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Getting Up to Speed with Recommendations and Medical Billing Opportunities for Vaccines

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Disclosure Statement

There are no relevant financial relationships with ACPE defined commercial interests for anyone who was in control of the content of the activity.

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Pharmacist and Technician Learning Objectives

1. Review updates to Advisory Committee on Immunization Practices (ACIP) recommendations on how to use vaccines to control disease in the United States.
2. Learn about updates related to vaccine-preventable diseases in the United States.
3. Explore strategies for obtaining reimbursement from health plans for vaccine administration.

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ACIP Adult Immunization Updates

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Table 1 COVID-19 vaccination recommendations have changed. Find the latest recommendations at www.cdc.gov/covidschedule

Recommended Adult Immunization Schedule for ages 19 years or older, United States, 2023

Vaccine	19–26 years	27–49 years	50–64 years	≥65 years
COVID-19	2- or 3- dose primary series and booster (See Notes)			
Influenza inactivated (IIV4) or **Influenza recombinant** (RIV4)	1 dose annually			
or	or			
Influenza live, attenuated (LAIV4)	1 dose annually			
Tetanus, diphtheria, pertussis (Tdap or Td)	1 dose Tdap each pregnancy; 1 dose Td/Tdap for wound management (see notes)			
	1 dose Tdap, then Td or Tdap booster every 10 years			
Measles, mumps, rubella (MMR)	1 or 2 doses depending on indication (if born in 1957 or later)			For healthcare personnel, see notes
Varicella (VAR)	2 doses (if born in 1980 or later)	2 doses		
Zoster recombinant (RZV)	2 doses for immunocompromising conditions (see notes)		2 doses	
Human papillomavirus (HPV)	2 or 3 doses depending on age at initial vaccination or condition	27 through 45 years		
Pneumococcal (PCV15, PCV20, PPSV23)	1 dose PCV15 followed by PPSV23 OR 1 dose PCV20 (see notes)			See Notes
				See Notes
Hepatitis A (HepA)	2, 3, or 4 doses depending on vaccine			
Hepatitis B (HepB)	2, 3, or 4 doses depending on vaccine or condition			
Meningococcal A, C, W, Y (MenACWY)	1 or 2 doses depending on indication, see notes for booster recommendations			
Meningococcal B (MenB)	2 or 3 doses depending on vaccine and indication, see notes for booster recommendations			
	19 through 23 years			
***Haemophilus influenzae* type b** (Hib)	1 or 3 doses depending on indication			

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

Recommended vaccination based on shared clinical decision-making

No recommendation/ Not applicable

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Table 2 Recommended Adult Immunization Schedule by Medical Condition or Other Indication, United States, 2023

Vaccine	Pregnancy	Immuno-compromised (excluding HIV infection)	HIV infection CD4 percentage and count		Asplenia, complement deficiencies	End-stage renal disease, or on hemodialysis	Heart or lung disease; alcoholism[a]	Chronic liver disease	Diabetes	Health care personnel[b]	Men who have sex with men
			<15% or <200 mm³	≥15% and ≥200 mm³							
COVID-19		See Notes									
IIV4 or RIV4 or LAIV4	1 dose annually									or 1 dose annually	
	Contraindicated							Precaution			
Tdap or Td	1 dose Tdap each pregnancy	1 dose Tdap, then Td or Tdap booster every 10 years									
MMR	Contraindicated*	Contraindicated	1 or 2 doses depending on indication								
VAR	Contraindicated*	Contraindicated			2 doses						
RZV		2 doses at age ≥19 years			2 doses at age ≥50 years						
HPV	Not Recommended*	3 doses through age 26 years			2 or 3 doses through age 26 years depending on age at initial vaccination or condition						
Pneumococcal (PCV15, PCV20, PPSV23)		1 dose PCV15 followed by PPSV23 OR 1 dose PCV20 (see notes)									
HepA					2, 3, or 4 doses depending on vaccine						
HepB	3 doses (see notes)	2, 3, or 4 doses depending on vaccine or condition									
MenACWY		1 or 2 doses depending on indication, see notes for booster recommendations									
MenB	Precaution	2 or 3 doses depending on vaccine and indication, see notes for booster recommendations									
Hib		3 doses HSCT[c] recipients only			1 dose						

- 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
- Recommended vaccination based on shared clinical decision-making
- Precaution–vaccination might be indicated if benefit of protection outweighs risk of adverse reaction
- Contraindicated or not recommended–vaccine should not be administered.

*Vaccinate after pregnancy.

- No recommendation/ Not applicable

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Table 1 COVID-19 vaccination recommendations have changed. Find the latest recommendations at www.cdc.gov/covidschedule

Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2023

These recommendations must be read with the notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars.
To determine minimum intervals between doses, see the catch-up schedule (Table 2).

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19–23 mos	2–3 yrs	4–6 yrs	7–10 yrs	11–12 yrs	13–15 yrs	16 yrs	17–18 yrs
Hepatitis B (HepB)	1st dose	◄---- 2nd dose ----►			◄---------- 3rd dose ----------►												
Rotavirus (RV): RV1 (2-dose series), RV5 (3-dose series)			1st dose	2nd dose	See Notes												
Diphtheria, tetanus, acellular pertussis (DTaP <7 yrs)			1st dose	2nd dose	3rd dose			◄---- 4th dose ----►				5th dose					
Haemophilus influenzae type b (Hib)			1st dose	2nd dose	See Notes		◄-- 3rd or 4th dose, See Notes --►										
Pneumococcal conjugate (PCV13, PCV15)			1st dose	2nd dose	3rd dose		◄---- 4th dose ----►										
Inactivated poliovirus (IPV <18 yrs)			1st dose	2nd dose	◄---------- 3rd dose ----------►							4th dose					See Notes
COVID-19 (1vCOV-mRNA, 2vCOV-mRNA, 1vCOV-aPS)					2- or 3- dose primary series and booster (See Notes)												
Influenza (IIV4)					Annual vaccination 1 or 2 doses								or	Annual vaccination 1 dose only			
or																	
Influenza (LAIV4)											Annual vaccination 1 or 2 doses			Annual vaccination 1 dose only			
Measles, mumps, rubella (MMR)					See Notes		◄---- 1st dose ----►					2nd dose					
Varicella (VAR)							◄---- 1st dose ----►					2nd dose					
Hepatitis A (HepA)					See Notes		2-dose series, See Notes										
Tetanus, diphtheria, acellular pertussis (Tdap ≥7 yrs)														1 dose			
Human papillomavirus (HPV)														See Notes			
Meningococcal (MenACWY-D ≥9 mos, MenACWY-CRM ≥2 mos, MenACWY-TT ≥2years)			See Notes											1st dose		2nd dose	
Meningococcal B (MenB-4C, MenB-FHbp)														See Notes			
Pneumococcal polysaccharide (PPSV23)											See Notes						
Dengue (DEN4CYD; 9-16 yrs)														Seropositive in endemic dengue areas (See Notes)			

Range of recommended ages for all children
Range of recommended ages for catch-up vaccination
Range of recommended ages for certain high-risk groups
Recommended vaccination can begin in this age group
Recommended vaccination based on shared clinical decision-making
No recommendation/ not applicable

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Table 3 Recommended Child and Adolescent Immunization Schedule by Medical Indication, United States, 2023

Always use this table in conjunction with Table 1 and the Notes that follow.

