vaccine administration (see Figure) is also recommended for all people, including those with treated and untreated/advanced HIV [CDC 2022c; FDA 2022a].

### Figure: COVID-19 Vaccine Booster Eligibility and Booster Vaccine Choice [a]
For more information, visit [www.fda.gov/covid19vaccines](http://www.fda.gov/covid19vaccines)

<table>
<thead>
<tr>
<th>Primary series completed</th>
<th>Pfizer-BioNTech</th>
<th>Moderna</th>
<th>J&amp;J (Janssen)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Booster-eligible if</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>It’s been ≥ 5 months since primary series completion and the patient is ≥12 years old</td>
<td>It’s been ≥5 months since primary series completion and the patient is ≥18 years old</td>
<td>It’s been ≥2 months since primary vaccine completion and the patient is ≥18 years old</td>
<td></td>
</tr>
<tr>
<td><strong>If booster-eligible, administer</strong></td>
<td>Pfizer-BioNTech [b]</td>
<td>Moderna</td>
<td>J&amp;J (Janssen)</td>
</tr>
</tbody>
</table>

Notes:
- a. Adapted from [FDA 2022b].
- b. Pfizer-BioNTech vaccine can only be used as a booster in individuals 12 to 17 years old.

The COVID-19 vaccine has 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. Reports of myocarditis have also been reported at higher rates, mostly among young men, mostly after the second dose of an mRNA vaccine, and mostly mild with spontaneous resolution. A rare blood clotting disorder has also been seen with the J&J (Janssen) vaccine in women <50 years old, as well as rare cases of Guillain-Barre Syndrome [Rosenblum, et al. 2022; Xu, et al. 2021].

To date, the clinical trials for all 3 vaccines approved under FDA EUA included approximately 900 participants with HIV, a number too small to determine efficacy specifically in this population [Baden, et al. 2021; Sadoff, et al. 2021; Polack, et al. 2020]. Nonetheless, there has also been no evidence of decreased vaccine efficacy and no reports of increased vaccine adverse effects in people with HIV. A small study showed that the Pfizer-BioNTech vaccine elicited a strong antibody response in people with HIV [Woldemeskel, et al. 2021].

→ **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 Conjugate (Hib)**

<table>
<thead>
<tr>
<th>Table 8: Hib 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:** 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 [CDC 2022a; Briere, et al. 2014; Rubin, 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>
<thead>
<tr>
<th>Table 9: HAV Vaccine</th>
</tr>
</thead>
</table>
| **Trade Names**      | • HAV: Havrix; Vaqta  
|                      | • HAV inactivated + hepatitis B virus (HBV): Twinrix |
| **Indications**      | Patients aged ≥1 year with HIV [CDC 2019] |
| **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 Prevention and Management of HAV in Adults With HIV  
|                      | • 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 2019]. 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, et al. 2011b]. 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/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, 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>
<th>Administration</th>
<th>Comments</th>
</tr>
</thead>
</table>
| • HBV 2-dose series: HEPLISAV-B (see note in comments)  
• HBV 3-dose series: Engerix-B; Recombivax HB  
• Hepatitis A virus (HAV) inactivated + HBV: Twinrix | 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 > Figure 3). | • 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] | • 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 2022a]. 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% [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. 2012; 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/mm³ may have an immune response [AIDSinfo 2019; Whitaker, et al. 2012]. 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 to standard dose only among adults with HIV with CD4 counts >350 cells/mm³ 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/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 [AIDSinfo 2019; Aberg, et al. 2014]. 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 CL, et al. 2005; Sasaki, et al. 2003], 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 [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]. HBV revaccination can be deferred among nonresponders who are initiating antiretroviral therapy until CD4 counts increase to ≥200 cells/mm³ [AIDSDepartment 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>
<thead>
<tr>
<th>Table 11: HPV 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>
</tbody>
</table>
| **Comments**          | • A 2-dose schedule is not recommended [CDC 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 4-valent vaccine  
• Follow recommendations for cervical and anal cancer screening in the 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 the Vaccine Injury Compensation Program |

**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 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 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 2021].

