# An Overview on Vaccinations for Adult Patients With Inflammatory Bowel Disease



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## **Vaccines and Considerations for Vaccinations**



### Patients With IBD and Vaccine-Preventable Infections

### Patients With IBD Have an Increased Risk of Infections

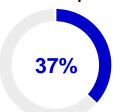
- Patients with IBD are often treated with long-term immunosuppressive therapies, which may increase their risk of infection<sup>1</sup>
- These infections include vaccine-preventable infections, such as pneumonia and herpes zoster, both of which occur more frequently in the IBD population than in the general population<sup>2,3</sup>

### Yet Patients With IBD May Not Receive Adequate Preventative Treatment

- Many patients with IBD do not receive routine preventative care,<sup>1,4</sup> resulting in low vaccination rates for many IBD patients<sup>5,6</sup>
- Gastroenterologists may often be the only clinicians that a patient with IBD will see<sup>1</sup>



% of gastroenterologists reported that providing vaccinations is the responsibility of primary care physicians<sup>5</sup>



% of family medicine practitioners reported being comfortable providing primary care to patients with IBD<sup>5,7,a</sup>



## Vaccination in Adult Patients With Altered Immunocompetence Based on CDC Guidelines

- All indicated vaccines should be administered before the initiation of immunosuppressive therapies
- Persons with most forms of altered immunocompetence should not receive live vaccines (MMR, varicella, MMRV, LAIV, yellow fever, Ty21a oral typhoid, BCG, smallpox, and rotavirus)
  - Administration of live vaccines may need to be withheld after treatment with certain immunosuppressive therapies
- All inactivated vaccines can be administered safely to persons with altered immunocompetence
  - The effectiveness of such vaccinations might be suboptimal in some immunocompromised patients
- Persons with altered immunocompetence generally are recommended to receive polysaccharide-based vaccines<sup>a</sup>
  - Pneumococcal vaccines (PCV13 and PPSV23)
  - Meningococcal vaccines (MenACWY, Hib-MenCY, and MPSV4)<sup>b</sup>
  - Hib vaccines

#### Please see the Prescribing Information for any vaccine before use.



<sup>a</sup>Recommendations may be outside of routine-age-based recommendation, as altered immunocompetence may increase the risk of vaccine-preventable disease. <sup>b</sup>Applies to specific categories of immunocompetence as defined within the respective sections of "Altered Immunocompetence as an Indication to Receive a Vaccine Outside of Routinely Recommended Age Groups."

BCG=bacillus Calmette—Guerin; CDC=Centers for Disease Control and Prevention; Hib=*Haemophilus influenzae* type b; Hib-MenCY=bivalent meningococcal conjugate and *Haemophilus influenzae* type b conjugate; LAIV=live attenuated influenza vaccine; MenACWY=meningococcal ACWY; MPSV4=meningococcal (quadrivalent) polysaccharide; MMR=measles, mumps, and rubella; MMRV=measles, mumps, rubella, and varicella; PCV13=13-valent pneumococcal conjugate vaccine; PPSV23=23-valent pneumococcal polysaccharide vaccine; Ty21a=typhoid vaccine live oral.

Kroger A, et al. https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf. Accessed November 19, 2021.

### Potential Strategies to Increase Vaccine Uptake in IBD Patients

- Education on the importance of vaccination for both gastroenterologists and patients<sup>1-3</sup>
- Incorporation of vaccination reminders and order panels into electronic medical records<sup>3,4</sup>
- Use of readily available health maintenance checklists<sup>4-7</sup>
- Gastroenterologists could offer vaccinations in their own office or refer patients to their primary care
  provider or local pharmacy with explicit vaccination recommendations or prescription<sup>5</sup>
- Gastroenterologists ideally should be proactive in formulating a series of recommendations for vaccinations during the first office visit of a newly diagnosed patient with IBD to increase vaccination rates<sup>5</sup>
- Immunization recommendations for most patients with IBD do not deviate from recommended schedules for the general population<sup>8</sup>



## **Available Resources for Vaccination Recommendations for Patients With IBD**

### **Centers for Disease Control and Prevention (CDC)**

Resource for Recommended Adult Immunization Schedules<sup>1</sup>

### **Advisory Committee on Immunization Practices (ACIP)**

 Sub-committee of CDC that creates vaccine recommendations and guidelines; meets 3 times a year to provide recommendations to CDC<sup>2</sup>

### **American College of Gastroenterology (ACG)**

- ACG Clinical Guideline: Preventive Care in Inflammatory Bowel Disease<sup>3</sup>
  - Resource of recommended vaccinations for patients with IBD; latest update is from 2017

### **Infectious Diseases Society of America (IDSA)**

- IDSA clinical practice guideline that includes vaccination guidance for immunocompromised patients<sup>4</sup>
  - Latest update is from 2014; currently in use by CDC

### International Organization for the Study of Inflammatory Bowel Diseases (IOIBD)

Global organization of clinician-researchers who meet annually and are dedicated to education and research in the field of IBD<sup>5</sup>



### **Vaccine Classification and Descriptions**<sup>1,2</sup>

### Live Attenuated<sup>1,2</sup>

- Contains weakened form of the live virus/bacterium
- Must replicate to produce an immune response
- Can pose risk to immunosuppressed recipients
- Must be stored and handled carefully

#### Examples:

- FluMist® Quadrivalent (influenza)
- M-M-R<sup>®</sup> II (MMR)
- ProQuad® (MMRV)

### Inactivated<sup>1,2</sup>

- Inactivated form of virus that cannot replicate and is not infectious to host or others
- Often requires multiple doses to obtain immunity

### Messenger RNA (mRNA)<sup>2</sup>

- Lipid-encapsulated mRNA encoding for noninfectious part of virus<sup>3,4</sup>
- Expression of the viral protein leads to adaptive and innate immune responses<sup>5</sup>
- Booster shots may be required for ongoing protection<sup>6</sup>

## Recombinant/ Polysaccharide/Conjugate<sup>2</sup>

- Consists of a specific piece of virus or bacterium (eg, its protein, sugar, or capsid) used to generate immune response
- Can be used in persons with weakened immune systems and chronic health problems
- Booster shots may be required for ongoing protection

## Other Vaccine Types<sup>2</sup>

Toxoid vaccines

 Immune response targets toxin produced

Viral vector vaccines

 Modified version of another virus is used to deliver protection

#### Examples:

- Vaqta® (HAV)
- Afluria<sup>®</sup> Quadrivalent (influenza)

#### Example:

Comirnaty® (COVID-19)

#### Examples:

- Recombinant: Recombivax® (HBV), Shingrix™ (HZ)
- Polysaccharide: Pneumovax<sup>®</sup> 23 (pneumococcal)
- Conjugate: Vaxneuvance™ (PCV15, pneumococcal), Prevnar 20™ (PCV20, pneumococcal)

#### Example:

 Toxoid: Diphtheria and Tetanus Toxoids Adsorbed

#### Please see the Prescribing Information for any vaccine before use.

COVID-19=coronavirus disease 2019; HAV=hepatitis A virus; HBV=hepatitis B virus; HZ=herpes zoster; MMR=measles, mumps, and rubella; MMRV=measles, mumps, rubella, and varicella; PCV15=15-valent pneumococcal conjugate vaccine; PCV20=20-valent pneumococcal conjugate vaccine.

