Influenza
and
Adult Immunization Guide

PharMerica

2023 - 2024

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Purpose of this Guide

This guide is for general informational purposes only. It is designed to consolidate key vaccine information and documents into a single resource for long-term care providers. Links to primary resources will be found throughout as a means to access primary sources that are subject to change. Please discuss individual patients' conditions with their medical provider(s) prior to administering any vaccine or pharmaceutical product. Refer to the product package insert for the full prescribing information of any vaccine or pharmaceutical listed.

This guide will provide information on select vaccines, including those that CMS requires long-term care facilities to offer residents. It is not intended to comment on all potential vaccines an individual is eligible for. Essential documents are included, such as **Vaccine Information Sheets** (VIS), **Consent Forms,** and **Declination Forms**.

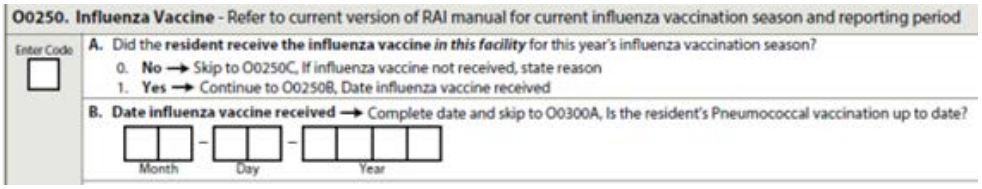
Acknowledgments

The majority of the information provided here is available publicly through various government websites that are referenced throughout this guide. Primarily, the Centers for Disease Control and Prevention (CDC), the Advisory Committee on Immunization Practices (ACIP), the Department of the U.S. Health and Human Service Department (HHS), the Immunization Action Coalition, and the Centers for Medicaid and Medicare Services (CMS) were instrumental in our information gathering. The nature of drug information is that it is constantly evolving due to ongoing research and clinical experience and is often subject to interpretation. While great care has been taken to ensure the accuracy of the information presented, the reader is advised that the authors, editors, reviewers, contributors, and publishers cannot be responsible for the continued currency of the information. All readers are advised that decisions regarding drug therapy and treatment must be based on the independent judgment of treating clinicians, current drug information (e.g., as reflected in literature and manufacturer's most current product information), and changing medical practices. The editors are not responsible for any inaccuracy of quotations or for any false or misleading implication that may arise due to the text or formulas as used or due to the quotation of revisions no longer official. PharMerica Corporation does not represent or warrant the accuracy of the information provided in this manual and nothing in this manual is intended to replace the treatment by an established clinician. No official support or endorsement by any federal or state agency or pharmaceutical company is intended or inferred.

CMS Requires INFLUENZA and PNEUMOCOCCAL Vaccinations to be Offered in Nursing Homes

The Centers for Medicare and Medicaid Services (CMS) historically **requires** nursing facilities participating in the Medicare and Medicaid programs to ***offer*** all residents **influenza** and **pneumococcal** vaccines, and to ***document*** the results. These requirements continue for this 2023-24 season. According to the mandates, each resident is to be vaccinated unless medically contraindicated, the resident or a legal representative refuses vaccination, or the vaccine is not available because of shortage (to be supported with documentation).

This information is to be reported in Section O of the CMS Minimum Data Set (MDS 3.0), which tracks nursing home health parameters. Specifically, MDS Items O0250 and O0300 of the RAI Version 3.0 Manual refer to the influenza and pneumococcal vaccines, respectively.



O0250. Influenza Vaccine - Refer to current version of RAI manual for current influenza vaccination season and reporting period

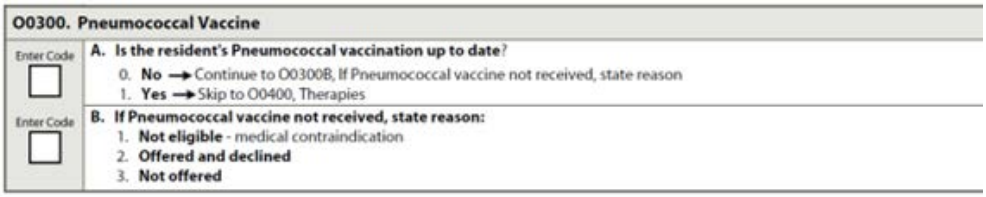
Enter Code

A. Did the **resident receive the influenza vaccine *in this facility*** for this year's influenza vaccination season?

0. **No** → Skip to O0250C, If influenza vaccine not received, state reason
1. **Yes** → Continue to O0250B, Date influenza vaccine received

B. Date influenza vaccine received → Complete date and skip to O0300A, Is the resident's Pneumococcal vaccination up to date?

Month – Day – Year



O0300. Pneumococcal Vaccine

Enter Code

A. Is the resident's Pneumococcal vaccination up to date?

0. **No** → Continue to O0300B, If Pneumococcal vaccine not received, state reason
1. **Yes** → Skip to O0400, Therapies

Enter Code

B. If Pneumococcal vaccine not received, state reason:

1. **Not eligible** - medical contraindication
2. **Offered and declined**
3. **Not offered**

Surveyors will assess each facility's vaccination policies and procedures for compliance during the annual survey. Noncompliance may be cited at F-tag 883.

In its collaborative effort to improve quality of care, CMS is also encouraging nursing facilities to provide influenza vaccine to their healthcare workers. Immunizing nursing staff has been shown to reduce mortality rates among residents of long-term care facilities.

CMS Issues Final Rule Lifting Mandatory COVID-19 Vaccination for Staff; Requirement to Educate on and Offer COVID-19 Vaccinations to Residents and Staff Continues

On May 11, 2021, CMS published an interim final rule with comment period (IFC), CMS-3414-IFC, titled "Medicare and Medicaid Programs, COVID-19 Vaccine Requirements for LTC Facilities and ICFs-IID Residents, Clients, and Staff." This IFC called for the novel COVID-19 vaccines to be treated in similar manner to influenza vaccines, with LTCFs bearing additional responsibility for ensuring all residents and staff receive appropriate education and the opportunity to be vaccinated.

In response to the expiration of the Public Health Emergency (PHE) on 5-11-23, CMS published a 6-5-23 final rule on this subject.

Notably, CMS provides guidance around the temporary regulations imposed during the PHE, stating that the final rule:

- **Removes** expired COVID-19 testing requirements, which were first implemented on September 2, 2020.
- **Withdraws** the interim rule's **requirement that all healthcare workers regulated by CMS be fully vaccinated**. Although this final rule that ends requirements related to staff vaccination for all provider types will not be effective until August 5, 2023, CMS has explicitly stated that it will not enforce the vaccination requirement in the interim.

- **Permanently adopts** policies requiring covered healthcare providers to **continue to educate and offer COVID-19 vaccinations to staff and residents**, essentially aligning the CMS approach for COVID-19 with that for other infectious diseases, specifically influenza.

Noncompliance related to the permanent requirements for **educating on** and **offering COVID-19 vaccination** will be cited at F-tag 887. Note, this tag does not appear in the current SOM Appendix PP. The tag is only viewable in the LTCSP software. Questions can be addressed to the CMS Nursing Home Survey team via email at NHSurveyDevelopment@cms.hhs.gov.

Medicare Coverage of Vaccinations

	Vaccine Preventable Disease	Examples of Products Covered
Part B	Influenza	Standard Quadrivalent, Recombinant Quadrivalent, High Dose, Adjuvanted
	Pneumococcal	Prevnar 13, Vaxneuvance, Prevnar 20, Pneumovax 23
	Hepatitis B[1]	Energix-B, Recombivax HB, Heplisav-B
	COVID-19[2]	Pfizer, Moderna (and other COVID-19 Vaccines under EUA/BLA)
	[1] Patients at Medium to High Risk for infection as designated by Medicare	
	[2] Medicare Part B covers COVID-19 vaccines/boosters, whether you have Original Medicare or a Medicare Advantage Plan.	
Part D[3]	Hep A/ Hep B	Twinrix
	Herpes Zoster	Shingrix
	HPV	Gardasil
	Tdap	Adacel, Boostrix
	Meningococcal	Menactra, Menveo
	RSV	Arexvy, Abrysvo
	Others	All commercially available vaccines (not otherwise covered by Part B) when they are reasonable and necessary to prevent illness
	[3] As of January 2023, all Medicare-covered vaccines should be free to beneficiaries (No cost-sharing through copayment, coinsurance, or deductible for covered vaccines)	
Part B with Clinical Review[4]	Rabies	Imovax, RabAvert
	Hep A	Havrix, VAQTA
	Tetanus Toxoid	Tetanus Toxoid
	Anthrax	BioThrax
	[4] Vaccines directly related to the treatment of an injury or a direct exposure to a disease or condition, such as rabies and tetanus	

What's New in Vaccines?

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Introduction

Vaccinations are an effective tool to protect against certain diseases and complications. Vaccines continue to reduce cases and deaths from preventable diseases in the United States.[1] The World Health Organization (WHO) estimates that vaccination prevents 3.5 -5 million deaths each year and helps individuals live healthier lives.[2] Through innovation, we have several types of vaccines (i.e., live-attenuated, nucleic acid based, viral vectored, virus-like particles, and recombinant protein) working through different mechanisms to engage the body's immune response.[1]

Respiratory Syncytial Virus

Respiratory Syncytial Virus (RSV) is a contagious respiratory virus that spreads via respiratory droplets or contaminated hard surfaces. It commonly causes mild cold-like symptoms including runny nose, coughing, sneezing, and fever. In older adults, especially those with underlying heart or lung disease, or weakened immune systems, RSV can develop into a serious infection such as bronchiolitis or pneumonia, requiring hospitalization.[3] Among adults 65 years of age and older, RSV leads to approximately 60,000-160,000 hospitalizations and 6,000-10,000 deaths each year.[4]

Currently, there are two vaccine products available: one adjuvanted recombinant RSV vaccine (RSVPreF3 Oa; Arexvy) and one non-adjuvanted recombinant RSV vaccine (RSVPreF; Abrysvo).[5] Table 1 provides additional information. Both vaccine products have demonstrated moderate to high efficacy in adults aged 60 years and over in the prevention of symptomatic RSV-associated lower respiratory tract disease (LRTD).[6]

Clinical Data Review

Papi and colleagues with GlaxoSmithKline are evaluating the efficacy of a single dose (Arexvy) and annual revaccination in adults aged 60 years and older via an ongoing Phase 3, randomized, placebo-controlled study. Approximately 25,000 participants were enrolled from 17 countries.[7,8] Participants will be followed for three consecutive RSV seasons in the Northern Hemisphere and two consecutive seasons in the Southern Hemisphere. The primary outcome is RSV-related LRTD confirmed by reverse-transcriptase polymerase chain reaction (RT-PCR). Surveillance for acute infection is completed through participants reporting as needed and through scheduled follow ups. Participants are required to report if they had at least two symptoms or signs of acute respiratory infection lasting at least 24 hours, starting 30 days after injection. Results from season 1 in the Northern Hemisphere were posted on June 22, 2023, and showed total vaccine efficacy (VE) against LRTD at 82.6% (96.95% CI, 57.9-94.1) and 56.1% (95% CI, 28.2% - 74.4%) during the second season.[8] VE against severe RSV related LRTD was 94.1% (95% CI, 62.4 – 99.9). Among participants with pre-existing comorbidities, VE was 94.6% (95% CI, 65.9-99.9). In adults aged 70-79 years of age, VE was 93.8% (95% CI, 60.2-99.9). Tolerability of the vaccine was favorable, and the adverse events reported most frequently included injection site pain, fatigue, myalgia, and headache.[9] Among participants from the exposed population, approximately 23,000, that completed 6 months of follow-up, 4.2% of the vaccine recipients and 4.0% of placebo recipients reported a serious adverse event. Fatalities were reported for both the vaccine and placebo groups, 49 (0.4%) and 58 (0.5%) respectively. A blinded assessment was completed, and alternative explanations were considered plausible based on time and presence of risk factors.[8] The trial is anticipated to end May 31, 2024.[7]

Walsh and colleagues with Pfizer are evaluating the efficacy, safety, and immunogenicity of a single dose (Abrysvo) vaccine to prevent LRTI-RSV in adults 60 years of age and older via an ongoing phase 3, randomized, double-blinded, placebo-controlled trial. Approximately 37,000 participants were enrolled from 7 countries.[10] There are two primary endpoints; VE against seasonal RSV-associated lower respiratory tract illness with at least two or three signs or symptoms and VE against RSV-associated acute respiratory illness. Analysis after the first season (August 31, 2021 through July 14, 2022) showed VE against a first episode of RSV-lower respiratory tract illness with at least two signs or symptoms as 66.7% (96.66% CI, 28.8-85.8).