VACCINE	INDICATION										
	Pregnancy	Immunocompromised status (excluding HIV infection)	HIV infection CD4+ count[a]: <15% or total CD4 cell count of <200/mm³	HIV infection CD4+ count[a]: ≥15% and total CD4 cell count of ≥200/mm³	Kidney failure, end-stage renal disease, or on hemodialysis	Heart disease or chronic lung disease	CSF leak or cochlear implant	Asplenia or persistent complement component deficiencies	Chronic liver disease	Diabetes
Hepatitis B										
Rotavirus		SCID[b]								
Diphtheria, tetanus, and acellular pertussis (DTaP)										
Haemophilus influenzae type b										
Pneumococcal conjugate										
Inactivated poliovirus										
COVID-19		See Notes	See Notes							
Influenza (IIV4) or Influenza (LAIV4)						Asthma, wheezing: 2–4yrs[c]				
Measles, mumps, rubella	*									
Varicella	*									
Hepatitis A										
Tetanus, diphtheria, and acellular pertussis (Tdap)										
Human papillomavirus	*									
Meningococcal ACWY										
Meningococcal B										
Pneumococcal polysaccharide										
Dengue										

- Vaccination according to the routine schedule recommended
- Recommended for persons with an additional risk factor for which the vaccine would be indicated
- Vaccination is recommended, and additional doses may be necessary based on medical condition or vaccine. See Notes.
- Precaution–vaccine might be indicated if benefit of protection outweighs risk of adverse reaction
- Contraindicated or not recommended–vaccine should not be administered
- No recommendation/not applicable

*Vaccinate after pregnancy

a. For additional information regarding HIV laboratory parameters and use of live vaccines, see the *General Best Practice Guidelines for Immunization*, "Altered Immunocompetence," at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html and Table 4-1 (footnote J) at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.
b. Severe Combined Immunodeficiency
c. LAIV4 contraindicated for children 2–4 years of age with asthma or wheezing during the preceding 12 months

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Pharmacist's Role

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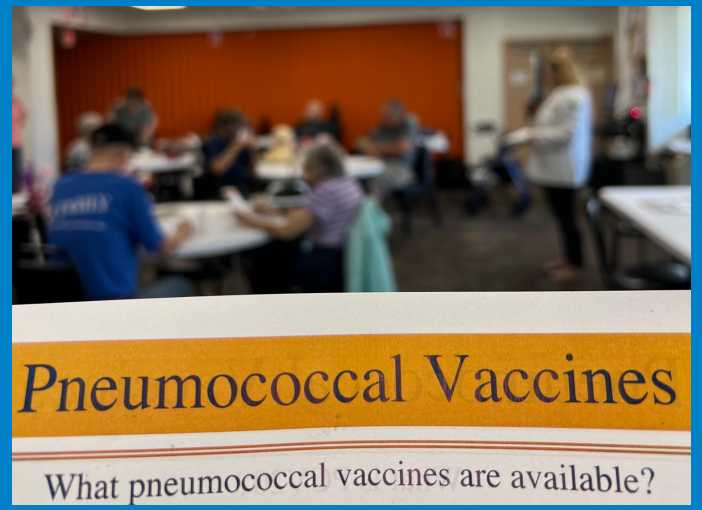
Workflow

1. Screening Patients
2. Overcoming Barriers
3. Vaccine Administration



Screening Patients

CDC Vaccine Schedule

- Review annual vaccine schedule for changes/updates
- Determine approach for addressing in community

Screening Assessment Questionnaires

- Utilize established services to screen patients
- Screen during vaccine appointments for additional vaccines

Apps

CDC

CDC

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https://www2.cdc.gov/nip/adultimmsched/

The Adult Vaccine Assessment Tool

Español (Spanish)

Adults need vaccines too! Answer a few quick questions to find out which vaccines you may need.

Vaccines are recommended for adults based on age, health conditions, job, and other factors. No personal information will be retained by CDC.

** This vaccine assessment tool applies to adults 19 years or older.*

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COVID Booster Screening Tool

Find Out When You Can Get Your Booster

Boosters are an important part of protecting yourself from getting seriously ill or dying from COVID-19. They are recommended for most people.

Use this tool to determine when or if you (or your child) can get one or more COVID-19 boosters.

Find Out When to Get a Booster >

This tool is intended to help you make decisions about getting COVID-19 vaccinations. It should not be used to diagnose or treat COVID-19.

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html?s_cid=11772:cdc%20covid%20booster%20recommendations:sem.ga:p:RG:GM:gen:PTN.Grants:FY22

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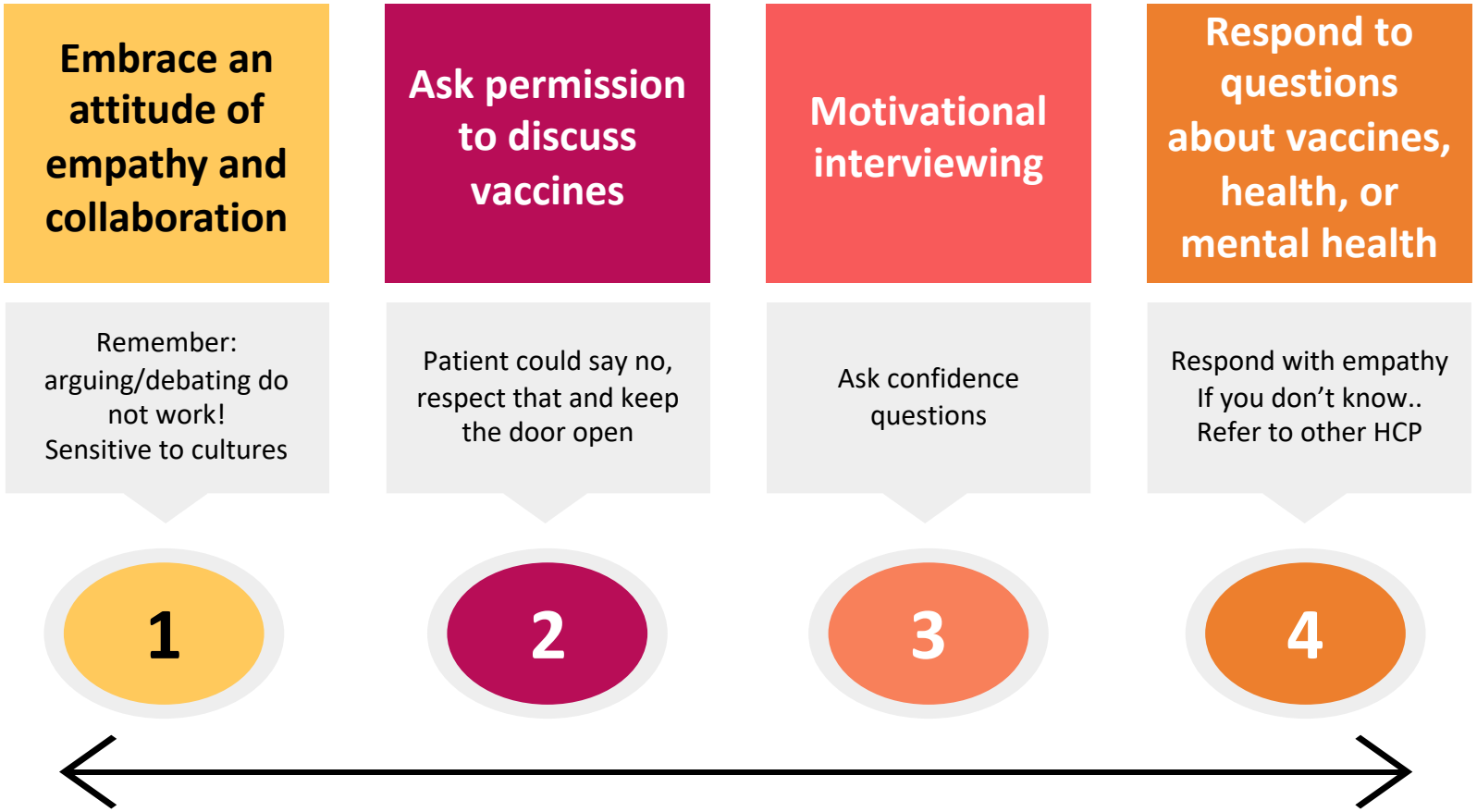
Motivational Interviewing Strategies