1. Centers for Disease Control and Prevention. https://www.cdc.gov/vaccines/pubs/pinkbook/prinvac.html. Accessed November 11, 2021. 2. US Department of Health and Human Services. https://www.vaccines.gov/basics/types. Accessed November 11, 2021. 3. Chaudhary N, et al. *Nat Rev Drug Discov*. 2021;20(880):817-838. 4. Pardi N, et al. *Nat Rev Drug Discov*. 2018;17(4):261-279. 5. Arunachalam PS, et al. *Nature*. 2021;596(7872):410-416. 6. Mbaeyi S, et al. *MMWR Morb Mortal Wkly Rep*. 2021;70(44):1545-1552.

### Levels of Immunosuppression in Patients With IBD

### Low-Level<sup>1,2</sup>

- Daily dose of systemic corticosteroids for ≥14 days (equivalent of 20 mg/day prednisone and within 3 months of stopping) or receiving alternate-day corticosteroid therapy
- MTX ≤0.4 mg/kg/week and within 3 months of stopping
- AZA ≤3.0 mg/kg/day, or 6-MP ≤1.5 mg/kg/day and within 3 months of stopping

### High-Level<sup>1-3</sup>

- Treatment with systemic corticosteroids (equivalent of >20 mg/day prednisone for ≥2 weeks and within 3 months of stopping)<sup>1,2</sup>
- Treatment with effective doses of MTX or within 3 months of stopping<sup>1,2</sup>
- Treatment with effective doses of AZA or 6-MP or within 3 months of stopping<sup>1,2</sup>
- Treatment with certain biologics or recent discontinuation within 3 months
- Treatment with Janus kinase inhibitor<sup>3</sup>

Please see the Prescribing Information for any vaccine and immunosuppressive therapy before use.



### Ability to Mount Vaccine Response in Patients With IBD

- Patients with IBD generally can mount an appropriate immune response to vaccines<sup>1-7</sup>
- However, patients with IBD on immunosuppressive therapy may have a diminished immune response to vaccinations<sup>1-7</sup>
- The level of immune response may correlate with the degree of immunosuppression
  - Combination therapy with a biologic agent and an immunomodulator may further diminish immune response to vaccines<sup>1-3,7</sup>

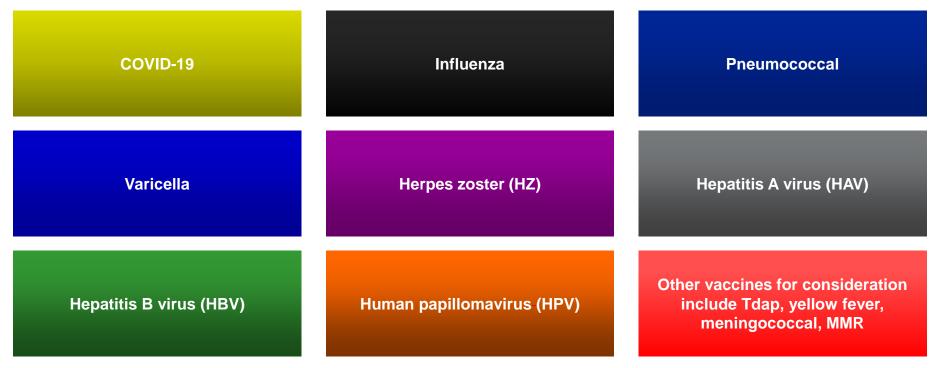


# Suggested Vaccinations for Patients With IBD and Specific Considerations for the Gastroenterologist



## Suggested Vaccines for Adult Patients With IBD According to ACG, ACIP, and IDSA Guidelines<sup>1-4</sup>





Click on a box to access corresponding vaccine guidance in presentation mode

#### Please see the Prescribing Information for any vaccine before use.

ACG=American College of Gastroenterology; ACIP=Advisory Committee on Immunization Practices; COVID-19=coronavirus disease 2019; IBD=inflammatory bowel disease; IDSA=Infectious Diseases Society of America; MMR=measles, mumps, and rubella; Tdap=tetanus, diphtheria, and pertussis.

1. Crohn's & Colitis Foundation. https://www.crohnscolitisfoundation.org/sites/default/files/legacy/science-and-professionals/programs-materials/health-maintenance-checklist.pdf. Accessed November 19, 2021. 2. Cornerstones Health. https://www.cornerstoneshealth.org/wp-content/uploads/2020/08/NEW-IBD-Checklist-for-Monitoring-Prevention-526a.pdf. Accessed November 19, 2021. 3. Farraye FA, et al. *Am J Gastroenterol*. 2017;112(2):241-258. 4. Centers for Disease Control and Prevention. https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf. Accessed November 22, 2021.



## **Guideline Recommendations for Administration of COVID-19 Vaccine**



IOIBD recommendations <sup>1</sup>		<ul> <li>Patients with IBD to be immunized with COVID-19 vaccine at the earliest opportunity</li> <li>COVID-19 vaccination should not be deferred because a patient with IBD is receiving immune-modifying therapies</li> <li>Vaccinated patients with IBD should be counselled that vaccine efficacy may be decreased if receiving systemic corticosteroids</li> </ul>	
	Recommendations <sup>2,3</sup>	<ul> <li>COVID-19 vaccination is recommended; age of vaccination is dependent on vaccine</li> <li>Moderately to severely immunocompromised persons can receive FDA-authorized or approved COVID-19 vaccine (dependent on vaccine)</li> <li>Additional immunizations may be required</li> </ul>	
CDC & ACIP	Contraindications <sup>3</sup>	History of severe or immediate <sup>a</sup> allergic reaction to the vaccine or any of its components	
	Most common adverse reactions <sup>4</sup>	<ul> <li>Injection-site pain, redness, swelling</li> <li>Fever, chills, muscle pain, headache, nausea, tiredness</li> </ul>	
	Vaccine administration <sup>2</sup>	Administer IM only	

#### Please see the Prescribing Information for any vaccine before use.

<sup>a</sup>Within 4 hours of exposure.