VE for RSV-associated lower respiratory tract illness with at least three signs or symptoms was 85.7% (96.66% CI, 32.0 – 98.7). In subgroup analyses by age group, VE was similar for 60 to 69 years of age, 70 to 79 years of age, or ≥ 80 years of age, leading to maintained vaccine efficacy throughout the first season. When evaluating safety, a subgroup of 7,196 participants was included. Local reactions were reported more frequently by the vaccine recipients versus placebo recipients (12% vs. 7%) and the incidence of systemic events was similar between the two groups (27% and 26% respectively). The most common adverse events reported include injection-site pain, fatigue, and headache. Serious or life-threatening adverse events were reported in both vaccine and placebo participants (0.5% and 0.4% respectively). Three serious events were related to trial intervention by investigators and included a delayed allergic reaction; a combination of diplopia, paresthesia of palms and soles, and oculomotor and abducens nerve paralysis 8 days after injection; and a myocardial infarction 6 days after injection. No trial intervention-related deaths were reported.[11] The trial is anticipated to end February 26, 2025.[10]

Table 1. Comparison of Arexvy and Abrysvo[12,13]

	Arexvy	Abrysvo
Product	Respiratory Syncytial Virus Vaccine, Adjuvanted Suspension for IM injection	Respiratory Syncytial Virus Vaccine, Non-adjuvanted Solution for IM injection
Manufacturer	GlaxoSmithKline	Pfizer Inc.
Pharmacologic category	Inactivated (Viral); Vaccine, Recombinant	
Indication	Prevention of LRTD caused by RSV in people 60 years of age and older	
Dosage	Adults ≥ 60 years of age: 0.5 ml IM as single dose	
Preparation for administration	Prior to use, powder (lyophilized antigen vial) must be reconstituted with the liquid (adjuvant vial)	Reconstitute with provided syringe of sterile water diluent component
Storage requirements after reconstitution	Administer immediately or store in the refrigerator between 2° C (35.6° F) and 8° C (46.4° F) or at room temperature [up to 25° C (77° F)] for up to 4 hours Protect vials from light Do not freeze	Administer immediately or store at room temperature [15° C to 30° C (59° F to 86° F)] and use within 4 hours Do not store in refrigerated conditions Do not freeze
Adverse reactions	Most commonly reported (≥ 10%) were injection site pain, fatigue, myalgia, headache, arthralgia	Most commonly reported (≥ 10%) were fatigue, headache, pain at injection site, muscle pain
Availability	FDA approved May 2023; anticipated availability Fall 2023	FDA approved May 2023; anticipated availability third quarter of 2023

Recommendations

According to the Advisory Committee on Immunization Practices (ACIP) and The American Academy of Family Physicians (AAFP) for the 2023-2024 season, a single dose of RSV vaccine is recommended for adults aged 60 years and over using shared clinical decision-making.[6,14,15] Shared clinical guidance involves a discussion between a patient and his/her provider and is guided by patient's risk for disease, benefit versus risk, patient preferences, and provider's discretion.[16] Box 1 provides additional information on risk factors for severe disease. For optimal effect, vaccination should occur prior to the RSV season. Due to the pandemic, RSV seasonal patterns have yet to be re-established, therefore, vaccination for the 2023-2024 season should be offered once the vaccine becomes available.[6]

Box 1. Risk Factors for Severe RSV Disease[6,16]

Risk Factors
• Chronic lung disease (e.g., COPD, asthma) • Cardiovascular diseases (congestive heart failure, coronary artery disease) • Moderate or severe immune compromise • Diabetes mellitus • Neurologic or neuromuscular conditions • Kidney disorders • Liver disorders • Hematologic disorders • Frail individuals • Individuals of advanced age • Residents of nursing homes and ≥60 years of age

COVID-19

COVID-19 is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and spreads via respiratory droplets ranging from larger droplets to smaller aerosols. COVID-19 has a variety of signs and symptoms ranging from mild cold and flu-like symptoms to more serious complications such as shortness of breath, pneumonia, heart problems, acute kidney injury, or organ failure. Individuals at risk for serious complications or hospitalizations include older people and those with underlying medical conditions (e.g., diabetes, cardiovascular disease, respiratory disease, cancer).[17]

Vaccinations have been integral in reducing severity of symptoms and saving lives. According to Watson et al, an estimated 14.4 million deaths from COVID-19 were prevented in 185 countries and territories from December 8, 2020, to December 8, 2021.18The current vaccines authorized and available by the FDA are bivalent mRNA vaccines (Moderna, Pfizer-BioNTech) and protein subunit vaccine (Novavax, Adjuvanted).[19] In June 2023, the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) advised that a monovalent vaccine, targeting the subvariant of Omicron, XBB.1.5 should be developed for the fall due to the fact that XBB sublineages accounted for more than 95% of the circulating variants.[20]However, monovalent vaccines targeting the subvariant, XBB 1.5, have not been addressed in current guidelines.

Recommendations

The CDC recommendations, as of July 2023, state that everyone age 6 years and older should get 1 updated bivalent Pfizer-BioNTech or Moderna COVID-19 vaccine regardless of original vaccination status. Individuals aged 65 years and older may get 1 additional dose of COVID-19 of updated Pfizer-BioNTech or Moderna COVID-19 vaccine 4 or more months after and individuals who are moderately or severely immunocompromised may get 1 additional dose 2 or more months after the last updated COVID-19 vaccine. Those that received 1 dose of Janssen/Johnson and Johnson Vaccine are recommended to receive 1 bivalent mRNA dose at least 2 months after the previous dose due to the discontinuation of the Janssen vaccine in the United States.[21] Table 2 provides detailed recommendations for bivalent vaccination in adults.

Table 2. Recommendations for COVID-19 bi-valent vaccinations in adults[22-24]

	Pfizer	Moderna
Individuals 12 to 64 years of age, Not previously vaccinated	Single dose, 0.3 mL, IM	Single dose, 0.5 mL, IM
Individuals ≥ 65 years of age, Not previously vaccinated	Single dose, 0.3 mL *One additional dose, 0.3 mL may be administered ≥ 4 months after first does of authorized bivalent vaccine.	Single dose, 0.5 mL *One additional dose, 0.5 mL may be administered ≥ 4 months after first does of authorized bivalent vaccine.
Individuals 12-64 years, previously vaccinated with 1 or more doses of any monovalent COVID-19 vaccine	Single dose, 0.3 mL, ≥ 2 months after monovalent vaccine.	Single dose, 0.5 mL, ≥ 2 months after monovalent vaccine.
Individuals ≥ 65 years, previously vaccinated with 1 or more doses of any monovalent COVID-19 vaccine	Single dose, 0.3 mL, ≥ 2 months after monovalent vaccine. *One additional dose, 0.3 mL, may be administered ≥ 4 months after first dose of authorized bivalent vaccine.	Single dose, 0.5 mL, ≥ 2 months after monovalent COVID-19 vaccine. *One additional dose, 0.5 mL, may be administered ≥ 4 months after first dose of authorized bivalent vaccine.
Immunocompromised	≥ 5 years of age with certain kinds of immunocompromises, single additional age-appropriate dose may be administered at least 2 months following initial dose. Additional age-appropriate doses may be administered at the discretion of the healthcare provider.	≥ 6 years of age with certain kinds of immunocompromises, single additional age-appropriate dose may be administered at least 2 months following initial dose. Additional age-appropriate doses may be administered at the discretion of the healthcare provider.

Influenza

Influenza (flu) is a contagious virus that causes acute respiratory infection of the nose, throat, and lungs. Most individuals experience mild symptoms and will recover quickly without medical intervention. However, influenza can cause severe illness requiring hospitalization or death, especially among the very young, the elderly, and those with serious health conditions.[25]

Recommendations

In June 2023, The CDC adopted ACIP's 2023-2024 recommendations on annual influenza vaccination for everyone 6 months and older in the United States. The recommended timing of flu vaccination has not changed, with September or October being the ideal time for adults, especially those 65 years of age and older. However, the composition of the United States flu vaccine has been updated to match the indicated flu viruses that research suggests will be prominent.[26] Additional flu vaccine information will be provided when the annual recommendations become available in the Morbidity and Mortality Weekly Report (MMWR). Table 3 provides the updated flu vaccine component.

Table 3. Influenza Vaccine Updated Components[26]

Influenza A(H1N1) pdm09	A/Victoria/4897/2022(H1N1) pdm09-like virus for egg-based vaccines
	A/Wisconsin/67/2022(H1N1) pdm09-like virus for cell-based or recombinant vaccines.

Conclusion

Due to evolving diseases and medical advancements, vaccine schedules and recommendations are updated frequently to reflect the most recent and current information. This allows for effective and safe care to reach communities and individuals for protection and prevention from severe disease, hospitalization, or death.[27] It is recommended to routinely check ACIP for updated guidelines because changes can occur throughout the year. As healthcare providers, we are a valuable resource to patients regarding vaccine information and administration; leaving a lasting impact on the communities we serve.