Zolezzi M, et al. *Int J Clin Pharm*. 2021. doi: 10.1007/s11096-021-01334-y [Epub ahead of print]

Talking with Patients about COVID-19 Vaccination. Centers for Disease Control and Prevention (CDC). Updated November 3, 2021. Accessed November 21, 2021. https://www.cdc.gov/vaccines/covid-19/hcp/engaging-patients.html

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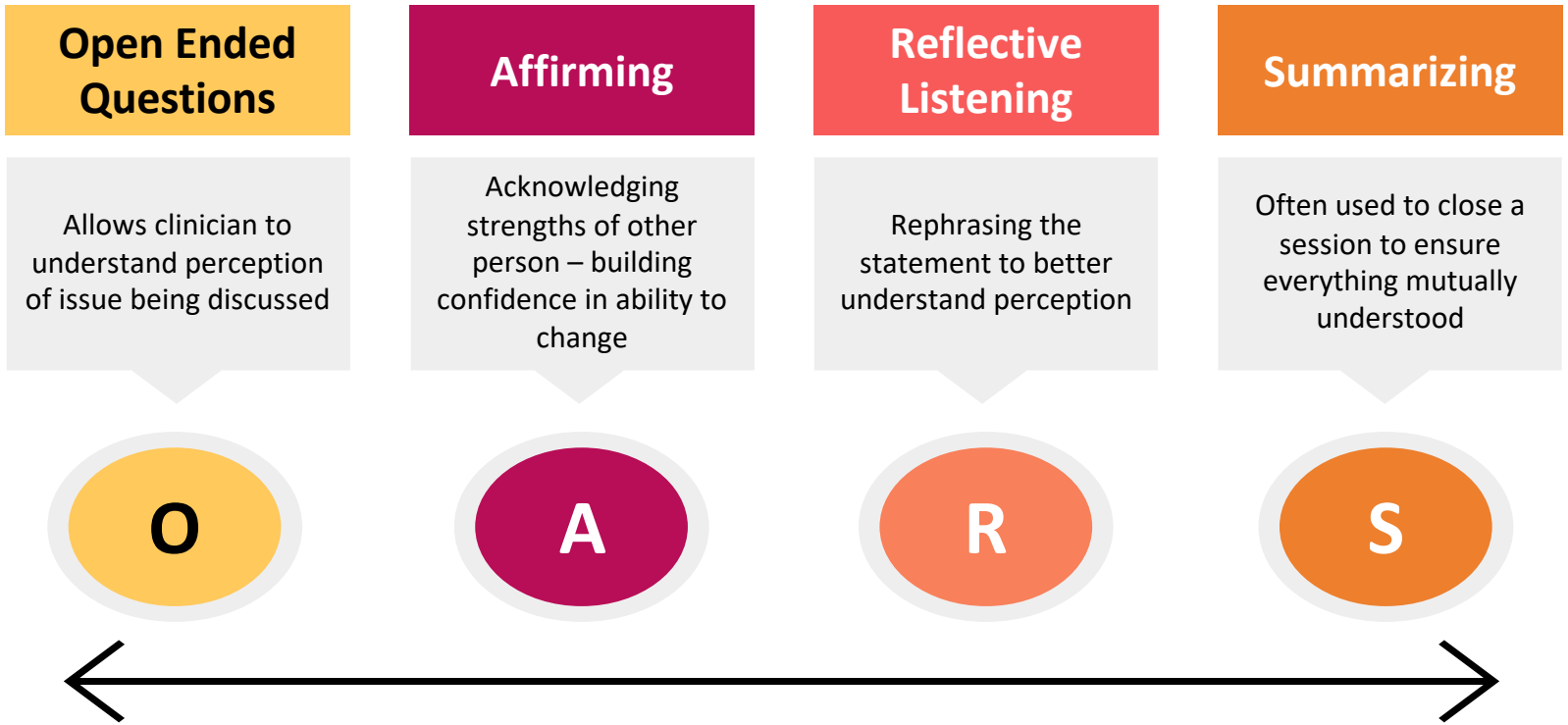
Motivational Interviewing Strategies

- "…The goal of motivational interviewing is to help people manage mixed feelings and move toward healthy behavior change that is consistent with their values and needs."
- Interviewing Techniques:



Zolezzi M, et al. Int J Clin Pharm. 2021. doi: 10.1007/s11096-021-01334-y [Epub ahead of print]

Talking with Patients about COVID-19 Vaccination. Centers for Disease Control and Prevention (CDC). Updated November 3, 2021. Accessed November 21, 2021. https://www.cdc.gov/vaccines/covid-19/hcp/engaging-patients.html

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Updates related to vaccine-preventable diseases

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Notable Vaccine Updates

Pneumococcal	• Pneumococcal conjugate vaccines (~~PCV13~~, PCV15, PCV20) • Pneumococcal polysaccharide (PPSV23)
RSV	• Respiratory Syncytial Virus vaccine
Influenza	• Influenza vaccine (inactivated) (IIV4) • Influenza vaccine (live, attenuated) (LAIV4) • Influenza vaccine (recombinant) (RIV4)
Herpes Zoster (Shingles)	• Zoster vaccine, recombinant (RZV)
Hepatitis B	• Hepatitis B vaccine (HepB)

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Pneumococcal Vaccine

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Formulations Pneumococcal Vaccines

	Pneumococcal conjugate vaccine – 13 (PCV-13)	Pneumococcal conjugate vaccine – 15 (PCV-15)	Pneumococcal conjugate vaccine – 20 (PCV-20)	Pneumococcal polysaccharide vaccine – 23 (PPSV-23)
Brand or Trade Name	Prevnar 13	Vaxneuvance	Prevnar 20	Pneumovax-23
Date Vaccine FDA Approved	Feb 2010	July 2021	June 2022	1983
Approved age	6 weeks – 17 years of age (no longer recommended for 18+)	18 years of age and older	18 years of age and older	2 years of age and older
Volume	0.5 mL	0.5 mL	0.5 mL	0.5 mL
Available preparations	Single-dose prefilled syringe	Single-dose prefilled syringe	Single-dose prefilled syringe	Single-dose vial or prefilled syringe
Injection route	IM	IM	IM	SQ or IM
Special Handling instructions	Shake vigorously	Shake vigorously	Shake vigorously	

Indication Pneumococcal Vaccines

Children less than 2 years old (4 dose series)

Children and adolescents 2 – 18 years old with certain medical conditions

Adults 19 – 64 years old with certain medical conditions, risk factors or immunocompromised

Routine vaccine for adults 65 years or older

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https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

Timing Pneumococcal Vaccine

Adults ≥ 65 years old

Prior vaccines	Option A	Option B
None*	**PCV20**	**PCV15** → ≥ 1 year† → **PPSV23**
PPSV23 only at any age	≥ 1 year → **PCV20**	≥ 1 year → **PCV15**
PCV13 only at any age	≥ 1 year → **PCV20**	≥ 1 year† → **PPSV23**
PCV13 at any age & **PPSV23** at <65 yrs	≥ 5 years → **PCV20**	≥ 5 years§ → **PPSV23**

*Also applies to people who received PCV7 at any age and no other pneumococcal vaccines

† Consider minimum interval (8 weeks) for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fuid leak (CSF) leak

§ For adults with an immunocompromising condition, cochlear implant, or CSF leak, the minimum interval for PPSV23 is ≥8 weeks since last PCV13 dose and ≥5 years since last PPSV23 dose; for others, the minimum interval for PPSV23 is ≥1 year since last PCV13 dose and ≥5 years since last PPSV23 dose

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Timing Pneumococcal Vaccine

Shared clinical decision-making for those who already completed the series with PCV13 and PPSV23

Prior vaccines	Shared clinical decision-making option	
Complete series: **PCV13** at any age & **PPSV23** at <65 yrs	≥ 5 years → **PCV20**	Together, with the patient, vaccine **providers may choose** to administer PCV20 to adults ≥65 years old who have already received PCV13 (but not PCV15 or PCV20) at any age and PPSV23 at or after the age of 65 years old.