ACIP=Advisory Committee on Immunization Practices; CDC=Centers for Disease Control and Prevention; COVID-19=coronavirus disease 2019; IBD=inflammatory bowel disease; IM=intramuscular; IOIBD=International Organization for the Study of Inflammatory Bowel Diseases.

**1.** Siegel CA, et al. *Gut.* 2021;70(4):635-640. **2.** Mbaeyi S, et al. *MMWR Morb Mortal Wkly Rep.* 2021;70(44):1545-1552. **3.** Centers for Disease Control and Prevention. https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf. Accessed November 22, 2021. **4.** Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/downloads/vaccines/324160-A-COVID-19\_VaccinationPoster\_WhatToExpect\_LTR-6.24.pdf. Accessed November 12, 2021.



## **Guideline Recommendations for Administration of Influenza Vaccine**



ACG recommendations <sup>1</sup>		<ul> <li>All adult patients with IBD should undergo annual vaccination against influenza</li> <li>Those on immunosuppressive therapies and their household contacts should receive a nonlive quadrivalent influenza vaccine but not the LAIV</li> </ul>	
ACIP recommendations <sup>2</sup>		<ul> <li>All persons aged ≥6 months who do not have any contraindications</li> <li>Approved dose volumes vary by age and product.</li> </ul>	
	Recommendations <sup>3</sup>	Recommended for prevention of influenza disease caused by influenza A and type B viruses	
CDC	Contraindications <sup>2</sup>	<ul> <li>History of severe allergic reaction to the vaccine or any vaccine component</li> <li>LAIV contraindicated for any immunosuppressed patient, pregnancy, children aged 2-4 years diagnosed with asthma,<sup>a</sup> concomitant aspirin/salicylate-containing therapy in children and adolescents, receipt of influenza medication within previous 48 hours, and close contacts and caregivers of severely immunosuppressed persons we require a protected environment</li> </ul>	
	Most common AEs <sup>4</sup>	<ul> <li>IIV (cell culture or egg based) – injection-site reactions</li> <li>RIV – injection-site pain, headache, fatigue, and muscle pain</li> <li>LAIV – runny nose or nasal congestion (all ages); fever &gt;100°F (children 2-6 years) and sore throat (adults)</li> </ul>	
	Vaccine administration <sup>2</sup>	IIV and RIV are administered intramuscularly     LAIV is administered intranasally	

Expert guidance<sup>b</sup> suggests 1 dose seasonally of high-dose inactivated influenza vaccine in all adults with IBD 65 years or older or those 18-64 years of age treated with anti-TNF monotherapy<sup>5</sup>

#### Please see the Prescribing Information for any vaccine before use.

<sup>a</sup>Or children whose parents or caregivers report that a health care provider has told them during the preceding 12 months that their child had wheezing or asthma or whose medical record indicates that a wheezing episode has occurred during the preceding 12 months. <sup>2</sup> bBased on a 2020 expert opinion article published by the ACG in the Red Section of the *American Journal of Gastroenterology*. <sup>5</sup> ACG=American College of Gastroenterology; ACIP=Advisory Committee on Immunization Practices; AE=adverse event; CDC=Centers for Disease Control and Prevention; IBD=inflammatory bowel disease; IIV=inactivated influenza vaccine; LAIV=live attenuated influenza vaccine; RIV=recombinant influenza vaccine; TNF=tumor necrosis factor.



1. Farraye FA, et al. *Am J Gastroenterol*. 2017;112(2):241-258. **2.** Centers for Disease Control and Prevention. https://www.cdc.gov/flu/pdf/professionals/acip/acip-2020-21-summary-of-recommendations.pdf. Accessed November 11, 2021. **3.** Centers for Disease Control and Prevention. https://www.cdc.gov/flu/prevent/quadrivalent.htm. Accessed November 11, 2021. **4.** Centers for Disease Control and Prevention. https://www.cdc.gov/flu/professionals/vaccination/vaccine\_safety.htm. Accessed November 19, 2021. **5.** Caldera F, et al. *Am J Gastroenterol*. 2020;115(9):1356-1361.

# Guideline Recommendations for Administration of Pheumococcal 23-Valent Polysaccharide Vaccine (PPSV23)



ACG recommendations <sup>1</sup>		Adult patients with IBD receiving immunosuppressive therapy in accordance with national guidelines	
ACIP recommendations <sup>2</sup>		<ul> <li>Routinely recommended in all immunocompetent adults aged ≥65 years</li> <li>Recommended in adults aged ≥19 years with underlying medical conditions that put them at greater risk for serious pneumococcal infection, including immunocompetent persons with chronic heart disease, chronic lung disease, diabetes, alcoholism, or chronic liver disease/cirrhosis and cigarette smokers</li> </ul>	
		<ul> <li>In adults aged ≥19 years with an immunocompromising condition, cerebrospinal fluid leak, or cochlear implant, sequential administration of PCV13 and PPSV23 is recommended</li> </ul>	
IDSA recommendations <sup>3</sup>		• Patients aged ≥2 years with planned initiation of immunosuppression	
	Recommendations <sup>4</sup>	• Recommended for all adults aged ≥65 years, persons aged ≥2 through 64 years with certain medical conditions, and adults ≥19 through 64 years who smoke cigarettes	
	Contraindications <sup>5</sup>	History of severe allergic reaction to the vaccine or any of its components	
CDC	Most common adverse reactions <sup>5</sup>	Injection-site pain, fever, muscle aches, and erythema	
	Vaccine administration <sup>6</sup>	Administer IM or SC only	

Expert guidance<sup>a</sup> suggests administering both pneumococcal vaccines to all adults at diagnosis of IBD and before starting immunosuppression<sup>7</sup>

#### Please see the Prescribing Information for any vaccine before use.

<sup>a</sup>Based on a 2020 expert opinion article published by the ACG in the Red Section of the American Journal of Gastroenterology.<sup>7</sup>

ACG=American College of Gastroenterology; ACIP=Advisory Committee on Immunization Practices; CDC=Centers for Disease Control and Prevention; IBD=inflammatory bowel disease; IDSA=Infectious Diseases Society of America; IM=intramuscular; PCV13=13-valent pneumococcal conjugate vaccine; PPSV23=23-valent pneumococcal polysaccharide vaccine; SC=subcutaneous.