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SEASONAL INFLUENZA

Summary of Recent Changes to Influenza Vaccines

Preferred Flu Vaccines in Older Adults: Since 2022, the CDC has endorsed the preferential recommendation for select flu vaccines in older adults, to include **higher dose (high dose** and **recombinant)** and **adjuvanted** vaccine products. Specifically, **Fluzone® High-Dose Quadrivalent, Flublok® Quadrivalent** and **Fluad® Quadrivalent** flu vaccines remain the preferred vaccine in older adults ≥65 years of age. However, if one of those vaccines is not available at the time of administration, people in this age group should get a standard-dose flu vaccine instead. There remains no preferential product recommendation for flu vaccination in people ≤ 65 years of age.[1]

Flu Vaccination Timing: The recommended timing of flu vaccination has not changed. **September** and **October** are the best times for most people to get vaccinated. Flu vaccination in July and August is not recommended for most people. For adults (especially those 65 years old and older) and pregnant people in the first and second trimester, vaccination in July and August should be avoided unless it won't be possible to vaccinate in September or October. Pregnant people who are in their third trimester can get a flu vaccine in July or August in order to ensure their babies are protected from flu after birth, when they are too young to get vaccinated. CDC continues to recommend vaccination as long as flu viruses pose a threat. During some seasons, that can be as late as May or June. Per **F883 – §483.80(d)(1)(ii):** *"Each resident is [to be] offered an influenza immunization October 1 through March 31 annually, unless the immunization is medically contraindicated, or the resident has already been immunized during this time period…"*

Flu Vaccination for People with Egg Allergies: The main change in the flu vaccine recommendations for this flu season relates to flu vaccination in people with egg allergies. Most flu vaccines today continue to be produced using an egg-based manufacturing process and therefore contain a small amount of egg proteins, such as ovalbumin. While ACIP has previously recommended that all people 6 months and older with egg allergy should be vaccinated for flu, in the past there have been additional safety measures recommended for administration of egg-based flu vaccine to people who have had severe allergic reactions to egg. The ACIP voted that **people with egg-allergy may receive any flu vaccine (egg-based or non-egg based) that is otherwise appropriate for their age and health status. Additional safety measures are no longer recommended for flu vaccination beyond those recommended for receipt of any vaccine.**

Most recently, the market consists of standard **quadrivalent, recombinant quadrivalent, high dose quadrivalent,** and **adjuvanted quadrivalent** formulations.

Standard Quadrivalent Vaccine

The quadrivalent flu vaccine targets four influenza strains: two influenza A viruses and two influenza B viruses, providing broader coverage against an additional B strain than the previous standard trivalent flu vaccine. Current standard formulations include Flu Vaccine Quad Vials (**AFLURIA®, FLUCELVAX®, FLUZONE® QUADRIVALENT**) and Flu Vaccine Quad Syringes (**AFLURIA®, FLUCELVAX®, FLULAVAL®, FLUARIX®, FLUZONE® QUADRIVALENT**).[2]

Recombinant Quadrivalent Vaccine

FLUBLOK® QUADRIVALENT is a recombinant flu vaccine. It is licensed in persons 18 years and older and is a *higher* dose vaccine, with three times the standard antigen amount, preferentially recommended in adults ages 65 years and older.

High Dose Quadrivalent Vaccine

FLUZONE® HD QUADRIVALENT is a high dose quadrivalent vaccine that contains four times the standard antigen amount, indicated specifically to engender a stronger immune response for persons 65 years of age and older.[3]

Adjuvanted Quadrivalent Vaccine

FLUAD® QUADRIVALENT is a standard dose quadrivalent flu vaccine licensed for adults 65 years of age and older that contains an adjuvant (MF59) designed to elicit a greater immune response to vaccination.[4]

1. CDC. Director Adopts Preference for Specific Flu Vaccines for Seniors. 30 Jun 2022. Web. 12 Jul 2023. https://www.cdc.gov/media/releases/2022/s0630-seniors-flu.html
2. CDC. Quadrivalent Influenza Vaccine. 25 Aug 2022. Web. 12 Jul 2023. https://www.cdc.gov/flu/prevent/quadrivalent.htm
3. CDC. Fluzone High-Dose Seasonal Influenza Vaccine. 30 May 2023. Web. 12 Jul 2023. https://www.cdc.gov/flu/prevent/qa_fluzone.htm
4. CDC. Adjuvanted Flu Vaccine. 25 Aug 2022. Web. 12 Jul 2023. https://www.cdc.gov/flu/prevent/adjuvant.htm

Influenza (Flu) Vaccine (Inactivated or Recombinant): *What you need to know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Influenza vaccine can prevent **influenza (flu)**.

Flu is a contagious disease that spreads around the United States every year, usually between October and May. Anyone can get the flu, but it is more dangerous for some people. Infants and young children, people 65 years and older, pregnant people, and people with certain health conditions or a weakened immune system are at greatest risk of flu complications.

Pneumonia, bronchitis, sinus infections, and ear infections are examples of flu-related complications. If you have a medical condition, such as heart disease, cancer, or diabetes, flu can make it worse.

Flu can cause fever and chills, sore throat, muscle aches, fatigue, cough, headache, and runny or stuffy nose. Some people may have vomiting and diarrhea, though this is more common in children than adults.

In an average year, **thousands of people in the United States die from flu**, and many more are hospitalized. Flu vaccine prevents millions of illnesses and flu-related visits to the doctor each year.

2. Influenza vaccines

CDC recommends everyone 6 months and older get vaccinated every flu season. **Children 6 months through 8 years of age** may need 2 doses during a single flu season. **Everyone else** needs only 1 dose each flu season.

It takes about 2 weeks for protection to develop after vaccination.

There are many flu viruses, and they are always changing. Each year a new flu vaccine is made to protect against the influenza viruses believed to be likely to cause disease in the upcoming flu season.

Even when the vaccine doesn't exactly match these viruses, it may still provide some protection.

Influenza vaccine **does not cause flu**.

Influenza vaccine may be given at the same time as other vaccines.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of influenza vaccine**, or has any **severe, life-threatening allergies**
- Has ever had **Guillain-Barré Syndrome** (also called "GBS")

In some cases, your health care provider may decide to postpone influenza vaccination until a future visit.

Influenza vaccine can be administered at any time during pregnancy. People who are or will be pregnant during influenza season should receive inactivated influenza vaccine.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting influenza vaccine.

Your health care provider can give you more information.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

4. Risks of a vaccine reaction

- Soreness, redness, and swelling where the shot is given, fever, muscle aches, and headache can happen after influenza vaccination.
- There may be a very small increased risk of Guillain-Barré Syndrome (GBS) after inactivated influenza vaccine (the flu shot).

Young children who get the flu shot along with pneumococcal vaccine (PCV13) and/or DTaP vaccine at the same time might be slightly more likely to have a seizure caused by fever. Tell your health care provider if a child who is getting flu vaccine has ever had a seizure.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at **www.cdc.gov/flu**.

Interim Guidance for Influenza Outbreak Management in Long-Term Care and Post-Acute Care Facilities

NOTE: This interim guidance was published for the 2022-2023 influenza season. No more recent version has been released. While information on outbreak management guidance is generally applicable year over year, users are reminded of this resource's publication date.

Co-circulation of Influenza Viruses and SARS-CoV-2

New Testing and Management Considerations for Nursing Home Residents with Acute Respiratory Illness Symptoms when SARS-CoV-2 and Influenza Viruses are Co-circulating

Please see Recommendations of the Advisory Committee on Immunization Practices – United States, 2022-2023 Season for the latest information regarding recommended influenza vaccines. Please see Antiviral Drugs: Information for Healthcare Professionals for the current summary of recommendations for clinical practice regarding the use of influenza antiviral medications. Please also refer to the Infectious Diseases Society of America (IDSA) 2018 Update on Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management of Seasonal Influenza

Long-term care facilities may be defined as institutions, such as nursing homes and skilled nursing facilities that provide healthcare to people (including children) who are unable to manage independently in the community. This care may represent custodial or chronic care management or short-term rehabilitative services.

Influenza can be introduced into a long-term care facility by newly admitted residents, healthcare personnel, and visitors. Spread of influenza can occur between and among residents, healthcare personnel and visitors. Residents of long-term care facilities can experience severe and fatal illness during influenza outbreaks.

Preventing transmission of influenza viruses and other infectious agents within healthcare settings, including in long-term care facilities, requires a multi-faceted approach that includes the following:

1. Influenza Vaccination
2. Influenza Testing
3. Infection Prevention and Control Measures
4. Antiviral Treatment
5. Antiviral Chemoprophylaxis

Before an Outbreak Occurs

Influenza vaccination should be provided routinely to all residents and healthcare personnel of long-term care facilities.

Residents

If possible, all residents should receive inactivated influenza vaccine (IIV) annually before influenza season. For persons aged ≥65 years, the following quadrivalent influenza vaccines are recommended: high-dose IIV, adjuvanted IIV, or recombinant influenza vaccine. If not available, standard-dose IIV may be given. In the majority of seasons, influenza vaccines will become available to long-term care facilities beginning in September, and influenza vaccination should be offered by the end of October. Informed consent is required to implement a standing order for vaccination, but this does not necessarily mean a signed consent must be present. Although vaccination by the end of October is recommended, influenza vaccine administered in December or later, even if influenza activity has already begun, is likely to be beneficial in the majority of influenza seasons because the duration of the season is variable, and influenza activity might not occur in certain communities until February or March.

In the event that a new patient or resident is admitted after the influenza vaccination program has concluded in the facility, the benefits of vaccination should be discussed, educational materials should be provided, and an opportunity for vaccination should be offered to the new resident as soon as possible after admission to the facility. Since October 2005, the Centers for Medicare and Medicaid Services (CMS) has required nursing homes participating in Medicare and Medicaid programs to offer all residents influenza and pneumococcal vaccines and to document the results. According to requirements, each resident is to be vaccinated unless contraindicated medically, the resident or legal representative refuses vaccination, or the vaccine is not available because of shortage. This information is to be reported as part of the CMS Minimum Data Set, which tracks nursing home health parameters.

Healthcare Personnel

CDC and the Advisory Committee on Immunization Practices (ACIP), recommend that all U.S. healthcare personnel get vaccinated annually against influenza.

Healthcare personnel who get vaccinated may help to reduce the following:

- Transmission of influenza
- Staff illness and absenteeism
- Influenza-related illness and death, especially among people at increased risk for severe influenza complications

Surveillance

When there is influenza activity in the local community, active daily surveillance (defined below) for influenza illness should be conducted among all new and current residents, healthcare personnel, and visitors of long-term care facilities, and continued until the end of influenza season. Healthcare personnel and visitors who are identified with any illness symptoms should be excluded from the facility until their illness has resolved. Older adults and other long-term care residents, including those who are medically fragile and those with neurological or neurocognitive conditions, may manifest atypical signs and symptoms of influenza virus infection (e.g. behavior change), and may not have fever. Ill residents should be placed on droplet precautions with room restriction and exclusion from participating in group activities as described below.

Influenza Testing

Even if it's not influenza season, influenza testing should occur when any resident has signs and symptoms of acute respiratory illness or influenza-like illness. Information about influenza testing is available at: https://www.cdc.gov/flu/professionals/diagnosis/index.htm.

More information about testing is included below.

When there is a confirmed or suspected influenza outbreak (2 or more ill residents)

If one laboratory-confirmed influenza positive case is identified along with other cases of acute respiratory illness in a unit of a long-term care facility, an influenza outbreak might be occurring. Active surveillance for additional cases should be implemented as soon as possible once one case of laboratory-confirmed influenza is identified in a facility. When 2 cases of laboratory-confirmed influenza are identified within 72 hours of each other in residents on the same unit, outbreak control measures should be implemented as soon as possible.

Implementation of outbreak control measures can also be considered as soon as possible when one or more residents have acute respiratory illness with suspected influenza and the results of influenza molecular tests are not available the same day of specimen collection. While unusual, an influenza outbreak can occur outside of the normal influenza season; therefore, testing for influenza viruses and other respiratory pathogens should also be performed during non-influenza season periods.

Even if it's not influenza season, influenza testing should occur when any resident has signs and symptoms that could be due to influenza*, and especially when two residents or more develop respiratory illness within 72 hours of each other.