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>


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 [McKittrick, et al. 2013; Cooper C, et al. 2011]. 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 [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>
<thead>
<tr>
<th>Table 13: MMR Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trade Names</strong></td>
</tr>
<tr>
<td>• M-M-R II</td>
</tr>
<tr>
<td>• MMR + varicella: ProQuad</td>
</tr>
<tr>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td>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</td>
</tr>
<tr>
<td><strong>Administration</strong></td>
</tr>
<tr>
<td>Two doses at least 28 days apart (see the CDC Immunization Schedule)</td>
</tr>
<tr>
<td><strong>Revaccination</strong></td>
</tr>
<tr>
<td>Recommended only in the setting of an outbreak (see the CDC Immunization Schedule)</td>
</tr>
<tr>
<td><strong>Comments</strong></td>
</tr>
<tr>
<td>• <strong>Contraindicated</strong> for patients with CD4 counts &lt;200 cells/mm³ (see the CDC Immunization Schedule)</td>
</tr>
<tr>
<td>• MMR + varicella (MMRV) should not be substituted for MMR [Rubin, et al. 2014; McLean, et al. 2013]</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, et al. 2018]</td>
</tr>
<tr>
<td>• Covered by the Vaccine Injury Compensation Program</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 [Abzug, et al. 2012; Aupribul, et al. 2007]. 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, 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 [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]. MMRV has not been adequately studied in individuals with HIV and is not recommended as a substitute for MMR in this population [Rubin, et al. 2014; McLean, et al. 2013].
Meningococcal Serotype Non-B (MenACWY)

Table 14: MenACWY Vaccine

<table>
<thead>
<tr>
<th>Trade Names</th>
<th>Indications</th>
<th>Administration</th>
<th>Revaccination</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>MenACWY: Menactra</td>
<td>All patients with HIV (see the CDC’s Recommended Immunization Schedule for Adults Aged 19 Years or Older, United States 2018)</td>
<td>Administer 2 doses of MenACWY at least 8 weeks apart in those not previously vaccinated (see the CDC Immunization Schedule)</td>
<td>Administer 1 booster dose of MenACWY every 5 years (see the CDC Immunization Schedule)</td>
<td>MenACWY is preferred over MPSV4 in adults with HIV &gt;55 years of age</td>
</tr>
<tr>
<td>MCV4: Menveo</td>
<td></td>
<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>
<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. [Folaranmi, et al. 2017; MacNeil, et al. 2016]. 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, 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 [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. 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>Indications</th>
<th>Administration</th>
<th>Revaccination</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bexsero; Trumenba</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>
<td>Administer according to the CDC Immunization Schedule for patients at risk</td>
<td>None</td>
<td>Not routinely recommended for people with HIV in the absence of other risk factors (see the CDC Immunizations Schedule)</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 2022a].
Monkeypox Vaccination in Adults With HIV

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Writing group: Steven M. Fine, MD, PhD; Rona M. Vail, MD; Joseph P. McGowan, MD, FACP, FIDSA; Samuel T. Merrick, MD; Asa E. Radix, MD, MPH, PhD, FACP, AAHIVS; Christopher J. Hoffmann, MD, MPH; Charles J. Gonzalez, MD
Committee: Medical Care Criteria Committee
Date published: July 29, 2022

☑️ RECOMMENDATIONS

Monkeypox Vaccine

- Clinicians should recommend vaccination against monkeypox for individuals ≥18 years old with HIV who are at high risk of or who have been exposed to monkeypox 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) monkeypox 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 count and degree of viral suppression. (A3)

Table: Monkeypox Vaccine [a]