- 1. Farraye FA, et al. Am J Gastroenterol. 2017;112(2):241-258. 2. Matanock A, et al. MMWR Morb Mortal Wkly Rep. 2019;68(46):1069-1075. 3. Rubin LG, et al. Clin Infect Dis. 2014;58(3):e44-e100.
- 4. Centers for Disease Control and Prevention. https://www.cdc.gov/pneumococcal/vaccination.html. Accessed November 19, 2021. 5. Centers for Disease Control and Prevention. https://www.cdc.gov/pneumococcal/resources/prevent-pneumococcal-factsheet.pdf. Accessed November 22, 2021. 6. Centers for Disease Control and Prevention.



https://www.cdc.gov/pneumococcal/resources/prevent-pneumococcal-factsheet.pdf. Accessed November 22, 2021. **6.** Centers for Disease Control and Prevention. https://www.cdc.gov/vaccines/vpd/pneumo/hcp/administering-vaccine.html#route. Accessed November 19, 2021. **7.** Caldera F, et al. *Am J Gastroenterol*. 2020;115(9):1356-1361.

## Guideline Recommendations for Administration of Pneumococcal 13-Valent Conjugate Vaccine (PCV13)



ACG recommendations <sup>1</sup>		Adult patients with IBD receiving immunosuppressive therapy should receive pneumococcal vaccination with PCV13, in accordance with national guidelines	
ACIP recommendations <sup>2</sup>		<ul> <li>Recommended in immunocompetent adults aged ≥65 years with or without specific chronic medical conditions, based on shared clinical decision-making. PPSV23 is routinely recommended in all immunocompetent adults aged ≥65 years. If the decision to administer PCV13 is made, it should be administered first in series with PPSV23</li> <li>In adults aged ≥19 years with an immunocompromising condition, cerebrospinal fluid leak, or cochlear implant, sequential administration of PCV13 and PPSV23 is recommended</li> </ul>	
IDSA re	commendations <sup>3</sup>	<ul> <li>PCV13 should be administered to adults aged ≥19 years with IBD treated with immunosuppression</li> </ul>	
Contraindications <sup>4</sup>		<ul> <li>History of severe allergic reaction to pneumococcal conjugate vaccines or to any of their components or to any diphtheria-containing vaccine</li> </ul>	
CDC	Most common adverse reactions <sup>4</sup>	<ul> <li>Injection-site erythema, swelling, pain, or tenderness; fever, loss of appetite, irritability, fatigue, headache, chills</li> </ul>	
	Vaccine administration <sup>5</sup>	Administer IM only	

Expert guidance<sup>a</sup> suggests administering both pneumococcal vaccines to all adults at diagnosis of IBD and before starting immunosuppression<sup>6</sup>

#### Please see the Prescribing Information for any vaccine before use.

<sup>a</sup>Based on a 2020 expert opinion article published by the ACG in the Red Section of the American Journal of Gastroenterology.<sup>6</sup>

ACG=American College of Gastroenterology; ACIP=Advisory Committee on Immunization Practices; CDC=Centers for Disease Control and Prevention; IBD=inflammatory bowel disease; IDSA=Infectious Diseases Society of America; IM=intramuscular; PCV13=13-valent pneumococcal conjugate vaccine; PPSV23=23-valent pneumococcal polysaccharide vaccine.

- **1.** Farraye FA, et al. *Am J Gastroenterol.* 2017;112(2):241-258. **2**. Matanock A, et al. *MMWR Morb Mortal Wkly Rep.* 2019;68(46):1069-1075. **3**. Rubin LG, et al. *Clin Infect Dis.* 2014;58(3):e44-e100.
- **4.** Centers for Disease Control and Prevention. https://www.cdc.gov/pneumococcal/resources/prevent-pneumococcal-factsheet.pdf. Accessed November 22, 2021. **5.** Centers for Disease Control and Prevention. https://www.cdc.gov/vaccines/vpd/pneumo/hcp/administering-vaccine.html#route. Accessed November 19, 2021. **6.** Caldera F, et al. *Am J Gastroenterol.* 2020;115(9):1356-1361.



# ACIP Recommendations for Pneumococcal Vaccination for Adults Aged ≥19 Years With Immunocompromising Conditions



## Pneumococcal vaccination is recommended for patients with the following immunocompromising conditions:

- Congenital or acquired immunodeficiency<sup>a</sup>
- Chronic renal failure
- Nephrotic syndrome
- Leukemia
- Lymphoma
- Sickle cell disease/other hemoglobinopathy
- Hodgkin disease
- Generalized malignancy

- Solid organ transplant
- Multiple myeloma
- Congenital or acquired asplenia
- HIV infection
- latrogenic immunosuppression
  - Diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids and radiation therapy



## **Guideline Recommendations for Administration of Varicella Vaccine**



ACG recommendations <sup>1</sup>		<ul> <li>Adults with IBD should be assessed for prior exposure to varicella and vaccinated if naïve before initiation of immunosuppressive therapy when possible</li> </ul>	
ACIP recommendations <sup>2,3</sup>		<ul> <li>Is recommended for persons aged ≥12 months and &lt;13 years and for persons aged ≥13 years who have never had chickenpox or never received the chickenpox vaccine</li> </ul>	
IDSA recommendations <sup>4</sup>		<ul> <li>VAR vaccine should be administered to patients with IBD without evidence of varicella immunity ≥4 weeks prior to initiation of immunosuppression if treatment initiation can be safely delayed</li> <li>VAR vaccine should be considered for patients without evidence of varicella immunity being treated for chronic inflammatory diseases with long-term, low-level immunosuppression</li> </ul>	
CDC/WHO	Contraindications <sup>2,3</sup>	<ul> <li>History of severe allergic reaction to any component of the vaccine (including neomycin and gelatin) or previous dose of VAR vaccine</li> <li>Primary or acquired immunodeficiency states</li> <li>Any febrile illness or active infection</li> <li>Pregnancy</li> </ul>	
	Most common adverse reactions <sup>5</sup>	Fever, injection-site reactions, injection-site rash, and varicella-like rash	
	Vaccine administration <sup>5,6</sup>	<ul> <li>Suspension for injection (approximately 0.5-mL dose) supplied as a lyophilized vaccine to be reconstituted.</li> <li>Adolescents ≥13 years and adults: Administered by SC injection in 2 doses, 4 to 8 weeks apart.</li> </ul>	

#### Please see the Prescribing Information for any vaccine before use.

ACG=American College of Gastroenterology; ACIP=Advisory Committee on Immunization Practices; CDC=Centers for Disease Control and Prevention; IBD=inflammatory bowel disease; IDSA=Infectious Diseases Society of America; VAR=varicella; SC=subcutaneous; WHO=World Health Organization.