*Note that older adults and other long-term care residents, including those who are medically fragile and those with neurological or neurocognitive conditions, may manifest atypical signs and symptoms of influenza virus infection (e.g. behavior change), and may not have fever (https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciy866/5251935).

- Determine if influenza virus is the causative agent by performing influenza testing on upper respiratory tract specimens (i.e. nasopharyngeal swab, nasal swabs, nasopharyngeal or nasal aspirates, or combined nasal and throat swabs) of ill residents with recent onset of signs and symptoms suggestive of influenza or acute respiratory illness.
- The following influenza tests are recommended: molecular assays, including rapid molecular assays, other molecular tests, or reverse transcription polymerase chain reaction (RT-PCR).
- If influenza molecular assays are not available and antigen detection tests are used such as rapid influenza diagnostic tests (RIDTs) or immunofluorescence assays, false negative results can occur because RIDTs and immunofluorescence assays have lower sensitivity than molecular assays for detection of influenza viruses. If influenza is suspected and RIDTs or immunofluorescence results are negative, perform confirmatory testing using molecular influenza assays. Information on influenza diagnostic testing is available online or by contacting your state public health laboratory.
- Influenza testing with molecular assays such as RT-PCR may be available at a local or state public health laboratory.
- Viral culture should be performed at a public health laboratory if additional information on influenza viruses, such as influenza A virus subtype, antigenic characterization to compare with influenza vaccine strains, or antiviral resistance data are needed.
- Determining influenza virus type or subtype of influenza A virus can help inform antiviral therapy decisions.

Implement daily active surveillance for acute respiratory illness among all residents, healthcare personnel and visitors to the facility.

- During an outbreak, once a single laboratory-confirmed case of influenza has been identified in a resident, it is likely there are other cases among exposed persons.
- Conduct daily active surveillance until at least 1 week after the last laboratory-confirmed influenza case was identified.
- Test for influenza with a molecular assay in the following:
    - Ill persons who are in the affected unit(s) as well as previously unaffected units in the facility
    - Persons who develop acute respiratory illness symptoms after beginning antiviral chemoprophylaxis

    **Note that older adults and other long-term care residents, including those who are medically fragile and those with neurological or neurocognitive conditions, may manifest atypical signs and symptoms of influenza virus infection (e.g. behavior change), and may not have fever.*
- Ensure that the laboratory performing influenza testing notifies the facility of tests results promptly.
- The local public health and state health departments should be notified of every suspected or confirmed influenza outbreak in a long-term care facility, especially if a resident develops influenza while on or after receiving antiviral chemoprophylaxis.

Implement Standard and Droplet Precautions for all residents with suspected or confirmed influenza.

CDC's guidance titled Prevention Strategies for Seasonal Influenza in Healthcare Settings contains details on the prevention strategies for all healthcare settings. Specific recommendations are highlighted below.

Standard Precautions are intended to be applied to the care of all patients in all healthcare settings, regardless of the suspected or confirmed presence of an infectious agent. Implementation of Standard Precautions constitutes the primary strategy for the prevention of healthcare-associated transmission of infectious agents among patients and healthcare personnel.

Examples of standard precautions include:

- Wearing gloves if hand contact with respiratory secretions or potentially contaminated surfaces is anticipated.
- Wearing a gown if soiling of clothes with a resident's respiratory secretions is anticipated.
- Changing gloves and gowns after each resident encounter and performing hand hygiene.
- Perform hand hygiene before and after touching the resident, after touching the resident's environment, or after touching the resident's respiratory secretions, whether or not gloves are worn. Gloves do not replace the need for performing hand hygiene.

Droplet Precautions are intended to prevent transmission of pathogens spread through close respiratory or mucous membrane contact with respiratory secretions. Droplet Precautions should be implemented for residents with suspected or confirmed influenza for 7 days after illness onset or until 24 hours after the resolution of fever and respiratory symptoms, whichever is longer, while a resident is in a healthcare facility.

Examples of Droplet Precautions include:

- Placing ill residents in a private room. If a private room is not available, place (cohort) residents suspected of having influenza residents with one another;
- Wear a facemask (e.g., surgical or procedure mask) upon entering the resident's room. Remove the facemask when leaving the resident's room and dispose of the facemask in a waste container.
- If resident movement or transport is necessary, have the resident wear a facemask (e.g., surgical or procedure mask), if possible.
- Communicate information about patients with suspected, probable, or confirmed influenza to appropriate personnel before transferring them to other departments.

These precautions are part of the overall infection control strategy to protect against influenza in healthcare settings and should be used along with other infection control measures, such as isolation or cohorting of ill residents, screening employees and visitors for illness, furloughing ill healthcare personnel, and discouraging ill visitors from entering the facility.

In some cases, facilities may choose to apply Standard Precautions and Droplet Precautions for longer periods based on clinical judgment, such as in the case of young children or severely immunocompromised residents, who may shed influenza virus for longer periods of time.

Because residents with influenza may continue to shed influenza viruses while on antiviral treatment, infection control measures to reduce transmission, including following Standard and Droplet Precautions, should continue while the resident is taking antiviral therapy. This will also reduce transmission of viruses that may have become resistant to antiviral drugs during therapy.

Administer influenza antiviral treatment and chemo-prophylaxis to residents and healthcare personnel according to current recommendations.

All long-term care facility residents who have confirmed or suspected influenza should receive antiviral treatment immediately.

Initiation of antiviral treatment should not wait for laboratory confirmation of influenza.

Antiviral treatment works best when started within the first 2 days of symptoms. However, these medications can still help when given after 48 hours to those that are very sick, such as those who are hospitalized, have progressive illness, or meet any of the high risk criteria outlined in this document from the CDC.

Four influenza antiviral drugs approved by the U.S. Food and Drug Administration are recommended for treatment of uncomplicated influenza in the United States: **neuraminidase inhibitors**: oral **oseltamivir** (available as a generic version or under the trade name Tamiflu®), as a pill or suspension; **zanamivir** (trade name Relenza®), available as an inhaled powder using a disk inhaler device; and intravenous **peramivir** (trade name Rapivab®); and a cap-dependent endonuclease inhibitor: **baloxavir marboxil** (trade name Xofluza®). It should be noted that some long-term care residents may have difficulty using the inhaler device for zanamivir.

Amantadine and **rimantadine** are **NOT** recommended for use because of high levels of antiviral resistance to these drugs among circulating influenza A viruses.

The recommended dosing and duration of antiviral treatment is twice daily for 5 days for neuraminidase inhibitors (oseltamivir and zanamivir), and one dose for intravenous peramivir. Oseltamivir is recommended for treatment of influenza in people of all ages. Baloxavir is approved for early treatment of uncomplicated influenza in people 5 years and older who are otherwise healthy or in people aged 12 years and older who are at higher risk for influenza complications and have been ill for no more than 2 days. A single oral dose of baloxavir is equivalent to 5 days of twice daily oral oseltamivir. Inhaled zanamivir is approved for early treatment of influenza in persons aged 7 years and older. Peramivir is approved for early treatment of influenza in persons aged 6 months and older. Dosage adjustment may be required for children and persons with certain underlying conditions. Clinicians should consult the manufacturers' package insert for approved ages, recommended drug dosing adjustments and contraindications.

In the setting of an influenza outbreak, empiric antiviral treatment should be given as soon as possible to residents with suspected influenza without waiting for influenza testing results, especially if results will not be available on the day of specimen collection. There are no data on use of baloxavir to control influenza outbreaks in long-term care facilities. Baloxavir is not recommended for pregnant women, severely immunosuppressed persons, those with severe disease, or hospitalized influenza patients. There are no data on baloxavir in these populations.

Having preapproved orders from physicians or plans to obtain orders for antiviral medications on short notice can substantially expedite administration of antiviral medications.

For more information on the antiviral agents, see CDC's influenza antiviral medication page for health professionals.

All exposed residents with influenza cases on units or wards in the long-term care facility (currently impacted wards) should receive antiviral chemoprophylaxis as soon as an influenza outbreak is determined (https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciy866/5251935).

When at least 2 patients are ill within 72 hours of each other and at least one resident has laboratory-confirmed influenza, the facility should promptly initiate antiviral chemoprophylaxis with oral oseltamivir to all non-ill residents living on the same unit as the resident with laboratory-confirmed influenza (outbreak affected units), regardless of whether they received influenza vaccination during the current season. Consideration may be given for extending antiviral chemoprophylaxis to residents on other unaffected units or wards in the long-term care facility based upon other factors (e.g. unavoidable mixing of residents or healthcare personnel from affected units and unaffected units).

Antiviral chemoprophylaxis is meant for residents who are not exhibiting influenza-like illness but who may be exposed or who may have been exposed to an ill person with influenza, to prevent transmission.

Use of antiviral drugs for chemoprophylaxis of influenza is a key component of influenza outbreak control in institutions that house residents at higher risk of influenza complications. While highly effective, antiviral chemoprophylaxis is not 100% effective in preventing influenza illness. Oseltamivir is the recommended antiviral drug for chemoprophylaxis of influenza in long-term care settings. Baloxavir is approved for post-exposure antiviral chemoprophylaxis of influenza in persons aged 5 years and older but no data are available from clinical trials of baloxavir chemoprophylaxis of influenza in long-term care facility residents.

CDC recommends antiviral chemoprophylaxis with oseltamivir for a minimum of 2 weeks and continuing for at least 7 days after the last known laboratory-confirmed influenza case was identified on affected units.

Persons whose need for antiviral chemoprophylaxis is attributed to potential exposure to a person with laboratory-confirmed influenza should receive oral oseltamivir or inhaled zanamivir. Zanamivir should be used when persons require chemoprophylaxis as a result of exposure to influenza virus strains that are suspected or known to be oseltamivir-resistant.

(For more information see Recommended Dosage and Duration of Treatment or Chemoprophylaxis for Influenza Antiviral Medications and https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciy866/5251935.)

Antiviral chemo-prophylaxis can be considered or offered to unvaccinated personnel who provide care to persons at higher risk of influenza complications.

While CDC recommends judicious use of antiviral medications for chemoprophylaxis to reduce the possibility of development and spread of antiviral resistant influenza viruses, chemoprophylaxis may be considered for healthcare personnel, regardless of their influenza vaccination status, if the outbreak is caused by a strain of influenza virus that is not well matched by the vaccine, or based upon other factors (e.g. to reduce the risk of short staffing in facilities and units where clinical staff are limited and to reduce staff reluctance to provide care to residents with suspected or laboratory-confirmed influenza).

Antiviral chemoprophylaxis should also be considered in personnel for whom influenza vaccine is contraindicated.

An emphasis on close monitoring and early initiation of antiviral treatment is an alternative to chemoprophylaxis in managing certain persons who have had a suspected exposure to influenza virus. Healthcare personnel who have occupational exposures can be counseled about the early signs and symptoms of influenza and advised to contact their healthcare provider immediately for evaluation and possible early initiation of antiviral treatment if clinical signs or symptoms develop.

For newly vaccinated healthcare personnel, antiviral chemoprophylaxis can be considered for up to 2 weeks following inactivated influenza vaccination until vaccine-induced immunity is acquired. Persons receiving antiviral

chemoprophylaxis should not receive live attenuated influenza virus vaccine (LAIV), and persons receiving LAIV should not receive antiviral treatment or chemoprophylaxis until 14 days after LAIV administration.

The latest CDC antiviral recommendations are available on CDC's influenza antiviral drugs page for health professionals.