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https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

Timing Pneumococcal Vaccine

Adults 19–64 years old with specified immunocompromising conditions

Prior vaccines	Option A	Option B
None*	**PCV20**	**PCV15** → ≥ 8 weeks → **PPSV23**
PPSV23 only	≥ 1 year → **PCV20**	≥ 1 year → **PCV15**
PCV13 only	≥ 1 year → **PCV20**	≥ 8 weeks → **PPSV23** → ≥ 5 years → **PPSV23**

Review pneumococcal vaccine recommendations again when your patient turns 65 years old

*Also applies to people who received PCV7 at any age and no other pneumococcal vaccines

† The minimum interval for PPSV23 is ≥8 weeks since last PCV13 dose and ≥5 years since last PPSV23 dose

https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

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Timing Pneumococcal Vaccine

Adults 19–64 years old with specified immunocompromising conditions

Prior vaccines	Option A	Option B
PCV13 at and **1 dose of PPSV23**	≥ 5 years → **PCV20**	≥ 5 years† → **PPSV23**
PCV13 and **2 doses of PPSV23**	≥ 5 years → **PCV20**	**No vaccines** recommended at this time. Review pneumococcal vaccine recommendations again when your patient turns 65 years old
Immunocompromising conditions	• Chronic renal failure • HIV infection • Multiple myeloma • Congenital or acquired asplenia • Hodgkin disease • Nephrotic syndrome • Congenital or acquired • Iatrogenic immunosuppression¶ • Sickle cell disease/other • immunodeficiency§ • Leukemia hemoglobinopathies • Generalized malignancy • Lymphoma • Solid organ transplant	

§ Includes B- (humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease)

¶ Includes diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids and radiation therapy

https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

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Timing Pneumococcal Vaccine

Adults 19–64 years old with a cochlear implant or cerebrospinal fluid leak

Prior vaccines	Option A	Option B
None*	**PCV20**	**PCV15** → ≥ 8 weeks → **PPSV23**
PPSV23 only	≥ 1 year → **PCV20**	≥ 1 year → **PCV15**
PCV13 only	≥ 1 year → **PCV20**	≥ 8 weeks → **PPSV23**

Review pneumococcal vaccine recommendations again when your patient turns 65 years old

*Also applies to people who received PCV7 at any age and no other pneumococcal vaccines

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https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

Timing Pneumococcal Vaccine

Adults 19–64 years old with a cochlear implant or cerebrospinal fluid leak

Prior vaccines	Option A	Option B
PCV13 and **1 doses of PPSV23**	≥ 5 years → **PCV20**	**No vaccines** recommended at this time. Review pneumococcal vaccine recommendations again when your patient turns 65 years old

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https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

Timing Pneumococcal Vaccine

Adults 19–64 years old with chronic health conditions

Prior vaccines	Option A	Option B
None*	**PCV20**	**PCV15** → ≥ 1 year → **PPSV23**
PPSV23 only	≥ 1 year → **PCV20**	≥ 1 year → **PCV15**
PCV13 only	≥ 1 year → **PCV20**	≥ 1 year → **PPSV23** Review pneumococcal vaccine recommendations again when your patient turns 65 years old

*Also applies to people who received PCV7 at any age and no other pneumococcal vaccines

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https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

Timing Pneumococcal Vaccine

Adults 19–64 years old with chronic health conditions

Prior vaccines	Option A	Option B
PCV13† and **PPSV23**	**No vaccines** recommended at this time. Review pneumococcal vaccine recommendations again when your patient turns 65 years old	
Immunocompromising conditions	• Alcoholism • Chronic liver disease • Chronic lung disease, including chronic obstructive pulmonary disease, emphysema, and asthma	• Chronic heart disease, including congestive heart failure and cardiomyopathies • Cigarette smoking • Chronic liver disease • Diabetes mellitus

† Adults with chronic medical conditions were previously not recommended to receive PCV13

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https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

Efficacy Pneumococcal Vaccines

PCV13:

- 85,000 adults, >65 years, 2008-2013, Netherlands

46% Efficacy	45% Efficacy	75% Efficacy
• against vaccine-type pneumococcal pneumonia	• against vaccine-type non-bacteremic pneumococcal pneumonia	• against vaccine-type invasive pneumococcal disease (IPD)

PCV15 and **PCV20:**

- FDA licensed in 2021 based on studies comparing the serologic response of adults who received either PCV15 or PCV20 to those who received PCV13
- PCV15 and PCV20 induced antibody levels ***comparable to those induced by PCV13*** and shown to be protective against invasive disease

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Centers for Disease Control and Prevention (CDC). Pneumococcal Vaccine Timing for Adults. https://www.cdc.gov/pneumococcal/vaccination.html.

Safety Pneumococcal Vaccines

Contraindication

- Severe allergic reaction to a previous dose of the vaccine or a component of the vaccine
- Note: conjugate pneumococcal vaccines use a diphtheria protein carrier – Do not give vaccine if allergy to previous diphtheria containing vaccine

Precautions

- Moderate to severe acute illness with or without fever

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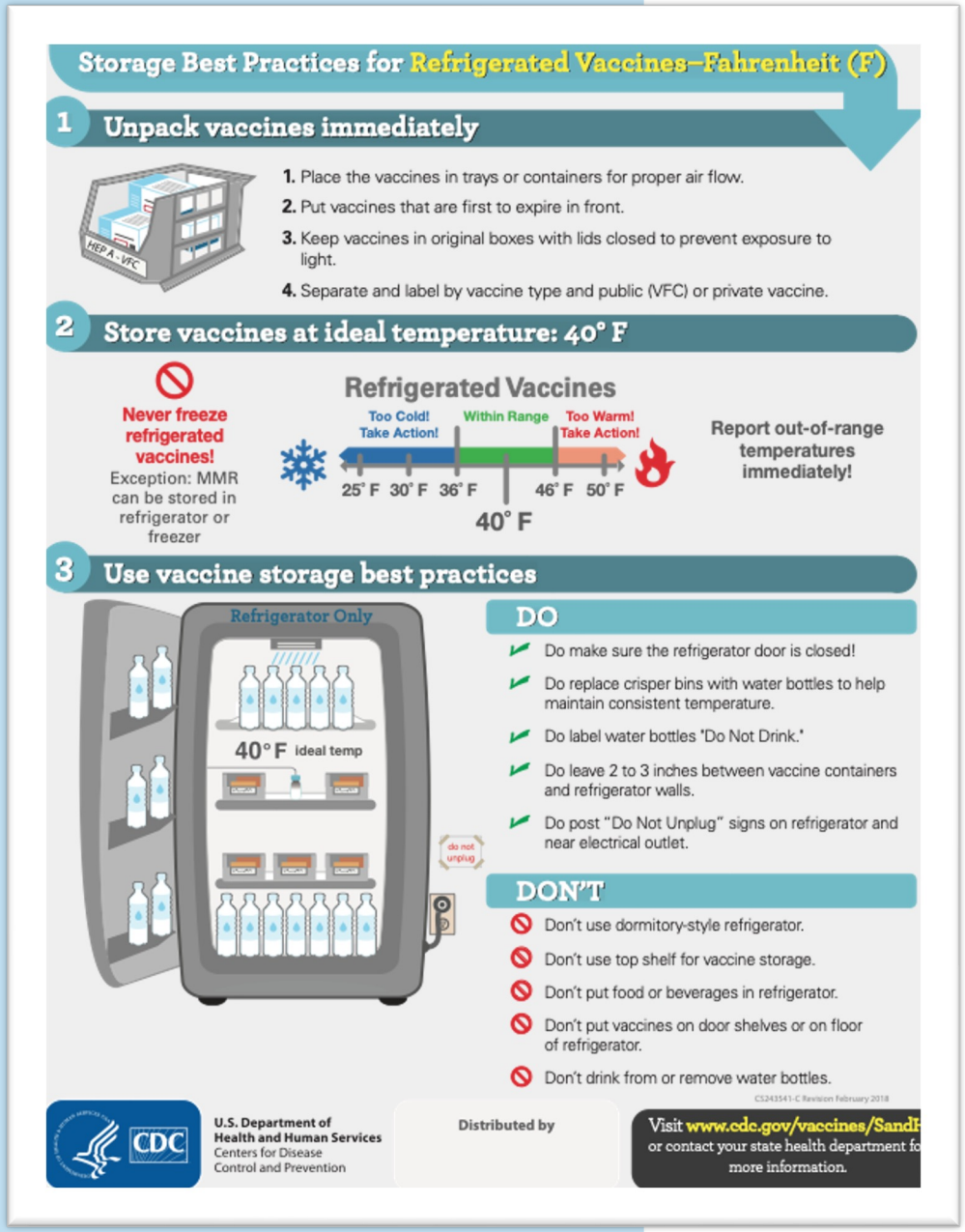
VAXNEUVANCE™ (Pneumococcal 15-valent Conjugate Vaccine). Prescribing information. Merck & Co., Inc.; 2021.
Prevnar 20™ (Pneumococcal 20-valent Conjugate Vaccine). Prescribing information. Wyeth Pharmaceuticals LLC.; 2021.