1. Farraye FA, et al. *Am J Gastroenterol*. 2017;112(2):241-258. 2. Freedman M, et al. *Ann Intern Med*. 2020;172:337-347. 3. Centers for Disease Control and Prevention. https://www.cdc.gov/vaccines/vpd/varicella/public/index.html. Accessed November 22, 2021. 4. Rubin LG, et al. *Clin Infect Dis*. 2014;58(3):e44-e100. 5. World Health Organization. https://www.who.int/vaccine\_safety/initiative/tools/Varicella\_Zoster\_Vaccine\_rates\_information\_sheet.pdf. Accessed November 22, 2021. 6. Centers for Disease Control and Prevention. https://www.cdc.gov/vaccines/vpd/varicella/hcp/about-vaccine.html. Accessed November 22, 2021.



## Guideline Recommendations for Administration of Recombinant Zoster Vaccine (RZV)



ACG recommendations <sup>1</sup>		<ul> <li>Adults aged &gt;50 years with IBD should consider vaccinating against HZ, including certain subgroups of immunosuppressed patients</li> </ul>	
ACIP recommendations <sup>2,3,4</sup>		<ul> <li>Is recommended for use in healthy persons aged ≥50 years or those with chronic medical conditions, those taking low-dose immunosuppressive therapy, those anticipating immunosuppression, or those who have recovered from an immunocompromising illness<sup>a,b</sup></li> <li>Recommended for adults aged ≥19 years who are or will be immunodeficient or immunosuppressed due to disease or therapy<sup>c</sup></li> <li>Patients who have received ZVL should receive RZV ≥2 months after administration of ZVL</li> <li>Consider delaying administration until after pregnancy, if RZV is otherwise indicated</li> </ul>	
	Contraindications <sup>3</sup>	History of a severe allergic reaction (eg, anaphylaxis) to any component of the vaccine	
	Most common adverse reactions <sup>3</sup>	<ul> <li>Local adverse reactions: pain, redness, and swelling</li> <li>General adverse events: myalgia, fatigue, headache, shivering, fever, and GI symptoms</li> </ul>	
CDC	Vaccine administration <sup>3</sup>	<ul> <li>0.5-mL of the reconstituted vaccine administered intramuscularly at month 0 for the first dose followed by a second dose administered anytime between 2 and 6 months later</li> <li>May be used irrespective of prior receipt of varicella vaccine or RZV and does not require screening for a history of chickenpox</li> <li>In patients with an acute episode of HZ, delay administration until recovery from acute illness stage</li> </ul>	

Expert guidance<sup>d</sup> suggests consider vaccination in adults with IBD aged 40-49 years with risk factors<sup>5,e</sup>

#### Please see the Prescribing Information for any vaccine before use.

<sup>a</sup>Chronic conditions, eg, diabetes mellitus, chronic renal failure, rheumatoid arthritis and chronic pulmonary disease. <sup>3</sup> bLow-dose immunosuppressive therapies, eg, prednisone <20 mg/d or MTX ≤0.4 mg/kg/week or 6-MP ≤1.5 mg/kg/day and within 3 months of stopping, or AZA ≤3.0 mg/kg/day. Anti-TNFs are considered to be highly immunosuppressive. <sup>1,3</sup> cACIP recommendation approved at meeting on October 20, 2021, and adopted by the CDC director. <sup>d</sup>Based on a 2020 expert opinion article published by the ACG in the Red Section of the *American Journal of Gastroenterology*. <sup>4</sup> elncreased risk for zoster (i) all patients with history of zoster; (ii) those requiring repeated courses of corticosteroids; (iii) patients on tofacitinib, with risk factors for zoster (such as concurrent steroid use, Asian race, diabetes mellitus, and prior anti-TNF failure); and (iv) those on combination therapy requiring corticosteroids. <sup>4</sup>

ACG=American College of Gastroenterology; ACIP=Advisory Committee on Immunization Practices; AZA=azathioprine; CDC=Centers for Disease Control and Prevention; GI=gastrointestinal; HZ=herpes zoster; IBD=inflammatory bowel disease; 6-MP=6-mercaptopurine; MTX=methotrexate; RZV=recombinant zoster vaccine; TNF=tumor necrosis factor; ZVL=zoster vaccine live.

- 1. Farraye FA, et al. Am J Gastroenterol. 2017;112(2):241-258. 2. Freedman M, et al. Ann Intern Med. 2020;172:337-347. 3. Dooling KL, et al. MMWR Morb Mortal Wkly Rep. 2018;67(3):103-108.
- 4. Centers for Disease Control and Prevention. https://www.cdc.gov/vaccines/acip/recommendations.html. Accessed November 12, 2021. 5. Caldera F, et al. Am J Gastroenterol. 2020;115(9):1356-1361.



## **Guideline Recommendations for Administration of HAV Vaccine**



ACG recommendations <sup>1</sup>		Vaccination against HAV should be administered as per ACIP guidelines	
ACIP recommendations <sup>2,3</sup>		<ul> <li>Unvaccinated adults not at risk but who want protection from HAV and those at risk for HAV (risk factors for HAV include injection or noninjection drug users, men who have sex with men, international travel to endemic areas, persons experiencing homelessness, persons with chronic liver disease, persons with occupational risk for HAV infection), unless contraindicated</li> </ul>	
IDSA recommendations <sup>4</sup>		HAV vaccine should be administered to patients with IBD per the usual schedule	
	Contraindications <sup>5</sup>	<ul> <li>Do not administer HAV vaccine to individuals with a history of immediate and/or severe allergic reactions (eg, anaphylaxis) after a previous dose of any component of HAV vaccine</li> </ul>	
CDC	Most common adverse reactions <sup>5</sup>	Injection-site pain, erythema, fever, rash, or swelling	
	Vaccine administration⁵	Adults: Administered intramuscularly; available as 2-dose or 3-dose series (schedule dependent on vaccine)	

#### Please see the Prescribing Information for any vaccine before use.

ACG=American College of Gastroenterology; ACIP=Advisory Committee on Immunization Practices; CDC=Centers for Disease Control and Prevention; HAV=hepatitis A virus; IBD=inflammatory bowel disease; IDSA=Infectious Diseases Society of America.