<table>
<thead>
<tr>
<th>Trade name</th>
<th>Prevnar 13 (PCV130); Pneumovax 23 (PPSV23)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of vaccine</td>
<td>Live virus that does not replicate efficiently in human cells</td>
</tr>
<tr>
<td>Administration</td>
<td>Two subcutaneous injections 4 weeks apart</td>
</tr>
<tr>
<td>Indication</td>
<td>Approved by FDA for prevention of smallpox or monkeypox in people ≥18 years old</td>
</tr>
<tr>
<td>Adverse reactions</td>
<td>Injection site reactions such as pain, swelling, and redness. Vaccination with JYNNEOS will not cause monkeypox infection</td>
</tr>
<tr>
<td>Contraindications</td>
<td>Severe allergy to any component of the vaccine (gentamicin, ciprofloxacin, or egg protein)</td>
</tr>
<tr>
<td>Immune response</td>
<td>Maximal development of the immune response takes 2 weeks after second dose</td>
</tr>
<tr>
<td>Breastfeeding/pregnancy</td>
<td>No evidence of reproductive harm from animal data. Pregnancy and breastfeeding are not contraindications for vaccination</td>
</tr>
</tbody>
</table>

Note: a. See the U.S. Food and Drug Administration (FDA) package insert and Centers for Disease Control and Prevention Considerations for Monkeypox Vaccination for more information

Immunization: The Centers for Disease Control and Prevention (CDC) considers people with HIV to be at risk for severe monkeypox disease and recommends prioritization of those at risk for receipt of the JYNNEOS monkeypox vaccine [CDC 2022b]. Vaccination is used to prevent monkeypox 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 monkeypox disease. See CDC: Considerations for Monkeypox Vaccination.

Two vaccines against monkeypox 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 monkeypox 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/mm³. 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 monkeypox vaccine be given within 4 days of exposure to prevent disease. If given 4 to 14 after exposure, vaccination may not prevent disease but may reduce symptoms [CDC 2022b]. Peak immunogenicity is achieved 2 weeks after the second JYNNEOS dose [Rao, et al. 2022].

### → KEY POINTS
- JYNNEOS (Imvamune or Imvanex) is the only monkeypox 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 monkeypox disease can vary from a few scattered papules and mild constitutional symptoms to severe illness. Symptoms of monkeypox 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 monkeypox 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.

**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 monkeypox. The virus that causes monkeypox is transmitted via the following:

### RESOURCES

**NYSDOH:**
- What to Know
- Vaccine Information
- Provider Information
- Events and Videos
- CEI: What You Need to Know About the Orthopox Virus
- County Health Departments: Links and phone numbers

**NYC Health:**
- Monkeypox: Information for Providers
- Testing
- Vaccination Appointments
- JYNNEOS Vaccine for Monkeypox: Frequently Asked Questions

**CDC:**
- 2022 U.S. Monkeypox Outbreak
- CDC Dear Colleague Letter: Pain Associated With Monkeypox Anogenital Lesions (7/28/22)
- About Monkeypox
- Prevention
- Signs and Symptoms
- Treatment
- Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat) for Treatment of Monkeypox
- Communication Resources

### 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 2022a; 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 2022a; 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 2019].

**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 previous PCV13/PPSV23* or unknown status *by clinical documentation or patient self-report</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 dose of PCV13, then</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st dose of PPSV23 ≥8 weeks later, then</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2nd dose of PPSV23 ≥5 years after 1st dose of PPSV23, then</td>
<td></td>
<td></td>
</tr>
<tr>
<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>
<td></td>
<td></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 |  

| 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 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>

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

Table 18: Tdap and Td Vaccines

| Trade Names | Tdap: Adacel; Boostrix  
|             | Td: Tenivac; Decavac (generic 9Td) |
| Indications | 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 |
| Administration | Administer according to the CDC Immunization Schedule for all adults |
| 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 the Vaccine Injury Compensation Program |

Discussion: The recommendations for Tdap and Td vaccination of adults with HIV are the same as for all adults [CDC 2022a]. The safety and efficacy of vaccination with Tdap has not been studied in this population [Rubin, et al. 2014].
Varicella