Be Aware of the Possibility of an Antiviral Drug-Resistant Virus

Residents receiving antiviral medications who do not respond to treatment or who become sick with influenza after starting chemoprophylaxis might have an infection with an antiviral-resistant influenza virus. Persons receiving chemoprophylaxis who become sick should be switched to treatment dosing. If infection with an antiviral-resistant influenza virus is suspected, the local or state public health department should be notified promptly.

To limit the potential transmission of antiviral drug-resistant influenza virus, whether in chronic or acute-care settings or other closed settings, measures should be taken to reduce contact between ill persons taking antiviral drugs for treatment and other persons, including those receiving antiviral chemoprophylaxis.

Infection prevention and control measures are especially important for patients who are immunocompromised to reduce the risk for transmission of oseltamivir-resistant viruses.

Notify the health department if a resident develops influenza while on or after receiving antiviral chemoprophylaxis.

Consider the following additional measures to reduce transmission among residents and healthcare personnel:

- Have symptomatic residents stay in their own rooms as much as possible, including restricting them from common activities, and have their meals served in their rooms when possible.
- Limit the number of large group activities in the facility and consider serving all meals in resident rooms if possible when the outbreak is widespread (involving multiple units of the facility).
- Avoid new admissions or transfers to wards with symptomatic residents.
- Limit visitation and exclude ill persons from visiting the facility via posted notices. Consider restricting visitation by children during community outbreaks of influenza.
- Monitor healthcare personnel absenteeism due to respiratory symptoms and exclude those with influenza-like symptoms from work until at least 24 hours after they no longer have a fever.
- Restrict healthcare personnel movement from areas of the facility having illness to areas not affected by the outbreak.
- Administer the current season's influenza vaccine to unvaccinated residents and healthcare personnel as per current vaccination recommendations. For the latest information on influenza vaccination, see CDC's seasonal influenza vaccination resources for health professionals page.

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*Patients with illness associated with influenza virus infection often have fever or feverishness with cough, chills, headache, myalgias, sore throat, or runny nose. Some patients, such as older adults, children with neuromuscular disorders, and young infants, may have atypical clinical presentations. Older adults and other long-term care residents, including those who are medically fragile and those with neurological or neurocognitive conditions, may manifest atypical signs and symptoms of influenza virus infection (e.g. behavior change), and may not have fever (https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciy866/5251935).

Last Reviewed: November 21, 2022

Influenza Antiviral Medications: Summary for Clinicians

The information on this page should be considered current for the 2022-2023 influenza season for clinical practice regarding the use of influenza antiviral medications. This CDC resource was last updated on September 9, 2022. Users are encouraged to check the primary resource here for more recent updates.

Priority Groups for Antiviral Treatment of Influenza

Antiviral treatment is recommended **as soon as possible** for any patient with suspected or confirmed influenza who:

- is hospitalized;
- has severe, complicated, or progressive illness; or
- is at higher risk for influenza complications.

Decisions about starting antiviral treatment for patients with suspected influenza should not wait for laboratory confirmation of influenza virus infection. Empiric antiviral treatment should be started as soon as possible in the above priority groups.

Clinicians can consider early empiric antiviral treatment of non-high-risk outpatients with suspected influenza [e.g., influenza-like illness (fever with either cough or sore throat)] based upon clinical judgement, if treatment can be initiated within 48 hours of illness onset.

Antiviral Drug Options

- For hospitalized patients with suspected or confirmed influenza, initiation of antiviral treatment with oral or enterically-administered **oseltamivir** is recommended as soon as possible.
- For outpatients with complications or progressive disease and suspected or confirmed influenza (e.g., pneumonia, or exacerbation of underlying chronic medical conditions), initiation of antiviral treatment with oral **oseltamivir** is recommended as soon as possible.
- For outpatients with suspected or confirmed uncomplicated influenza, oral oseltamivir, inhaled zanamivir, intravenous peramivir, or oral baloxavir may be used for treatment, depending upon approved age groups and contraindications. In one randomized controlled trial, baloxavir had greater efficacy than oseltamivir in adolescents and adults with influenza B virus infection (Ison, 2020).

Co-circulation of Influenza Viruses and SARS-CoV-2

During periods of community co-circulation of influenza viruses and SARS-CoV-2, empiric antiviral treatment of influenza is recommended as soon as possible for the following priority groups: a) hospitalized patients with respiratory illness; b) outpatients with severe, complicated, or progressive respiratory illness; and c) outpatients at higher risk for influenza complications who present with any acute respiratory illness symptoms (with or without fever).

- Influenza and COVID-19 have overlapping signs and symptoms. Testing can help distinguish between influenza virus infection and SARS-CoV-2 infection. However, clinicians should not wait for the results of influenza testing (view CDC Table 3), SARS-CoV-2 testing, or multiplex molecular assays that detect influenza A and B viruses and SARS-CoV-2 (View CDC Table 4) to initiate empiric antiviral treatment for influenza in the above priority groups.
- Co-infection with influenza A or B viruses and SARS-CoV-2 can occur and should be considered, particularly in hospitalized patients with severe respiratory disease.
    - Clinicians should be aware that a positive SARS-CoV-2 test result does not preclude influenza virus infection. For hospitalized patients with suspected influenza who are started on empiric antiviral treatment with oseltamivir, use of influenza molecular assays (view Table 3) or multiplex assays that detect both influenza viruses and SARS-CoV-2 (view Table 4) can inform clinical management.

  - Clinicians should be aware that a positive influenza test result does not preclude SARS-CoV-2 infection. For hospitalized patients with a positive influenza test result, antiviral treatment of influenza with oseltamivir should be started as soon as possible, and clinicians should also follow guidelines for diagnosis and treatment of community-acquired pneumonia (view community acquired pneumonia treatment guidance for adults: Metlay, 2019) and other respiratory infections, including SARS-CoV-2 infection (view NIH COVID-19 treatment guidelines and IDSA COVID-19 treatment guidelines) if clinically indicated, while awaiting SARS-CoV-2 testing results. Oseltamivir does not have in vitro activity against SARS-CoV-2 (Choy, 2020).

- Clinicians can utilize telemedicine in place of office visits for patients with acute respiratory illness. It may be useful for providers to implement phone triage lines to enable high-risk patients to discuss symptoms over the phone. Please see https://www.cdc.gov/flu/professionals/antivirals/office-evaluation.htm.
- Patients at higher risk for influenza complications should be advised to call their provider as soon as possible if they have acute respiratory illness symptoms (with or without fever) for consideration of infection with influenza A or B viruses (and early antiviral treatment), SARS-CoV-2, and other respiratory pathogens.
- Clinicians can consider starting early (≤48 hours after illness onset) empiric antiviral treatment of non-high-risk outpatients with suspected influenza [e.g., influenza-like illness (fever with either cough or sore throat)], based upon clinical judgement, including without an office visit. SARS-CoV-2 and other etiologies of influenza-like illness should also be considered.
- National Institutes of Health (NIH) COVID-19 Treatment Guidelines: Influenza and COVID-19 are available.
- Clinical algorithms for the testing and treatment of influenza when SARS-CoV-2 and influenza viruses are circulating are also available.

Abridged Overview of Influenza Antiviral Medications

Antiviral medications with activity against influenza viruses are an important adjunct to influenza vaccine in the control of influenza.

- Influenza antiviral prescription drugs can be used to **treat** influenza, and some can be used to **prevent** influenza.
- **Six** licensed prescription influenza antiviral drugs are approved in the United States.
  - **Four** influenza antiviral medications approved by the U.S. Food and Drug Administration (FDA) were recommended for use in the United States during the 2022-2023 influenza season.
    - **Three** drugs are chemically related antiviral medications known as neuraminidase inhibitors that block the viral neuraminidase enzyme and have activity against both influenza A and B viruses: oral **oseltamivir phosphate** (available as a generic version or under the trade name Tamiflu®), inhaled **zanamivir** (trade name Relenza®), and intravenous **peramivir** (trade name Rapivab®).
    - The fourth drug is oral **baloxavir marboxil** (trade name Xofluza®), which is active against both influenza A and B viruses but has a different mechanism of action than neuraminidase inhibitors. Baloxavir is a cap-dependent endonuclease inhibitor that interferes with viral RNA transcription and blocks virus replication.
    - More information regarding the four recommended antiviral medications is available: Table 1.
- **Amantadine and rimantadine** are **not** recommended for antiviral treatment or chemoprophylaxis of currently circulating influenza A viruses.
- Antiviral resistance and reduced susceptibility to the neuraminidase inhibitors and to baloxavir among circulating influenza viruses is currently very low, but this can change.
- Clinical trials and observational data show that early antiviral treatment can shorten the duration of fever and illness symptoms, and may reduce the risk of some complications from influenza (e.g., otitis media in young children, pneumonia, and respiratory failure).
  - Early treatment of hospitalized adult influenza patients with oseltamivir has been reported to reduce death in some observational studies.

- In hospitalized children, early antiviral treatment with oseltamivir has been reported to shorten the duration of hospitalization in observational studies.
- Clinical benefit is greatest when antiviral treatment is administered early, especially within 48 hours of influenza illness onset in clinical trials and observational studies.

Last Reviewed September 9, 2022

Table 1. Antiviral Medications Recommended for Treatment and Chemoprophylaxis of Influenza

Antiviral Agent	Activity Against	Use	Recommended For	Not Recommended for Use in	Adverse Events
Oral Oseltamivir	Influenza A and B	Treatment	Any age[1]	N/A	**Adverse events:** nausea, vomiting, headache. Post marketing reports of serious skin reactions and sporadic, transient neuropsychiatric events[2]
		Chemo-prophylaxis	3 months and older[1]	N/A	
Inhaled Zanamivir	Influenza A and B	Treatment	7 yrs and older[3]	people with underlying respiratory disease (e.g., asthma, COPD)[3]	**Adverse events:** risk of bronchospasm, especially in the setting of underlying airways disease; sinusitis, and dizziness. Post marketing reports of serious skin reactions and sporadic, transient neuropsychiatric events[2]
		Chemo-prophylaxis	5 yrs and older[3]	people with underlying respiratory disease (e.g., asthma, COPD)[3]	
Intravenous Peramivir	Influenza A and B[4]	Treatment	6 months and older[4]	N/A	**Adverse events:** diarrhea. Post marketing reports of serious skin reactions and sporadic, transient neuropsychiatric events[2]
		Chemo-prophylaxis[5]	Not recommended	N/A	
Oral Baloxavir	Influenza A and B[6]	Treatment	5 yrs and older[6]	N/A	**Adverse events:** non more common than placebo in clinical trials
		Chemo-prophylaxis[6]	Approved for post-exposure prophylaxis in persons 5 yrs and older[6]		

Abbreviations: N/A = not applicable, COPD = chronic obstructive pulmonary disease.

Table 1 Resources

[1] Oral oseltamivir phosphate is approved by the FDA for treatment of acute uncomplicated influenza within 2 days of illness onset in people 14 days and older, and for chemoprophylaxis in people 1 year and older. Although not part of the FDA-approved indications, use of oral oseltamivir for treatment of influenza in infants less than 14 days old, and for chemoprophylaxis in infants 3 months to 1 year, is recommended by the CDC and the American Academy of Pediatrics. If a child is younger than 3 months old, use of oseltamivir for chemoprophylaxis is not recommended unless the situation is judged critical due to limited data in this age group.