1. Farraye FA, et al. Am J Gastroenterol. 2017;112(2):241-258. 2. Freedman M, et al. Ann Intern Med. 2020;172:337-347. 3. Nelson NP, et al. MMWR Recomm Rep. 2020;69(5):1-38. 4. Rubin LG, et al. Clin Infect Dis. 2014;58(3):e44-e100. 5. Centers for Disease Control and Prevention. In: Hamborsky J, et al, eds. Epidemiology and Prevention of Vaccine-Preventable Diseases. 13th ed. Washington, DC: Public Health Foundation; 2015:135-148.

## **Guideline Recommendations for Administration of HBV Vaccine**



ACG recommendations <sup>1</sup>		Vaccination against HBV should be administered as per ACIP guidelines	
ACIP recommendations <sup>2,3</sup>		<ul> <li>Infants at birth and unvaccinated children aged &lt;19 years</li> <li>Unvaccinated adults not at risk but who want protection from HBV and those at risk for HBV infection (HCV infection, chronic liver disease, HIV infection, sexual exposure risk, current or recent injection drug use, percutaneous or mucosal risk for exposure to blood, incarcerated persons, travel in countries with high or intermediate endemic HBV, pregnant women)</li> </ul>	
IDSA recommendations <sup>4</sup>		HBV vaccine should not be withheld because of concerns about exacerbation of IBD	
	Contraindications <sup>5</sup>	<ul> <li>Severe allergic reactions (eg, anaphylaxis) after a previous dose of hepatitis B-containing vaccine or to any vaccine components</li> <li>Hypersensitivity to yeast</li> </ul>	
CDCa	Most common adverse reactions <sup>2</sup>	Nausea/dizziness, fever, headache	
	Vaccine administration <sup>2</sup>	• 2 or 3 doses given IM depending on age  — For adults aged ≥20 years: administer 3 doses (1.0 mL each) at 0-, 1-, and 6-month schedule	

#### Please see the Prescribing Information for any vaccine before use.

<sup>a</sup>Persons needing immunosuppressive therapy—including chemotherapy, immunosuppression related to organ transplantation, and immunosuppression for rheumatologic or gastroenterologic disorders—are recommended to receive serologic testing prior to vaccination.

ACG=American College of Gastroenterology; ACIP=Advisory Committee on Immunization Practices; CDC=Centers for Disease Control and Prevention; HBV=hepatitis B virus; HCV=hepatitis C virus; HIV=human immunodeficiency virus; IBD=inflammatory bowel disease; IDSA=Infectious Diseases Society of America; IM=intramuscular(ly).

1. Farraye FA, et al. *Am J Gastroenterol.* 2017;112(2):241-258. **2.** Schillie S, et al. *MMWR Recomm Rep.* 2018;67(15):455-458. **3.** Freedman M, et al. *Ann Intern Med.* 2020;172:337-347. **4.** Rubin LG, et al. *Clin Infect Dis.* 2014;58(3):e44-e100. **5.** Centers for Disease Control and Prevention. https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.pdf. Accessed November 22, 2021.



## **Guideline Recommendations for Administration of HPV Vaccine**



ACG recommendations <sup>1</sup>		Vaccination against HPV should be administered as per ACIP guidelines	
ACIP recommendations <sup>2,3</sup>		<ul> <li>HPV vaccination recommended for all adults through 26 years of age</li> <li>Catch-up vaccination: inadequately vaccinated individuals through age 26 years<sup>a</sup></li> <li>Recommended to vaccinate after pregnancy but pregnancy test not required before vaccination through 26 years</li> </ul>	
IDSA recommendations <sup>4</sup>		<ul> <li>Individuals aged 11-26 years: administer as usual per recommendations for immunocompetent persons in risk and age categories</li> </ul>	
	Contraindications <sup>5</sup>	<ul> <li>Severe allergic reactions to any component or previous dose of HPV vaccine; hypersensitivity to yeast</li> <li>Pregnancy</li> </ul>	
	Most common adverse reactions <sup>5</sup>	Injection-site pain, erythema, or swelling; fever, headache, fatigue, nausea, muscle or joint pain	
CDC	Vaccine administration <sup>5,6</sup>	<ul> <li>Administered IM:</li> <li>As a 2-dose series for most persons who initiated vaccination at age 9-14 years, except immunocompromised persons</li> <li>As a 3-dose series for persons who initiated vaccination at age 15-45 years and for immunocompromised persons</li> </ul>	

#### Please see the Prescribing Information for any vaccine before use.

<sup>a</sup>Catch-up HPV vaccination is not recommended for all adults aged >26 years. Instead, shared clinical decision-making regarding HPV vaccination is recommended for some adults aged 27 through 45 years who are not adequately vaccinated.

ACG=American College of Gastroenterology; ACIP=Advisory Committee on Immunization Practices; CDC=Centers for Disease Control and Prevention; HPV=human papillomavirus; IDSA=Infectious Diseases Society of America: IM=intramuscular.

- 1. Farraye FA, et al. Am J Gastroenterol. 2017;112(2):241-258. 2. Freedman M, et al. Ann Intern Med. 2020;172:337-347. 3. Meites E, et al. MMWR Morb Mortal Wkly Rep. 2019;68(32):698-702.
- 4. Rubin LG, et al. Clin Infect Dis. 2014;58(3):e44-e100. 5. Centers for Disease Control and Prevention. https://www.cdc.gov/vaccinesafety/vaccines/hpv-vaccine.html. Accessed November 19, 2021.
- 6. Centers for Disease Control and Prevention. https://www.cdc.gov/vaccines/vpd/hpv/hcp/administration.html. Accessed November 19, 2021.