Table 19: Varicella Vaccine

<table>
<thead>
<tr>
<th>Trade Names</th>
<th>Trade Names</th>
</tr>
</thead>
<tbody>
<tr>
<td>Varicella: Varivax</td>
<td>Measles, mumps, and rubella (MMR) + varicella (MMRV): ProQuad</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Indications</th>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>For patients with CD4 counts $\geq 200$ cells/mm$^3$ who do not have evidence of immunity to varicella, as determined by the CDC’s <em>Recommended Immunization Schedule for Adults Aged 19 Years or Older, United States 2018</em></td>
<td></td>
</tr>
<tr>
<td>HIV-infected children $\geq 12$ months old with CD4+ T-lymphocyte percentages $\geq 15%$</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Administration</th>
<th>Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administer according to the <em>CDC Immunization Schedule</em> for all adults</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Revaccination</th>
<th>Revaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Comments</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Contraindicated</em> for patients with CD4 counts $&lt; 200$ cells/mm$^3$ (see the <em>CDC Immunization Schedule</em>)</td>
<td></td>
</tr>
<tr>
<td>Anti-varicella IgG screening should be performed in patients with no known history of chickenpox or shingles [Marin, et al. 2007]</td>
<td></td>
</tr>
<tr>
<td>MMRV should not be used [Rubin, et al. 2014]</td>
<td></td>
</tr>
<tr>
<td>Antitherpetic agents should be avoided at least 24 hours before and 14 days after administration [Ezeanolue, et al. 2019]</td>
<td></td>
</tr>
<tr>
<td>An interval of at least 3 months is recommended between administration of post-exposure varicella IgG (VariZIG) and varicella vaccination [Cohn, et al. 2013]</td>
<td></td>
</tr>
<tr>
<td>Clinical disease due to varicella after vaccination, a very rare event, should be treated with acyclovir [AIDSinfo 2019]</td>
<td></td>
</tr>
<tr>
<td>Covered by the <em>Vaccine Injury Compensation Program</em></td>
<td></td>
</tr>
</tbody>
</table>

**Discussion:** Patients with HIV who have CD4 counts $\geq 200$ 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 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 2022a; 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].

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, 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 [AIDSinfo 2019; Marin, et al. 2007]. 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 [Ezeanolue, et al. 2019; Rubin, et al. 2014; Marin, et al. 2007]. Because they can interfere with vaccine virus replication and decrease vaccine effectiveness, all antitherpetic 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

<table>
<thead>
<tr>
<th>Trade Names</th>
<th>Trade Names</th>
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</thead>
<tbody>
<tr>
<td>Shingrix: Recombinant zoster vaccine (RZV), adjuvanted—PREFERRED</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Indications</th>
<th>Indications</th>
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<tbody>
<tr>
<td><em>Medical Care Criteria Committee</em> recommendation: Patients with HIV $\geq 18$ years old (A2); updated December 2021 per Advisory Committee on Immunization Practices (ACIP) approval</td>
<td></td>
</tr>
</tbody>
</table>
Table 20: Zoster Vaccine

<table>
<thead>
<tr>
<th>Administration</th>
<th>Comments</th>
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</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 contraindicated in patients with CD4 count &lt;200 cells/mm³ (see Centers for Disease Control and Prevention [CDC] guidelines). 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 antiherpetic agents for 1 to 2 days before vaccination through 14 days after [Marin, et al. 2007]</td>
</tr>
<tr>
<td></td>
<td>– Separate administration of ZVL from administration of pneumococcal vaccine by at least 4 weeks [Merck 2019]</td>
</tr>
</tbody>
</table>

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.

In October 2021, the ACIP approved a recommendation for 2 doses of RZV to prevent herpes zoster in adults >19 years old who are immunosuppressed; the previous recommendation was for vaccination of adults ≥50 years old. On December 1, 2021, the Medical Care Criteria Committee 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, 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. 2018; Shafran 2016]. If ZVL is used due to lack of access to RZV, CDC guidelines recommend that, if possible, antiherpetic 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 2019]. 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>
<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: ≥5 years old  
• Moderna COVID-19 Vaccine: ≥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:** See Table 7 | 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  
• **Revaccination:** Nonresponders to the primary HBV vaccination series (anti-HBs) | 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  
• A 2-dose (1 month apart) recombinant HBV surface antigen vaccine with a novel adjuvant (HEPLISAV-B) is available. There are no data available on use among people with HIV. There were no |
Table 21: Summary of Recommended Vaccines for Adults With HIV