[2] Self-injury or delirium; mainly reported among Japanese pediatric patients.

[3] Inhaled zanamivir is contraindicated in patients with underlying airways disease such as asthma or chronic obstructive pulmonary disease, and those with a history of allergy to lactose or milk protein.

[4] Intravenous peramivir is approved by the FDA for treatment of acute uncomplicated influenza within 2 days of illness onset in people 6 months and older. Peramivir efficacy is based on clinical trials versus placebo in which the predominant influenza virus type was influenza A; in one trial, a very limited number of subjects infected with influenza B virus were enrolled.

[5] There are no data available for use of peramivir for chemoprophylaxis of influenza.

[6] Oral baloxavir marboxil is approved by the FDA for treatment of acute uncomplicated influenza within 2 days of illness onset in people aged ≥5 years who are otherwise healthy, or in people aged ≥12 years who are high risk of developing influenza-related complications. Baloxavir efficacy for initial FDA approval in October 2018 was based on clinical trials in previously healthy outpatients 12 to 64 years old (Hayden, 2018). Single-dose baloxavir treatment was superior to placebo and had similar clinical efficacy in time to alleviation of symptoms to a 5-day treatment course of oseltamivir. In October 2019, FDA approved an indication for baloxavir treatment of acute uncomplicated influenza within 2 days of illness onset in people 12 years and older at high risk of developing influenza-related complications, based upon the findings of a clinical trial (Ison, 2020). In this clinical trial of early initiation of antiviral treatment for uncomplicated influenza in high-risk patients, baloxavir was superior to placebo and had similar overall efficacy to oseltamivir in the time to alleviation of symptoms. For patients with influenza B virus infection, baloxavir significantly reduced the median time to improvement of symptoms compared with oseltamivir by more than 24 hours. However, there are no available data for baloxavir treatment of influenza in pregnant women, immunocompromised people, or in people with severe influenza who are not hospitalized. In August 2022, FDA expanded approval of baloxavir for treatment of acute uncomplicated influenza within 2 days of illness onset in children aged 5 years to <11 years who are otherwise healthy. [package insert]. This was based upon the secondary clinical outcomes of a randomized clinical trial of baloxavir versus oseltamivir for treatment of uncomplicated influenza in children aged 1 year to <12 years (Baker, 2021). In November 2020, FDA expanded approval of baloxavir to include post-exposure prophylaxis of influenza for persons aged ≥12 years within 48hours of contact with an individual with influenza, based on the findings of a clinical trial among household contacts of index patient with influenza (Ikematsu, 2020). In this study, baloxavir post-exposure prophylaxis (PEP) of influenza in household members (19% were younger than 12 years; 73% received baloxavir within 24 hours of onset of symptoms in the index household case who received antiviral treatment) significantly reduced the risk of laboratory-confirmed by 86%among those who received baloxavir PEP than among those who received placebo (1.9% [7 of 374] vs. 13.6% [51 of 375];adjusted risk ratio, 0.14; 95% confidence interval [CI], 0.06 to 0.30; P<0.001). In August 2022, FDA expanded approval of baloxavir for post-exposure prophylaxis of influenza in persons aged 5 years and older within 48 hours of contact with an individual with influenza. [package insert]. A randomized clinical trial reported that combination neuraminidase inhibitor (primarily oseltamivir) and baloxavir for treatment of hospitalized influenza patients aged ≥12 years did not result in superior clinical benefit (time to clinical improvement) compared with neuraminidase inhibitor and placebo (Kumar, 2022).

Abridged Summary of Influenza Antiviral Treatment Recommendations

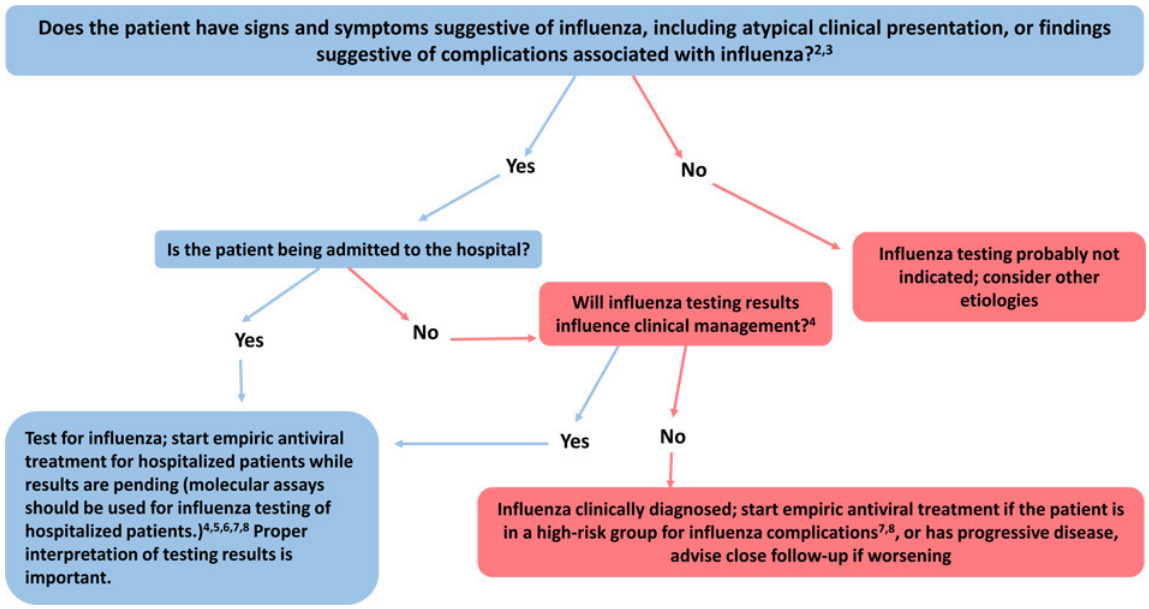
Antiviral treatment is recommended ***as soon as possible*** for any patient with suspected or confirmed influenza who:

- is hospitalized;*
- has severe, complicated, or progressive illness;* or
- is at higher risk for influenza complications.

Note: Oral oseltamivir is the recommended antiviral for patients with severe, complicated, or progressive illness who are not hospitalized, and for hospitalized influenza patients.

- Antiviral treatment also can be considered for any previously healthy, symptomatic outpatient not at high risk for influenza complications, who is diagnosed with confirmed or suspected influenza, on the basis of clinical judgment, if treatment can be initiated within 48 hours of illness onset.

Figure 1. Guide for considering influenza testing and treatment when influenza viruses are circulating in the community (regardless of influenza vaccination history) [1]



Complete footnotes (1-8) for this algorithm are available.

- Clinical judgment, on the basis of the patient's disease severity and progression, age, underlying medical conditions, likelihood of influenza, and time since onset of symptoms, is important when making antiviral treatment decisions for outpatients at increased risk of severe disease.
- When indicated, antiviral treatment should be started as soon as possible after illness onset, ideally within 48 hours of symptom onset. However, antiviral treatment might have some benefits in patients with severe, complicated or progressive illness, and in hospitalized patients when started after 48 hours of illness onset.
- ***Decisions about starting antiviral treatment should not wait for laboratory confirmation of influenza*** (see resources regarding Clinical Description and Lab Diagnosis of Influenza for more information on influenza diagnostic testing).
    - Clinical benefit is greatest when antiviral treatment is started as close to illness onset as possible.
- Antiviral treatment also can be considered for any previously healthy, symptomatic outpatient not at increased risk of severe disease with confirmed or suspected influenza on the basis of clinical judgment, if treatment can be initiated within 48 hours of illness onset.

- ***For outpatients with acute uncomplicated influenza, oral oseltamivir, inhaled zanamivir, intravenous peramivir, or oral baloxavir may be used for treatment.***
    - The recommended treatment course for uncomplicated influenza is two doses per day of oral oseltamivir or inhaled zanamivir for 5 days, or one dose of intravenous peramivir or oral baloxavir for 1 day.
    - Only one randomized clinical trial has compared baloxavir to oseltamivir for treatment of influenza B. This study found that baloxavir treatment was superior to oseltamivir among outpatients with influenza B virus infection (Ison, 2020).
    - CDC does not recommend use of baloxavir for treatment of influenza in pregnant women or breastfeeding mothers. There are no available efficacy or safety data for baloxavir in pregnant women, and there are no available data on the presence of baloxavir in human milk, the effects on the breastfed infant, or the effects on milk production.
    - CDC does not recommend use of baloxavir for monotherapy of influenza in severely immunosuppressed persons. There are no available efficacy, safety, or resistance data for baloxavir monotherapy of influenza in severely immunosuppressed patients and emergence of resistance during treatment is a concern because of prolonged influenza viral replication in these patients.
    - There are no available data on the use of baloxavir for treatment of influenza more than 2 days after illness onset.
- ***Oral oseltamivir is preferred for treatment of pregnant people.***
    - Baloxavir is not recommended for the treatment of influenza in pregnant people, as there are no available efficacy or safety data for baloxavir in this population.
- ***For patients with severe or complicated illness with suspected or confirmed influenza (e.g. pneumonia, or exacerbation of underlying chronic medical condition) who are not hospitalized, antiviral treatment with oral or enterically-administered oseltamivir is recommended as soon as possible.*** There are insufficient data for inhaled zanamivir and intravenous peramivir in patients with severe influenza disease. There are no available data from clinical trials on use of baloxavir treatment in patients with severe influenza disease.

Last Reviewed September 9, 2022

Table 2. Recommended Dosage and Duration of Influenza Antiviral Medications for Treatment or Chemoprophylaxis

Antiviral Agent	Use	Children	Adults
Oral Oseltamivir	**Treatment (5 days)[1]**	**If younger than 1 yr old[2]:** 3 mg/kg/dose twice daily[3,4] **If 1 yr or older, dose varies by child's weight:** 15 kg or less, the dose is 30 mg **twice** a day >15 to 23 kg, the dose is 45 mg **twice** a day >23 to 40 kg, the dose is 60 mg **twice** a day >40 kg, the dose is 75 mg **twice** a day	75 mg **twice** daily
	Chemo-prophylaxis (7 days)[5]	If child is younger than 3 months old, use of oseltamivir for chemoprophylaxis is not recommended unless situation is judged critical due to limited data in this age group. **If child is 3 months or older and younger than 1 yr old[2]** 3 mg/kg/dose once daily[3] **If 1 yr or older, dose varies by child's weight:** 15 kg or less, the dose is 30 mg **once** a day >15 to 23 kg, the dose is 45 mg **once** a day >23 to 40 kg, the dose is 60 mg **once** a day >40 kg, the dose is 75 mg **once** a day	75 mg **once** daily
Inhaled Zanamivir[6]	**Treatment (5 days)**	10 mg (two 5-mg inhalations) **twice** daily (**FDA approved and recommended for use in children 7 yrs or older**)	10 mg (two 5-mg inhalations) **twice** daily
	Chemo-prophylaxis (7 days)[5]	10 mg (two 5-mg inhalations) **once** daily (**FDA approved for and recommended for use in children 5 yrs or older**)	10 mg (two 5-mg inhalations) **once** daily
Intravenous Peramivir[7]	**Treatment (1 day)[1]**	(6 months to 12 yrs of age) One 12 mg/kg dose, up to 600 mg maximum, via intravenous infusion for a minimum of 15 minutes (**FDA approved and recommended for use in children 6 months or older**)	(13 yrs and older) One 600 mg dose, via intravenous infusion for a minimum of 15 minutes
	Chemo-prophylaxis[8]	Not recommended	N/A
Oral Baloxavir[9]	**Treatment (1 day)**	(5 yrs and older weighing <20 kg: single dose of 2 mg/kg by suspension; weighing 20 kg to <80 kg: single dose of 40 mg by tablet or suspension; weighing ≥80 kg: single dose of 80 mg by tablet or suspension) **FDA approved and recommended for use in otherwise healthy children 5 yrs and older.**	Weight <80 kg: One 40 mg dose; weight ≥80 kg: One 80 mg dose[9]
	Chemo-prophylaxis[9]	**FDA-approved for post-exposure prophylaxis for persons aged 5 years and older. Dosage is the same as for treatment.**	Dosage is the same as for treatment

Abbreviations: N/A = not applicable,

Table 2 Resources

[1]Longer treatment duration may be needed for severely ill patients.