## Guideline Recommendations on Other Vaccinations for Consideration in Patients With IBD



Vaccine	Indications	
Tetanus, diphtheria, pertussis <sup>1,2,a</sup>	Administer per ACIP guidelines	
Yellow fever <sup>3</sup>	Patients with IBD who are immunosuppressed and traveling to areas endemic for yellow fever should consult with a travel medicine or infectious disease specialist before travel <sup>b</sup>	
Meningococcal <sup>3</sup>	Adolescents with IBD should receive meningococcal vaccination in accordance with routine vaccination recommendations	
MMR <sup>3,4,c</sup>	Check titers. If negative, vaccinate with MMR vaccine ≥6 weeks before initiation of immunosuppressive therapy	

For information on travel-related vaccinations, visit http://www.cdc.gov/travel

#### Please see the Prescribing Information for any vaccine before use.

<sup>a</sup>Administered as tetanus toxoid, diphtheria toxoid, and acellular pertussis (Tdap) vaccine. <sup>1</sup> Regions with risk of yellow fever virus transmission include Africa (28 countries) and Central and South America (13 countries). <sup>5</sup> Administered as measles, mumps, rubella (MMR) vaccine. <sup>3,4</sup>

ACIP=Advisory Committee on Immunization Practices; IBD=inflammatory bowel disease; MMR=measles, mumps, and rubella.

1. Centers for Disease Control and Prevention. https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf. Accessed November 09, 2021. 2. Rubin LG, et al. *Clin Infect Dis.* 2014;58(3):e44-e100. 3. Farraye FA, et al. *Am J Gastroenterol.* 2017;112(2):241-258. 4. Reich J, et al. *Gastroenterol Hepatol (N Y).* 2016;12(9):540-546. 5. Gershman MD, Staples JE. http://wwwnc.cdc.gov/travel/yellowbook/2016/infectious-diseases-related-to-travel/yellow-fever#4273. Accessed November 22, 2021.



## Vaccination of Contacts of Persons With Altered Immunocompetence





Household contacts and other close contacts of persons with altered immunocompetence should receive all age- and exposure-appropriate vaccines, with the exception of smallpox vaccine

### **ACIP** Recommendations for Contacts of Persons With Altered Immunocompetence

Recommendation		Specific Considerations
MMR		No specific considerations for MMR
Varicella and Zoster	Administer, when indicated	Avoid direct contact with immunocompromised patients if rash develops after vaccination
Rotavirus		Wash hands after changing the diaper of an infant who received rotavirus vaccine to minimize rotavirus transmission (shedding may occur up to 1 month after the last dose)
Influenza		Do not administer LAIV to contacts if the person with altered immunocompetence is in a protective environment, typically defined as a specialized patient-care area with a positive airflow relative to the corridor, high-efficiency particulate air filtration, and frequent air changes



## Postexposure Vaccination Recommendations for Patients Exposed to Specific Pathogens



	General Recommendations for Patients Without Immunity	Recommendations for Patients Without Immunity and at High Risk of Infection (Immunocompromised Patients)
Varicella <sup>1,2</sup> (chickenpox and herpes zoster)	<ul> <li>Administer the vaccine within 3 to 5 days after exposure</li> <li>Even if it has been more than 5 days, the vaccine should still be offered</li> </ul>	Administer varicella-zoster immune globulin as soon as possible, within 10 days, after exposure
Hepatitis A <sup>3</sup>	<ul> <li>HAV vaccine should be administered to persons aged ≥12 months within 2 weeks of exposure<sup>a</sup></li> <li>In addition to HAV vaccine, IG may be administered<sup>b</sup> to persons aged &gt;40 years, depending on the provider's risk assessment</li> </ul>	<ul> <li>Co-administer the HAV vaccine and IG (0.1 mL/kg)<sup>a,b</sup> within 2 weeks of exposure</li> </ul>
Measles <sup>4,5</sup>	<ul> <li>Administer the MMR vaccine within 72 hours of exposure or IG within 6 days of exposure. Do not administer MMR vaccine and IG simultaneously, because this practice invalidates the vaccine</li> </ul>	Administer intravenous IG after exposure (400 mg/kg)

#### Please see the Prescribing Information for any vaccine before use.

<sup>a</sup>A second dose is not required for postexposure prophylaxis; however, for long-term immunity, the HAV vaccination series should be completed with a second dose at least 6 months after the first dose. <sup>b</sup>Vaccine and IG should be administered simultaneously at different anatomic sites.

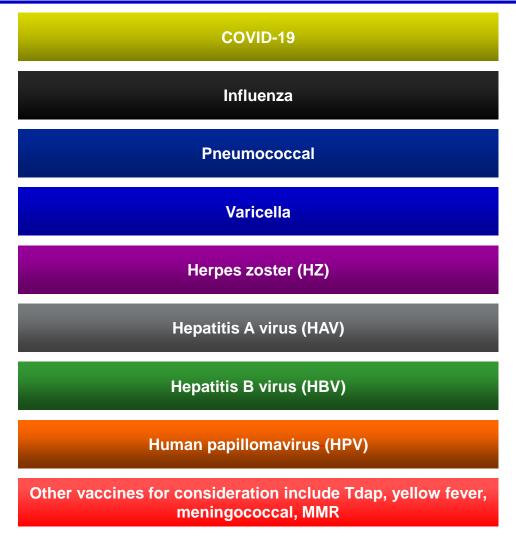
HAV=hepatitis A virus; IG=immunoglobulin; MMR=measles, mumps, and rubella.

<sup>1.</sup> Centers for Disease Control and Prevention. https://www.cdc.gov/vaccines/vpd-vac/varicella/hcp-post-exposure.htm. Accessed November 22, 2021. 2. Centers for Disease Control and Prevention. https://www.cdc.gov/chickenpox/hcp/index.html. Accessed November 22, 2021. 3. Nelson NP, et al. MMWR Morb Mortal Wkly Rep. 2020;69(5):1-38. 4. Centers for Disease Control and Prevention. https://www.cdc.gov/measles/hcp/index.html. Accessed November 22, 2021. 5. McLean HQ, et al. MMWR Recomm Rep. 2013;62(RR-04):1-34.



### **Summary**

- Patients with IBD have a higher risk for developing vaccine-preventable infections
- Immunosuppressive treatments may heighten the risk of infections<sup>1</sup>
- COVID-19, influenza, pneumococcal, varicella, HZ, HAV, HBV, and HPV vaccinations are suggested for infection-related risk reduction in patients with IBD
- Prescribing Information for IBD treatments should be checked to ensure there are no relevant warnings or precautions before administering a vaccine





### **Resources and References**



### **Available Resources**

### **Checklists for Monitoring and Care of Patients With IBD**

- Crohn's & Colitis Foundation (Health Maintenance Checklist for Adult IBD Patients)
- Cornerstones Health (IBD Checklist for Monitoring & Prevention)

### **Society Guidelines**

- American College of Gastroenterology (ACG)
- Infectious Diseases Society of America (IDSA)
- International Organization for the Study of Inflammatory Bowel Diseases (IOIBD)

### **US Department of Health and Human Services**

- Centers for Disease Control and Prevention (CDC)
  - Advisory Committee of Immunization Practices (ACIP)
- Vaccines.gov



IBD=inflammatory bowel disease.