Storage Pneumococcal Vaccines

PCV15	PCV20
• Upon receiving, store in **refrigerator at 36ºF to 46ºF** • Tip cap/stopper are not made with natural rubber latex	• Upon receiving, store in **refrigerator at 36ºF to 46ºF** • Horizontal storage to minimize resuspension time • Tip cap/stopper are not made with natural rubber latex



VAXNEUVANCE™ (Pneumococcal 15-valent Conjugate Vaccine). Prescribing information. Merck & Co., Inc.; 2021.
Prevnar 20™ (Pneumococcal 20-valent Conjugate Vaccine). Prescribing information. Wyeth Pharmaceuticals LLC.; 2021.

Clinical Pearls Pneumococcal Vaccines

- Check the expiration date
- Pneumococcal vaccines are not ‘interchangeable’.
  - Confirm what should be administered
- No data on stability for pre-drawing vaccines
- **Never** administer pneumococcal conjugate (PCV13, PCV15, or PCV20) with a pneumococcal polysaccharide (PPSCV23) in the same visit
- Capitalize on face time during influenza season
- No data on administering PCV15 or PCV20 with other vaccines (i.e., tetanus, zoster)

If you *only* stock PCV20, you’d meet requirements for Option A

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Patient Counseling

Pneumococcal Vaccines

- Provide patient with the **Vaccine Information Statement** (VIS)
- Discuss the benefits and risks of each product,
  - including follow-up for each vaccine
- If any side effects, adverse reactions, should report to the **Vaccine Adverse Event Reporting System** (VAERS)

- Ask patient to complete a comprehensive vaccine evaluation while waiting 15-minute waiting period
  - Student project: take blood pressure, counsel on medications, health screening, etc.

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Respiratory Syncytial Virus (RSV) Vaccine

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Formulations RSV Vaccines

	Respiratory Syncytial Virus Vaccine, Adjuvanted (GlaxoSmithKline)	**Respiratory Syncytial Virus Vaccine** (Pfizer)
Brand or Trade Name	Arexvy	Abrysvo
Date Vaccine FDA Approved	May 3, 2023	May 31, 2023
Approved age	60 years of age and older	60 years of age and older
Volume	0.5 mL	0.5 mL
Available preparations	Solution, reconstituted	Solution, kit (vial of Lyophilized Antigen Component (a sterile white powder), a prefilled syringe containing Sterile Water Diluent Component and a vial adapter)
Injection route	IM	IM
Special Handling instructions	Must use within 4 hours of mixing	Must use within 4 hours of mixing

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Indication RSV Vaccines

Vaccine indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals **60 years of age and older**

Pfizer has also submitted trial results for Abrysvo in **pregnant patients** to help protect newborns and young infants from RSV disease after birth.

- An FDA decision for this use is expected in August 2023.

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Abrexvy (respiratory syncytial virus vaccine). Prescribing Information. GlaxoSmithKline. May 2023.
Abrysvo (respiratory syncytial virus vaccine). Prescribing Information. Pfizer. May 2023.

Efficacy RSV Vaccines

Respiratory Syncytial Virus Vaccine, Adjuvanted (GlaxoKlineSmith):

- 15,845 vaccine recipients

85.7% Efficacy	66.7% Efficacy
• Reduction in risk of first episode of RSV-LRTD with ≥ 3 symptoms	• Reduction in risk of first episode of RSV-LRTD with ≥ 2 symptoms

Respiratory Syncytial Virus Vaccine (Pfizer):

- 17,197 vaccine recipients

82.6% Efficacy	94.6% Efficacy
• Reduction in risk of first episode of RSV-LRTD with ≥ 3 symptoms	• Reduction in risk in participants with at least 1 comorbidity of interest

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Abrexvy (respiratory syncytial virus vaccine). Prescribing Information. GlaxoSmithKline. May 2023.
Abrysvo (respiratory syncytial virus vaccine). Prescribing Information. Pfizer. May 2023.

Safety RSV Vaccines

Contraindication

- Severe allergic reaction to a previous dose of the vaccine or a component of the vaccine

Precautions

- Syncope
- Altered Immunocompetence

Side Effects

- Arexvy - local: injection site pain; systemic: fatigue, myalgia, headache, arthralgia
- Abrysvo – local: injection site pain; systemic: fatigue, headache, muscle pain

Abrexvy (respiratory syncytial virus vaccine). Prescribing Information. GlaxoSmithKline. May 2023.
Abrysvo (respiratory syncytial virus vaccine). Prescribing Information. Pfizer. May 2023.

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Reconstitution RSV Vaccines

- **Respiratory Syncytial Virus Vaccine, Adjuvanted** (Arexvy)

Figure 1. Cleanse both vial stoppers. Using a sterile needle and sterile syringe, withdraw the entire contents of the vial containing the adjuvant suspension component (liquid) by slightly tilting the vial. Vial 1 of 2.

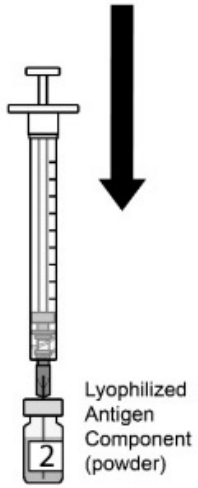


Figure 2. Slowly transfer entire contents of syringe into the lyophilized antigen component vial (powder). Vial 2 of 2.

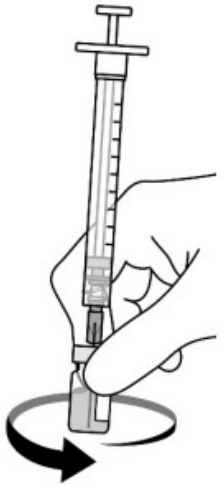


Figure 3. Gently swirl the vial until powder is completely dissolved. **Do not shake vigorously.**