[2]Oral oseltamivir is approved by the FDA for treatment of acute uncomplicated influenza within 2 days of illness onset with twice-daily dosing in people 14 days and older, and for chemoprophylaxis with once-daily dosing in people 1 year and older. Although not part of the FDA-approved indications, use of oral oseltamivir for treatment of influenza in infants less than 14 days old, and for chemoprophylaxis in infants 3 months to 1 year of age, is recommended by CDC and the American Academy of Pediatrics (Committee on Infectious Diseases, 2022).

[3]This is the FDA-approved oral oseltamivir treatment dose for infants 14 days and older and less than 1 year old and provides oseltamivir exposure in children similar to that achieved by the approved dose of 75 mg orally twice daily for adults, as shown in two studies of oseltamivir pharmacokinetics in children (Kimberlin, 2013 [CASG 114], EU study WP22849, FDA Clinical Pharmacology Review). The American Academy of Pediatrics has recommended an oseltamivir treatment dose of 3.5 mg/kg orally twice daily for infants 9-11 months old, on the basis of data which indicated that a higher dose of 3.5 mg/kg was needed to achieve the protocol-defined targeted exposure for this cohort as defined in the CASG 114 study (Kimberlin, 2013). It is unknown whether this higher dose will improve efficacy or prevent the development of antiviral resistance. However, there is no evidence that the 3.5 mg/kg dose is harmful or causes more adverse events to infants in this age group.

[4]Current weight-based dosing recommendations are not appropriate for premature infants. Premature infants might have slower clearance of oral oseltamivir because of immature renal function, and doses recommended for full-term infants might lead to very high drug concentrations in this age group. CDC recommends dosing as also recommended by the American Academy of Pediatrics (Committee on Infectious Diseases, 2018): limited data from the National Institute of Allergy and Infectious Diseases Collaborative Antiviral Study Group provide the basis for dosing preterm infants using their postmenstrual age (gestational age + chronological age): 1.0 mg/kg/dose, orally, twice daily, for those <38 weeks postmenstrual age; 1.5 mg/kg/dose, orally, twice daily, for those 38 through 40 weeks postmenstrual age; 3.0 mg/kg/dose, orally, twice daily, for those >40 weeks postmenstrual age.

[5]See Special Considerations for Institutional Settings section below for details regarding duration of chemoprophylaxis for outbreaks in institutional settings.

[6]Inhaled zanamivir is approved for treatment of acute uncomplicated influenza within 2 days of illness onset with twice-daily dosing in people aged ≥7 years, and for chemoprophylaxis with once-daily dosing in people aged ≥5 years.

[7]Intravenous peramivir is approved for treatment of acute uncomplicated influenza within 2 days of illness onset with a single dose in people aged ≥6 months. Daily dosing for a minimum of 5 days was used in clinical trials of hospitalized patients with influenza (de Jong, 2014, Ison, 2014).

[8]There are no data for use of peramivir for chemoprophylaxis of influenza.

[9] Oral baloxavir marboxil is approved by the FDA for treatment of acute uncomplicated influenza within 2 days of illness onset in people aged ≥5 years who are otherwise healthy, or in people aged ≥12 years at high risk of developing influenza-related complications. (Baloxavir marboxil (Xofluza) [package insert]. Baloxavir marboxil should not be administered with dairy products, calcium-fortified beverages, polyvalent cation-containing laxatives, antacids or oral supplements (e.g., calcium, iron, magnesium, selenium, or zinc); co-administration with polyvalent cation-containing products may decrease plasma concentrations of baloxavir which may reduce efficacy. There are no available published data from clinical trials for baloxavir treatment of influenza in non-hospitalized patients who are pregnant, immunocompromised, or have severe disease. A randomized clinical trial reported that combination neuraminidase inhibitor (primarily oseltamivir) and baloxavir for treatment of hospitalized influenza patients aged ≥12 years did not result in superior clinical benefit (time to clinical improvement) compared with neuraminidase inhibitor and placebo (Kumar, 2022). Oral baloxavir is approved by the FDA for post-exposure prophylaxis of influenza for persons aged ≥5 years within 48 hours of contact with an individual with influenza.

Duration of Treatment or Chemoprophylaxis

- **Treatment:** Recommended duration for antiviral treatment is 5 days for oral oseltamivir or inhaled zanamivir. For the treatment of uncomplicated influenza with intravenous peramivir or oral baloxavir, a single dose is recommended. Longer daily dosing (oral oseltamivir or intravenous peramivir) can be considered for patients who remain severely ill after 5 days of treatment. Treatment should be started as soon as possible for the greatest clinical benefit.
- **Chemoprophylaxis:** Recommended duration is 7 days (after last known exposure). For control of outbreaks in institutional settings (e.g., long-term care facilities for older adults and children) and hospitals, CDC recommends antiviral chemoprophylaxis with oral oseltamivir or inhaled zanamivir for a minimum of 2 weeks and continuing up to 1 week after the last known case was identified. Antiviral chemoprophylaxis is recommended for all residents, including those who have received influenza vaccination. Baloxavir is approved for post-exposure prophylaxis (single-dose) of influenza in persons aged 5 years and older within 48 hours of contact with an individual with influenza.

Dosing in Adult Patients with Renal Impairment

Dose adjustment of oseltamivir is recommended for patients with creatinine clearance between 10 and 60 mL/min and patients with end-stage renal disease (ESRD) undergoing hemodialysis or continuous peritoneal dialysis receiving oseltamivir for the treatment or chemoprophylaxis of influenza. Oseltamivir is not recommended for patients with ESRD not undergoing dialysis. The recommended doses are detailed in Table 3; duration of treatment and chemoprophylaxis is the same as recommended for patients with normal renal function. The dose of intravenous peramivir should be reduced for patients with baseline creatinine clearance below 50 mL/min (see Table 3 below).

No dose adjustment is recommended for inhaled zanamivir for a 5-day course of treatment for patients with renal impairment. Pharmacokinetic analysis did not identify a clinically meaningful effect of renal function on the pharmacokinetics of baloxavir in patients with creatinine clearance 50 mL/min and above. The effects of severe renal impairment on the pharmacokinetics of baloxavir marboxil or its active metabolite, baloxavir, have not been evaluated.

Table 3. Recommended Oseltamivir and Peramivir Dose Adjustments for Treatment or Chemoprophylaxis of Influenza in Adult Patients with Renal Impairment or ESRD on Dialysis*:

	Creatinine Clearance	Recommended Treatment Regimen	Recommended Chemoprophylaxis Regimen
Oral oseltamivir[1]	Creatinine clearance 61 to 90 mL/min	75 mg twice a day	75 mg once daily
	Creatinine clearance 31 to 60 mL/min	30 mg twice a day	30 mg once daily
	Creatinine clearance 11 to 30 mL/min	30 mg once daily	30 mg every other day
	ESRD Patients on Hemodialysis Creatinine clearance ≤10 mL/min	30 mg after every hemodialysis cycle. Treatment duration not to exceed 5 days[2]	30 mg after alternate hemodialysis cycles[3]

Table 3. Recommended Oseltamivir and Peramivir Dose Adjustments for Treatment or Chemoprophylaxis of Influenza in Adult Patients with Renal Impairment or ESRD on Dialysis*, *cont.*

	Creatinine Clearance	Recommended Treatment Regimen	Recommended Chemoprophylaxis Regimen
	ESRD Patients on Continuous Ambulatory Peritoneal Dialysis[4] Creatinine clearance ≤10 mL/min	A single 30 mg dose administered immediately after a dialysis exchange	30 mg once weekly immediately after dialysis exchange
Intravenous Peramivir (single dose)[5]	Creatinine clearance ≥50 mL/min	600 mg	N/A
	Creatinine clearance 30 to 49 mL/min	200 mg	N/A
	Creatinine clearance 10 to 29 mL/min	100 mg	N/A
	ESRD Patients on Hemodialysis	Dose administered after dialysis at a dose adjusted based on creatinine clearance	

Table 3 Resources

* From package inserts for oseltamivir and peramivir; see FDA Influenza (Flu) Antiviral Drugs and Related Information.

[1] Renal dosing of oseltamivir is not available in the package insert for pediatric patients. However, these tables may be useful for children who qualify for adult doses based on weight >40 kg.

[2] Assuming 3 hemodialysis sessions are performed in the 5-day period. Treatment can be initiated immediately if influenza symptoms develop during the 48 hours between hemodialysis sessions; however, the post-hemodialysis dose should still be administered independently of time of administration of the initial dose.

[3] An initial dose can be administered prior to the start of dialysis.

[4] Data derived from studies in continuous ambulatory peritoneal dialysis (CAPD) patients.

[5] Renal dosing from peramivir package insert is available for pediatric patients: Creatinine clearance ≥50 mL/min: 12 mg/kg (up to maximum dose of 600 mg); Creatinine clearance 30 to 49 mL/min: 4 mg/kg; Creatinine clearance 10 to 29 mL/min: 2 mg/kg.

PNEUMOCOCCAL DISEASE

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Centers for Disease Control and Prevention

Pneumococcal Disease

Pneumococcal Disease Home

Pneumococcal Disease in Adults and the Vaccines to Prevent It

Pneumococcal disease in adults can range from mild to serious, and can sometimes be deadly. Two types of vaccines provide protection against this disease. Talk to your doctor to see if they recommend these or any other vaccines for you.

What is pneumococcal disease?

Pneumococcal disease is a term used for a wide range of infections caused by bacteria called *Streptococcus pneumoniae* (pneumococcus), including:

- Ear infections
- Sinus infections
- Pneumonia (lung infection)
- Bacteremia (bloodstream infection)
- Meningitis (infection of the lining of the brain and spinal cord)
- Sepsis (the body's extreme response to an infection)

What are the symptoms of pneumococcal disease?