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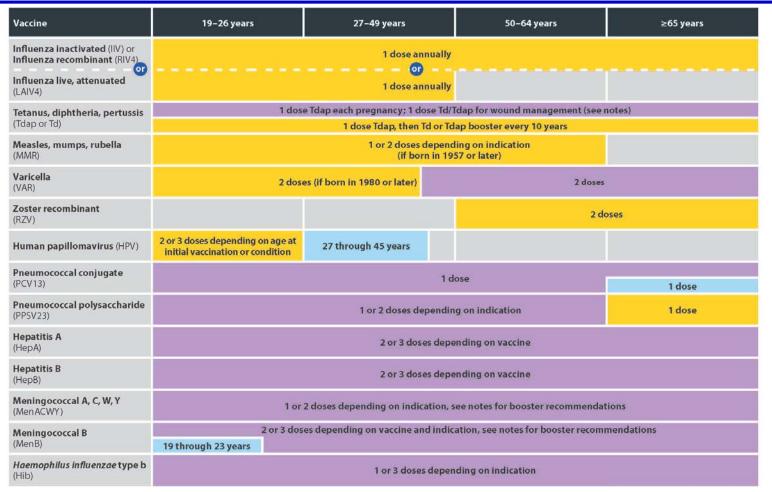
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## **Supplemental Slides**



## ACIP Recommended Immunization Schedule for Adults Aged ≥19 Years by Age Group (United States, 2021)



Centers for Disease Control and Prevention. https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf. Accessed November 9, 2021.

Recommended vaccination for adults who meet age requirement,

Recommended vaccination for adults with an additional risk factor or another indication

Recommended vaccination based on shared clinical decision-making

No recommendation/ Not applicable

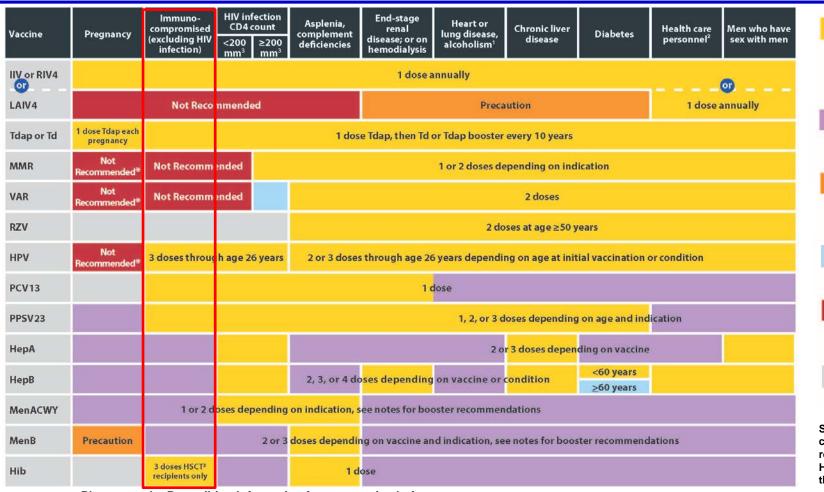
Source: CDC; material developed by CDC. Reference to specific commercial products or trademarks does not constitute endorsement or recommendation by the U.S. Government, Department of Health and Human Services, or Centers for Disease Control and Prevention (CDC); this material is available through the CDC website at no charge.

#### Please see the Prescribing Information for any vaccine before use.

ACIP=Advisory Committee on Immunization Practices; HepA=hepatitis A; HepB=hepatitis B; Hib=Haemophilus influenzae type b conjugate vaccine; HPV=human papillomavirus; IIV=inactivated influenza vaccine; LAIV=live attenuated influenza vaccine; MenACWY=serogroups A, C, W, and Y meningococcal conjugate vaccine; MenB=serogroup B meningococcal vaccine; MMR=measles, mumps, and rubella vaccine; PCV13=13-valent pneumococcal conjugate vaccine; PSV23=23-valent pneumococcal polysaccharide vaccine; RIV=recombinant influenza vaccine; RZV=recombinant zoster vaccine; Td=tetanus and diphtheria toxoids; Tdap=tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine; VAR=varicella vaccine.



## ACIP Recommended Immunization Schedule for Adults Aged ≥19 Years by Medical Condition and Other Indications (United States, 2021)



- Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of past infection
- Recommended vaccination for adults with an additional risk factor or another indication
- Precaution—vaccination might be indicated if benefit of protection outweighs risk of adverse reaction
- Recommended vaccination based on shared clinical decision-making
- Not recommended/ contraindicated—vaccine should not be administered.
  - \*Vaccinate after pregnancy.
- No recommendation/ Not applicable

- **1.** Precaution for LAIV4 does not apply to alcoholism.
- **2.** See reference for notes on influenza; hepatitis B; measles, mumps, and rubella; and varicella vaccinations.
- **3.** Hematopoietic stem cell transplant.

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Please see the Prescribing Information for any vaccine before use.



ACIP=Advisory Committee on Immunization Practices; CD4=cluster of differentiation 4; HepA=hepatitis A; HepB=hepatitis B; Hib=*Haemophilus influenzae* type b conjugate vaccine; HIV=human immunodeficiency virus; HPV=human papillomavirus; HSCT=hematopoietic stem cell transplant; IIV=inactivated influenza vaccine; LAIV=live attenuated influenza vaccine; MenACWY=serogroups A, C, W, and Y meningococcal conjugate vaccine; MenB=serogroup B meningococcal vaccine; MMR=measles, mumps, and rubella vaccine; PCV13=13-valent pneumococcal conjugate vaccine; PPSV23=23-valent pneumococcal polysaccharide vaccine; RIV=recombinant influenza vaccine; RZV=recombinant zoster vaccine; Td=tetanus and diphtheria toxoids; Tdap=tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine; VAR=varicella vaccine. Centers for Disease Control and Prevention. https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf. Accessed November 9, 2021.