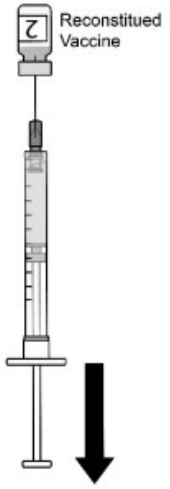
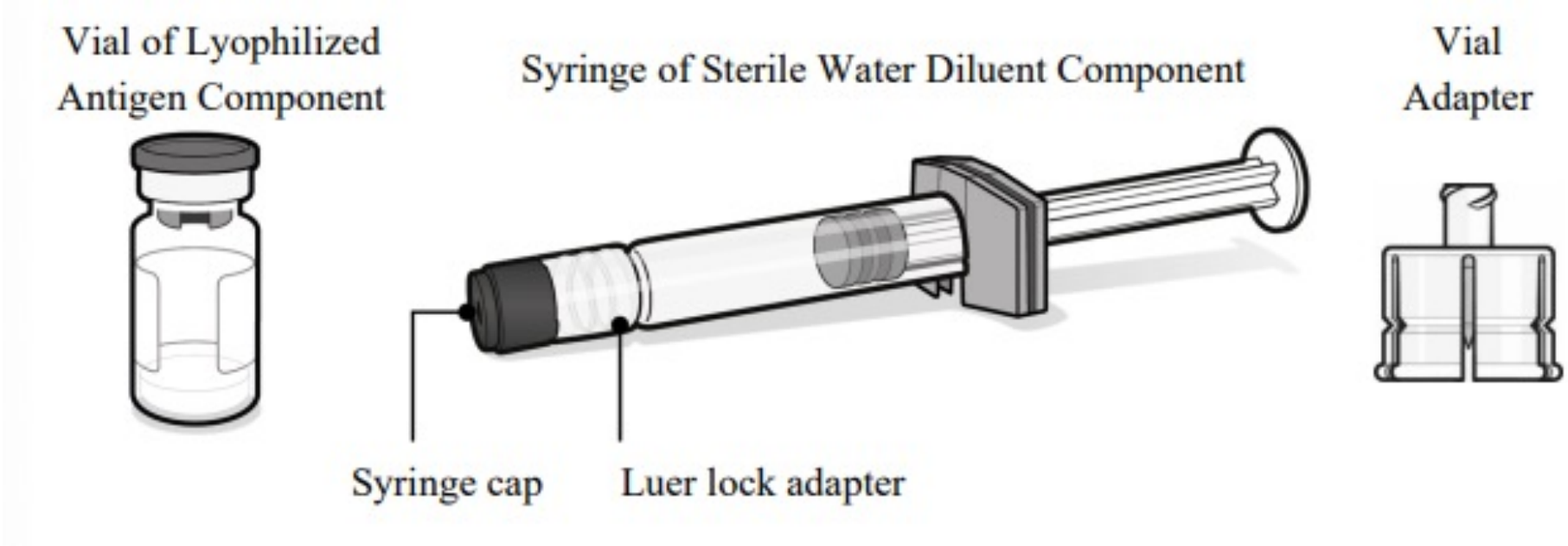


Figure 4. After reconstitution, withdraw 0.5 mL from the vial containing the reconstituted vaccine and administer intramuscularly.

Abrexvy (respiratory syncytial virus vaccine). Prescribing Information. GlaxoSmithKline. May 2023.

Reconstitution RSV Vaccines

Respiratory Syncytial Virus Vaccine (Abrysvo)



Abrysvo (respiratory syncytial virus vaccine). Prescribing Information. Pfizer. May 2023.

Reconstitution RSV Vaccines

Respiratory Syncytial Virus Vaccine (Abrysvo)

1: Prepare

2: Attach vial adapter

3: Remove syringe cap

4: Connect syringe to vial

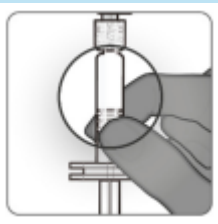
5: Reconstitute

6: Withdraw

7: Disconnect syringe

8: Attach needle

9: Visual inspection



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Abrysvo (respiratory syncytial virus vaccine). Prescribing Information. Pfizer. May 2023.

Clinical Pearls RSV Vaccines

- Administer immediately or store in the refrigerator between 2°C and 8°C (36°F to 46°F) or at room temperature [up to 25°C (77°F)] for up to 4 hours prior to use
- Protect vials from light
- **Discard reconstituted vaccine if not used within 4 hours**.
- Do not freeze. Discard if the vaccine has been frozen

- Atrial fibrillation within 30 days of vaccination was reported in 10 participants who received **Arexvy** and 4 participants who received placebo
  - The FDA is requiring the company to conduct a postmarketing study to assess the signals of serious risks for Guillain-Barré syndrome and ADEM

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Abrexvy (respiratory syncytial virus vaccine). Prescribing Information. GlaxoSmithKline. May 2023.
Abrysvo (respiratory syncytial virus vaccine). Prescribing Information. Pfizer. May 2023.

Patient Counseling RSV Vaccines

- Provide patient with the **Vaccine Information Statement** (VIS)
- Discuss the benefits and risks of each product:
  - Infants, young children and older adults are most at risk for severe RSV (58,000 to 80,000 children and 60,000 to 120,000 adults over 65 are hospitalized from RSV)
  - Injection site pain, fatigue, muscle pain, headache, joint stiffness
- If any side effects, adverse reactions, should report to the **Vaccine Adverse Event Reporting System** (VAERS)

- Ask patient to complete a comprehensive vaccine evaluation while waiting 15-minute waiting period
  - Student project: take blood pressure, counsel on medications, health screening, etc.

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Influenza Vaccine

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Updates Influenza Vaccine

Annual vaccine recommended for all patients 6 months and older

Pediatric patients 6 months – 8 years of age that have never received an influenza vaccine should receive 2 doses at least 4 weeks apart

Continue administering vaccine through flu season

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Adult Immunization Schedule

Influenza Vaccine

- Addition of sub-bullet in “Routine Vaccination” section
  - Any one of quadrivalent high-dose inactivated influenza vaccine, quadrivalent recombinant influenza vaccine, or quadrivalent adjuvanted inactivated influenza vaccine is preferred for adults aged 65 years or older
  - If one of the three vaccines are available can use an age-appropriate influenza vaccine

Adult Immunization Schedule

Influenza Vaccine

Quadrivalent Inactivated Influenza Vaccine (HD IIV4) – High Dose – Egg-based ****Approved for ages 65 years and older****		
Fluzone High-dose Quadrivalent	0.7mL prefilled syringe	≥ 65 years – 0.7mL IM
Adjuvanted Quadrivalent Inactivated Influenza Vaccine (aIIV4) – Egg-based ****Approved for ages 65 years and older****		
Fluad Quadrivalent	0.5 mL prefilled syringe	≥ 65 years – 0.5mL IM
Quadrivalent Recombinant Influenza Vaccine (RIV4) ****Approved for ages 18 years and older****		
Flublok Quadrivalent	0.5 mL prefilled syringe	≥ 18 years – 0.5mL IM

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Adult and Pediatric Immunization Schedule Influenza Vaccine

- Clarifying language added to “Special Populations” section
  - live attenuated influenza vaccines should not be administered to close contacts of immunosuppressed persons who require a protected environment
- Moved Recommendation for persons with egg allergy other than hives to “Special Populations” section

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Special Populations Influenza Vaccine

Egg allergy, hives only	• any influenza vaccine appropriate for age and health status annually
Egg allergy–any symptom other than hives (e.g., angioedema, respiratory distress or required epinephrine or another emergency medical intervention)	• Any influenza vaccine appropriate for age and health status may be administered. If using egg-based IIV4 or LAIV4, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions.
Close contacts (e.g., caregivers, healthcare workers) of severely immunosuppressed persons who require a protected environment	• these persons should not receive LAIV4. If LAIV4 is given, they should avoid contact with/caring for such immunosuppressed persons for 7 days after vaccination.
Severe allergic reaction (e.g., anaphylaxis) to a vaccine component or a previous dose of any influenza vaccine	• see Appendix listing contraindications and precautions
History of Guillain-Barré syndrome within 6 weeks after previous dose of influenza vaccine	• Generally, should not be vaccinated unless vaccination benefits outweigh risks for those at higher risk for severe complications from influenza

https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html

Herpes Zoster (Shingles) Vaccine

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Indication Herpes Zoster (Shingles) Vaccine

Two dose series of recombinant zoster vaccine (RZV)

Routine vaccine for patients 50 years of age and older

Special Populations: Recommended for immunocompromised patients 19 – 49 years of age

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https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

Adult Immunization Schedule

Herpes Zoster (Shingles) Vaccine

- **Routine Vaccination** for Adults 50 years or older
  - Serologic evidence of prior varicella is **NOT** necessary for zoster vaccination.
  - However, if serologic evidence of varicella susceptibility becomes available, providers should follow ACIP guidelines for varicella vaccination first.