<table>
<thead>
<tr>
<th>Vaccine Trade Name</th>
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<th>Comments</th>
</tr>
</thead>
</table>
| **Human Papillomavirus (HPV)**      | All patients aged 9 to 45 years who were not previously vaccinated or did not receive a complete 3-dose series | • Administer through age 45 years as a 3-dose series according to CDC guidelines for adults with immunocompromising conditions  
  • **Revaccination:** None                                                       | autoimmune adverse events among people with HIV exposed to the adjuvant  
  • See NYSDOH AI guideline HBV-HIV Coinfection  
  • Covered by the Vaccine Injury Compensation Program*  
  • 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 the 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 the Vaccine Injury Compensation Program*  
  • MenACWY is preferred over MPSV4 in adults with HIV >55 years of age  
  • Covered by the Vaccine Injury Compensation Program* |
| **Influenza**                        | For all patients, as determined by CDC guidelines for all adults            | • 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)** | For patients with CD4 cell counts ≥200 cells/mm³ who do not have evidence of MMR immunity, as determined by CDC guidelines for all adults | • 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  
  • Covered by the Vaccine Injury Compensation Program* |
| **Meningococcal Serotype Non-B (MenACWY)** | • All patients with HIV  
  • See NYSDOH Health Advisories on Meningococcal Disease                      | • Administer 2 doses of MenACWY at least 8 weeks apart in those not previously vaccinated  
  • For those previously vaccinated with 1 dose of MenACWY, administer the 2nd dose at the earliest | MenACWY is preferred over MPSV4 in adults with HIV >55 years of age  
  • Covered by the Vaccine Injury Compensation Program* |
<table>
<thead>
<tr>
<th>Vaccine Trade Name</th>
<th>Indications</th>
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<th>Comments</th>
</tr>
</thead>
</table>
| Meningococcal Serotype B (MenB) | Patients at risk of MenB infection, as determined by CDC guidelines | • Administer according to CDC guidelines for patients at risk  
• Revaccination: None | • Not routinely recommended for people with HIV in the absence of other risk factors  
• Covered by the Vaccine Injury Compensation Program* |
| Pneumococcal | All patients with HIV | • 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 Table 17 for detailed administration guidelines based on age and previous vaccination history | The PCV13 vaccine should not be deferred for patients with CD4 count <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 >200 cells/mm³ and/or viral load is undetectable |
| Tetanus, Diphtheria, and Pertussis (Td) and Tetanus-Diphtheria (Td) | For all patients, as determined by CDC guidelines for all adults | • Administer according to CDC guidelines for all adults  
• 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 | Covered by the Vaccine Injury Compensation Program* |
| Varicella | • 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  
• HIV-infected children ≥12 months old with CD4+ T-lymphocyte percentages ≥15% | • Administer according to CDC guidelines for all adults  
• Revaccination: None | • Contraindicated for patients with CD4 counts <200 cells/mm³  
• Anti-varicella IgG screening should be performed in patients with no known history of chickenpox or shingles  
• MMRV should not be used  
• Antitherpetic agents should be avoided at least 24 hours before and 14 days after administration  
• An interval of at least 3 months is recommended between administration of post-exposure varicella IgG (VariZIG) and varicella vaccination  
• Clinical disease due to varicella after vaccination, a very rare event, should be treated with acyclovir  
• Covered by the Vaccine Injury Compensation Program* |
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>
| Zoster             | • RZV: Shingrix—PREFERRED  
• For information on ZVL (brand name Zostavax), see Table 20  
• MCCC recommendation: Patients ≥18 years old with HIV (A2)  
• Updated 12/2021  
• Two IM doses, spaced 2 to 6 months apart, regardless of past receipt of ZVL  
• See CDC information on administering Shingrix  
• Perform anti-varicella IgG screening in patients with no known history of chickenpox or shingles  
• Revaccination: None  
• RZV is preferred over ZVL (A2)  
• 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  
• 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. | |

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

References


CDC. Adult immunization schedule. 2022a https://www.cdc.gov/vaccines/schedules/hcp/adult.html [accessed 2022 Jul 27]