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https://www.cdc.gov/mmwr/volumes/71/wr/mm7103a2.htm

Adult Immunization Schedule

Herpes Zoster (Shingles) Vaccine

- **Special Populations** for Immunocompromising conditions
  - If there is no documented history of varicella, varicella vaccination, or herpes zoster, providers should refer to the clinical considerations for use of RZV in immunocompromised adults aged ≥19 years and the ACIP varicella vaccine recommendations for further guidance

Recombinant zoster vaccine (RZV) is not indicated for the prevention of varicella, and there are limited data on the use of RZV in persons without a history of varicella or varicella vaccination

https://www.cdc.gov/mmwr/volumes/71/wr/mm7103a2.htm

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Immunocompromising Conditions

Herpes Zoster (Shingles) Vaccine

- Solid organ or stem cell transplant
- Cancer
- HIV regardless of CD4 Count
- Autoimmune and inflammatory conditions
- Immunosuppressive medications

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https://www.cdc.gov/mmwr/volumes/71/wr/mm7103a2.htm

Immunocompromising Conditions
Herpes Zoster (Shingles) Vaccine

- Verify patient immunity to varicella (If no history of immunity varicella administer varicella vaccine first)
  - Documentation of 2 dose varicella vaccine
  - Laboratory evidence of immunity or confirming disease
  - Diagnosis or verification of disease by healthcare provider
  - Born in US prior to 1980
- If possible, vaccinate patients before becoming immunosuppressed
  - https://www.cdc.gov/shingles/vaccination/immunocompromised-adults.html
- May administer second dose 1-2 months after first dose if completing series quicker could be beneficial

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https://www.cdc.gov/mmwr/volumes/71/wr/mm7103a2.htm

Clinical Pearls Herpes Zoster (Shingles) Vaccine

- Can be administered while patients are taking antivirals
- Can be administered with other adult vaccines
- Patients should have previously received varicella vaccine or had chicken pox
  - Patients born in the US before 1980 are considered to have had been exposed to the varicella virus – no confirmation necessary

https://www.cdc.gov/mmwr/volumes/71/wr/mm7103a2.htm

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Hepatitis B Vaccine

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Adult Formulations Hepatitis B Vaccines

Vaccine	Approved Age	Series	Intervals	Notes
Heplisav-B	≥ 18 years	2-dose	≥ 4 weeks apart	Adjuvanted Not recommended during pregnancy due to lack of safety data
PreHevbrio	≥ 18 years	3-dose	0, 1, 6 months	Not recommended during pregnancy due to lack of safety data
Recombivax HB	Newborn and older	3-dose	0, 1, 6 months	
Engerix-B	Newborn and older	3-dose	0, 1, 6 months	Minimum intervals: dose 1 to dose 2: 4 weeks dose 2 to dose 3: 8 weeks dose 1 to dose 3: 16 weeks
Engerix-B ≥ 20 years old on hemodialysis or immunocompromised	Newborn and older	4-dose	0, 1, 2, and 6 months	Each dosage is double that of normal adult dose, i.e., 2 mL instead of 1 mL)

Adult Formulations Hepatitis A and B Vaccines

Vaccine	Approved Age	Series	Intervals	Notes
HepA-HepB (Twinrix)	≥ 18 years	3-dose	0, 1, 6 months	Minimum intervals: dose 1 to dose 2: 4 weeks dose 2 to dose 3: 5 months
HepA-HepB (Twinrix)	≥ 18 years	4-dose	Accelerated schedule of 3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months	

Note: Hepatitis A vaccinations are on routinely recommended for a specific adult age group, the immunization schedule states that those without risk factors that want protection from Hepatitis A may receive a Hepatitis A vaccine

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https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hepb.html

Indication Hepatitis B Vaccines

All infants

Unvaccinated children < 19 years old

Adults 19 – 59 years old

Adults 60 years and older with risk factors for hepatitis B

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https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

Adult Immunization Schedule

Hepatitis B Vaccines

- PreHevbrio added to description of 3-dose series
- Addition of language regarding recommendations for patients 60 years and older added to “Routine Vaccination” section
  - persons aged ≥ 60 years **with** known risk factors for hepatitis B virus infection **should** complete a HepB vaccine series.
  - Persons aged ≥ 60 years **without** known risk factors for hepatitis B virus infection **may** complete a HepB vaccine series.

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https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hepb.html

Risk Factors Hepatitis B

At risk of blood or mucus exposure

Current or recent injection use

At risk by sexual contact

Living with someone who has active hepatitis B infection

Traveling outside the US to an area where hepatitis B is common

Certain Chronic conditions

- End stage renal disease or on dialysis
- Chronic liver disease
- Hep C infection
- HIV infection

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https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hepb.html

Clinical Pearls Hepatitis B Vaccine

- Ideally use same vaccine manufacturer to complete series, but vaccination should not be delayed if previous manufacturer is unknown or unavailable
- Heplisav-B and PreHevbrio administration is **not** recommended during pregnancy due to lack of safety data in pregnant women
- Can be administered with other vaccines

https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hepb.html

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Strategies for Obtaining Reimbursement for Vaccine Administration

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Strategies for Obtaining Reimbursement

- Compensation Sources
- Medicare Part B
- Medical Billing
  - Contracting / Credentialing
  - Claim Submission

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Compensation for Vaccinations

- Direct payment from patients
  - Out-of-pocket (i.e., self-pay)
  - Patient may receive reimbursement through employer plans
    - Includes payment applied to deductibles, health savings accounts, or flexible spending accounts
- Private employers
- Medicare (Part B, Part D)
- Medicaid and Vaccines for Children Program (VFC)
- Third-party insurance payers
- Prescription Assistance Programs
- Tricare
- Direct Primary Care (DPC) or other shared clinical relationships

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Compensation for Vaccinations

How will you get paid for the service...

...and by who?

Cash Claims:

- **Private Pay**
- **Employer Groups**

Medical Claims:

- Medicare Part B
- Medicaid
- Commercial (Blues, UHC, Aetna, etc)
- VFC

Submit **medical claim** using 3rd party service, 1500 Forms, or insurance portal.

Pharmacy Claims:

- Commercial
- Medicare Part D
- Medicaid

Submit using NCPDP Professional Service Codes to PBM via Pharmacy Switch

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Compensation Pearls

- Bill for the vaccine **and administration**
- Tell patients what they must pay for the vaccine and your service *before* you prepare the dose
- Give all cash-paying patients a receipt so they can seek reimbursement from insurance
- You cannot charge Medicare or other third-party payers more than your usual and customary fee

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2023: Medicare and Vaccines

- 2023: Medicare **Part D** covers all Medicare vaccines at **zero out of pocket (OOP)**
- Historical Part B vaccines *are still/also covered under the Part B benefit*
  - Influenza
  - Pneumococcal
  - Hepatitis B
  - COVID-19

Benefits:

1. Increases Access
2. Reduces beneficiaries OOP

Forbes

You Won't Pay For Medicare Vaccines In 2023

For you, a vaccination is a vaccination; it protects you against something. But, under Medicare, all vaccines are not equal and that means...

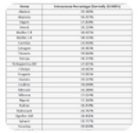
Oct 13, 2022

The White House

FACT SHEET: Seniors Across the Country Are Saving Millions of Dollars in Health Care Costs Because of President ...

New data from the Department of Health and Human Services shows how much seniors in every state could save because of cost-saving provisions...

Mar 15, 2023



Healthnews

Does Medicare Cover the Shingles Vaccine? | HealthNews

The shingles vaccine is covered only by some Medicare plans. Learn what are the coverage options by Medicare, private insurers, and how much can you expect...

Mar 28, 2023

Tampa Bay Times

Toni Says: Medicare Part D now covers shingles vaccine at no cost

Toni: I was recently told if I was to receive a shingles vaccination, I need to have a Medicare Part D prescription drug plan or pay $200.

Mar 22, 2023

VERIFYThis.com

Shingles shot is now free for people with Medicare Part D as of January 2023

The shingles vaccine will be free for seniors with Medicare who have Part D prescription drug coverage beginning January 2023.

Dec 8, 2022

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Reimbursement: Medicare Part B

- Request a National Provider Identification (NPI) Number from CMS or use current pharmacy NPI

- Medicare Enrollment
  - Accept “Any willing provider”
  - **Seperate from DMEPOS Medicare Provider Number**
    - *If you already have a DMEPOS Medicare Part B provider number, you will still need to applying!*
  - Request to become a ***mass immunization provider***
    - Contact local carrier and apply using the appropriate Form CMS-855 through PECOS
    - Allow 4–8 weeks for provider number
    - *If using a 3rd party billing service, they can assist*

If you enroll with Medicare Part B for immunizations, ***you must accept assignment***

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Reimbursement: Medicare Part B

CMS.gov Centers for Medicare & Medicaid Services

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Medicare > Provider Enrollment and Certification > Enrollment Applications

- Provider Enrollment and Certification
- Become a Medicare Provider or Supplier
- Introducing PECOS 2.0
- **Enrollment Applications**
- Enroll as a DMEPOS Supplier
- Ordering & Certifying
- Revalidations (Renewing Your Enrollment)

Enrollment Applications

Did you know you can enroll online using PECOS? PECOS is the online Medicare enrollment management system which allows you to:

- Enroll as a Medicare provider or supplier
- Review information currently on file
- Upload your supporting documents
- Electronically sign and submit your information online

Because PECOS is paperless, you no longer need to submit anything by mail. Additionally, PECOS applications tend to process faster than paper applications.

Enroll online using PECOS.

Medical Billing

- What do you need to be **in Network and bill Medical Claims**
  - Contract
  - Credentialed Providers *(some plans)*
  - Mechanism to submit **medical claims**

- Some insurance plans **require** provider credentialing
  - Provider = Person Rendering Service = Pharmacist
  - Credentialing can take hours
  - Medicare Part B will accept “any willing provider”
  - Evaluate if being in network with Insurance Plan is worth the process

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Medical Contracts

- Need **separate/direct contract** with the insurance provider
- PSAOs do not hold medical billing contracts!
- Pharmacy must contract direct with each insurance company for Immunization Services

Examples of insurances

- Blue Cross / Blue Shield
- United Healthcare
- Aetna

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Credentialing

Provider credentialing is a **regulated process** of **assessing the qualifications** of specific types of providers. This important safety check requires providers such as doctors, dentists, and other allied healthcare professionals to show they have the proper education, training and licenses to care for patients.

Hospitals and **health plans verify** the information supplied by the provider before they are included as an in-network provider.

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Credentialing Process

1. The provider supplies the information required for review.
   - Contact information
   - Current CV, education and training history, licensing and certificates, medical group and hospital affiliations, Board certifications
   - Sanctions or malpractice history, proof of liability insurance and peer references.
2. Health plan or provider organization checks that all the information is correct and up to date.
3. If no problems are encountered, the provider organization or health plan awards a credential to the provider.

The provider credentialing process can take as little as 30 days to complete up to as much as six months or more, particularly if the credentialing information is being transmitted via fax or mail.

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Credentialing Process

Organizations, like CAQH, can streamline the process by creating a credentialing packet for the provider.

This packet can then be shared with multiple insurance plans and/or providers for credentialing.

Eliminates the need to complete a new credentialing packet for each insurance plan and streamlines submission.

https://www.caqh.org/

Medical Billing vs Pharmacy Billing

	Medical	Pharmacy
Billing Codes	CPT or HCPCS https://www.cdc.gov/vaccines/programs/iis/code-sets.html	NCPDP format (NDC + Pharmacy Service Codes)
System for Submission	**3rd Party Billing Service:** TransactRx, Enliven, Omnisys, EBS **Printed 1500 Form** *(if allowed by plan)* **Insurance Portal,** i.e. Availity	Pharmacy Management System
Reimbursement	**$$**	**$**
Ease of Claim Transmission and Payment		
PSAO Existing Contracts	NO - Need to contract with each plan and possibly credential	Yes, however might need to complete some attestations or amendments.
Extra Fees	Yes if using a 3rd Party Billing Service	No
Reconciliation / Collections	Will need a system to work EOBs from insurance, process rejected claims, and collect patient amount due.	Patient amount due **collected at time of service.** Will still need to reconcile (same as prescription claims).

Final Thoughts

What if I don’t want to go through Medical Billing?

- Use pharmacy insurance
- Provide Cash paying customers a receipt to submit to their plans
  - *Does not work for Medicare Beneficiaries*

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Helpful Resources

CMS How to Bill Medicare for Influenza and Pneumococcal Vaccinations: https://www.cms.gov/files/document/flupdfpdf

CMS Enrollment Applications

https://www.caqh.org/for-providers

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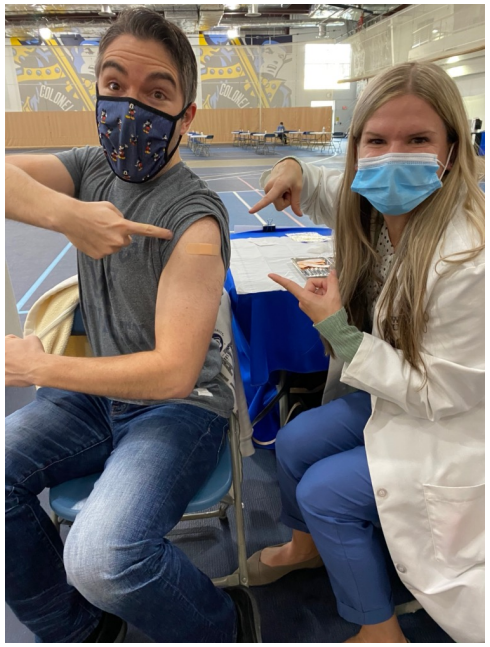
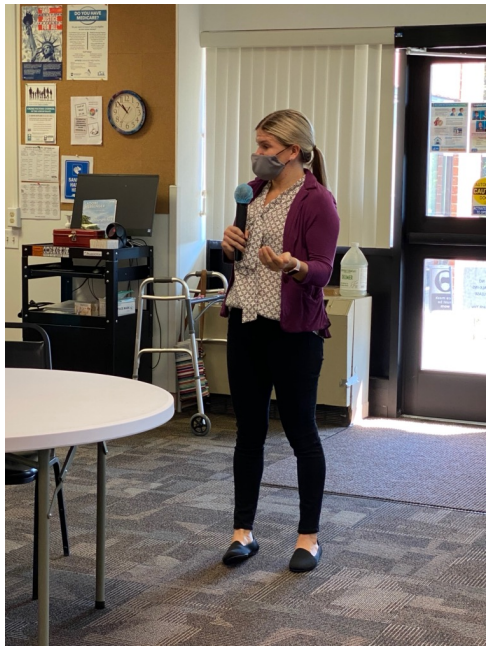
My Team in Action





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Helpful Resources

- ACIP Recommendations: https://www.cdc.gov/vaccines/acip/recommendations.html
- CDC Vaccine Information: https://www.cdc.gov/vaccines/index.html
- Association Resources (NCPA): https://ncpa.org/immunizations

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Game Plan

1. **Lesson Learned:** ACIP updates to vaccine-preventable diseases

2. **Replication**: Identify your patients eligible for immunization services at the pharmacy

3. **Call to Action**: Develop plan for sustaining vaccine administration within workflow

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