Symptoms depend on the part of the body the bacteria are affecting. For **sinus and ear infections**, symptoms are usually relatively mild, such as:

- Cough
- Ear pain
- Fever
- Sore throat

For **pneumonia, bloodstream infections, meningitis, and sepsis**, you can also have more severe symptoms, including:

- Fever or chills
- Cough
- Rapid or difficult breathing
- Chest pain
- Headache
- Stiff neck
- Increased pain when looking at bright lights

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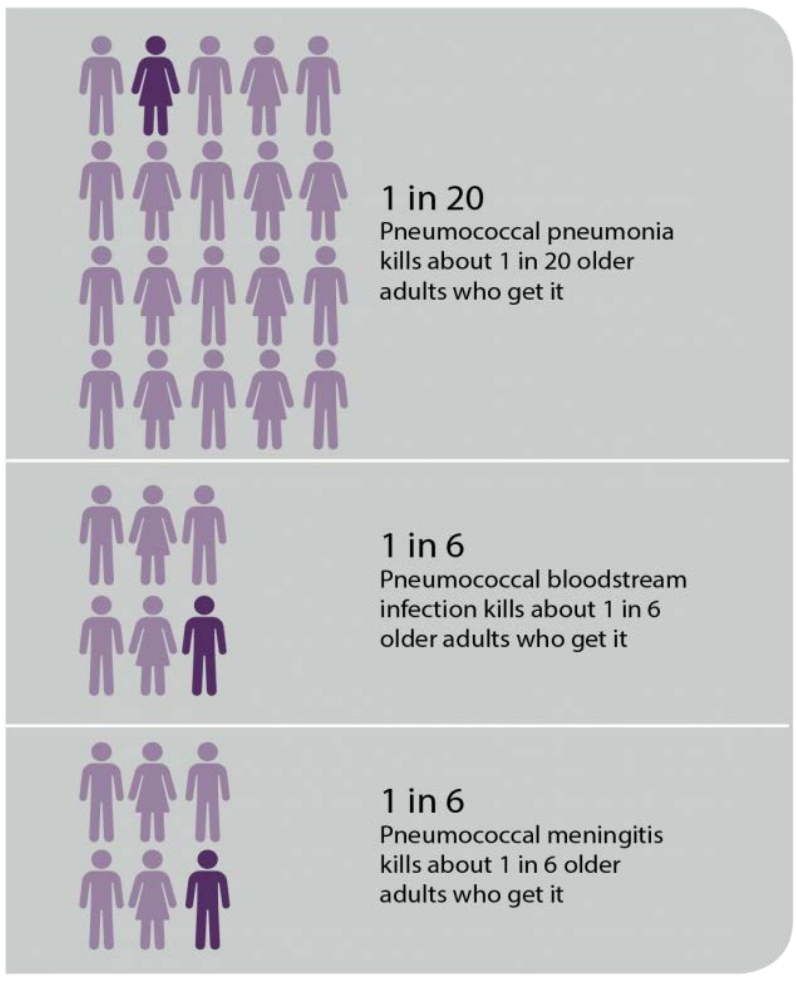
- Confusion or low alertness

How do doctors diagnose and treat pneumococcal disease?

Early diagnosis and treatment are very important for serious pneumococcal infections. Diagnosis depends on which type of infection a doctor thinks a patient may have. For meningitis or bloodstream infections, doctors will collect samples of cerebrospinal fluid or blood and send them to a laboratory for testing. Doctors can also use a urine test to diagnose some cases of pneumonia. For illnesses like ear and sinus infections, doctors usually diagnose them based on history, symptoms, and a physical exam. Doctors can treat pneumococcal disease with antibiotics.



How do the bacteria that cause pneumococcal disease spread?

Pneumococcal bacteria spread from person to person through coughing, sneezing, and close contact. People can carry the bacteria in their nose and throat without being sick and spread the bacteria to others.

Which adults are at increased risk for pneumococcal disease?

Adults 65 years or older are at increased risk for pneumococcal disease.

Adults of **all ages** are also at increased risk for pneumococcal disease if they have:

- Alcoholism
- Cerebrospinal fluid leak (a health problem where fluid surrounding and protecting the brain and spinal cord leaks)
- Chronic **heart, lung, kidney, or liver** disease
- Cochlear implant (a small electronic device that is surgically implanted to help people with severe hearing loss be able to hear)
- Diabetes
- HIV infection, cancer, solid organ transplant, or another **condition or taking medicine that weakens the immune system**
- Nephrotic syndrome
- Sickle cell disease, a damaged spleen, or no spleen

Adults who **smoke cigarettes** are also at increased risk for pneumococcal disease.

Chronic lung illnesses that increase an adult's risk for pneumococcal disease include chronic obstructive lung disease, emphysema, and asthma.

Which vaccines help prevent pneumococcal disease in adults?

There are two types of vaccines used in the United States to help prevent pneumococcal disease in adults: conjugate and polysaccharide vaccines. **CDC recommends pneumococcal conjugate vaccination (PCV15 or PCV20) for all adults 65 years or older and adults 19 through 64 years old at increased risk for pneumococcal disease if they have never received a pneumococcal conjugate vaccine before.** If PCV15 is used, this should be followed by a dose of polysaccharide vaccine (PPSV23).

Adults who received an earlier pneumococcal conjugate vaccine (PCV13 or PCV7) should talk with a vaccine provider to learn about available options to complete their pneumococcal vaccine series.

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Adults 65 years or older have the option to get PCV20 if they have already received

- PCV13 (but not PCV15 or PCV20) at any age

and

- PPSV23 at or after the age of 65 years old

These adults can talk with their doctor and decide, together, whether to get PCV20. In addition, getting an influenza (flu) vaccine every year can help because having flu can increase your chances of getting pneumococcal disease.

What are the risks of pneumococcal vaccination?

Pneumococcal vaccines are safe, but side effects can occur. Adults receiving pneumococcal conjugate and polysaccharide vaccines have reported mild side effects such as redness, pain, and swelling at the injection site. Mild fever, fatigue, headache, chills, or muscle pain have also been reported. Life-threatening allergic reactions from either type of vaccine are rare.

Last Reviewed: January 20, 2023

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Vaccines and Preventable Diseases

Vaccines and Preventable Diseases Home

About Pneumococcal Vaccines

The Food and Drug Administration (FDA) licensed 4 pneumococcal vaccines for use in the United States. Learn about the types, composition, immunogenicity, and efficacy of these vaccines, as well as view package inserts, below.

Types and Composition of Pneumococcal Vaccines

The FDA licensed 3 conjugate and 1 polysaccharide vaccines for protection against pneumococcal disease.

Pneumococcal Conjugate Vaccines

Pneumococcal conjugate vaccines (PCVs) are differentiated by the number of serotypes they provide protection against — PCV13, PCV15, and PCV20.

PCV13 (Prevnar13®) includes purified capsular polysaccharide of 13 serotypes of *Streptococcus pneumoniae* (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 19A, 19F, 18C, and 23F) conjugated to a nontoxic variant of diphtheria toxin known as CRM197. A 0.5 milliliter (mL) PCV13 dose contains approximately 2.2 micrograms (µg) of polysaccharide from each of 12 serotypes and approximately 4.4 µg of polysaccharide from serotype 6B; the total concentration of CRM197 is approximately 34 µg. The vaccine contains 0.02% polysorbate 80, 0.125 milligrams of aluminum as aluminum phosphate adjuvant, and 5 mL of succinate buffer.

PCV15 (Vaxneuvance®) is a sterile suspension of purified capsular polysaccharides from 15 serotypes of *S. pneumoniae* (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F) individually conjugated to a nontoxic variant of diphtheria toxin known as CRM197. A 0.5 mL PCV15 dose contains 2.0 µg of polysaccharide from each of 14 serotypes and 4.0 µg of polysaccharide from serotype 6B, 30 µg of CRM197 carrier protein, 1.55 mg L-histidine, 1 mg of polysorbate 20, 4.50 mg sodium chloride, and 125 µg of aluminum as aluminum phosphate adjuvant. The vaccine does not contain any preservatives.

PCV20 (Prevnar20®) is a sterile suspension of saccharides from 20 serotypes of *S. pneumoniae* (1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F) individually linked to a nontoxic variant of diphtheria toxin known as CRM197. A 0.5 mL dose contains approximately 2.2 µg of saccharides from each of 19 serotypes, approximately 4.4 µg of saccharides from serotype 6B, 51 µg CRM197 carrier protein, 100 µg polysorbate 80, 295 µg succinate buffer, 4.4 mg sodium chloride, and 125 µg aluminum as aluminum phosphate adjuvant.

Pneumococcal Polysaccharide Vaccine

Pneumococcal polysaccharide vaccine or PPSV23 (Pneumovax 23®) includes purified preparations of pneumococcal capsular polysaccharide. PPSV23 contains polysaccharide antigen from 23 types of pneumococcal bacteria. It contains 25 µg of each antigen per dose and contains 0.25% phenol as a preservative.

Helpful Terms

- **Conjugate:** A type of vaccine that joins a protein to an antigen in order to improve the protection the vaccine provides
- **Polysaccharide:** A type of vaccine that is composed of long chains of sugar molecules that resemble the surface of certain types of bacteria in order to help the immune system mount a response

Immunogenicity and Vaccine Efficacy

PCVs

FDA licensed the first pneumococcal conjugate vaccine (PCV7) in 2000. A large clinical trial showed PCV7 reduced invasive disease caused by vaccine serotypes by 97%. Compared to unvaccinated children, children who received PCV7:

- Had 20% fewer episodes of chest X-ray confirmed pneumonia
- Had 7% fewer episodes of acute otitis media
- Underwent 20% fewer tympanostomy tube placements

PCV7 also reduced nasopharyngeal carriage, among children, of pneumococcal serotypes in the vaccine.

FDA licensed PCV13 in 2010 based on studies comparing the serologic response of children who received PCV13 to those who received PCV7. These studies showed PCV13 induced antibody levels comparable to those induced by PCV7 and shown to be protective against invasive disease.

In another study, children aged 7 through 71 months received up to 3 PCV13 doses according to age-appropriate immunization schedules. None of the children had previously received a pneumococcal conjugate vaccine. The antibody responses were comparable to those achieved after the 3-dose infant PCV13 series in the U.S. immunogenicity trial with the exception of serotype 1. The IgG geometric mean concentration was lower for serotype 1 among children aged 24 through 71 months.

Researchers conducted a randomized placebo-controlled trial (CAPiTA trial) in the Netherlands among approximately 85,000 adults 65 years or older from 2008 through 2013. This trial evaluated the clinical benefit of PCV13 in the prevention of pneumococcal pneumonia. The results of the CAPiTA trial demonstrated:

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

Substantial evidence demonstrates routine infant PCV7 and PCV13 vaccination reduced carriage and transmission of vaccine serotypes. This resulted in lower IPD incidence among unvaccinated persons of all ages, including infants too young to receive the vaccine.

FDA licensed PCV15 and PCV20 in 2021 for use in adults based on studies comparing the serologic response of adults who received either PCV15 or PCV20 to those who received PCV13. These studies showed PCV15 and PCV20 induced antibody levels comparable to those induced by PCV13. The studies also showed PCV15 and PCV20 were safe compared with PCV13. FDA licensed PCV15 in 2022 for use in children 6 weeks through 17 years of age. This was based on clinical trial data showing PCV15 induced antibody levels comparable to those induced by PCV13 and that PCV15 was safe.

PPSV23

More than 80% of healthy adults who receive PPSV23 develop antibodies against the serotypes contained in the vaccine. This immune response usually occurs within 2 to 3 weeks after vaccination. Older adults and persons with some chronic illnesses or immunodeficiency may not respond as well. Elevated antibody levels persist for at least 5 years in healthy adults but decline more quickly in persons with certain underlying illnesses. Children younger than 2 years of age generally have a poor antibody response to PPSV23.

PPSV23 vaccine efficacy studies have resulted in various estimates of clinical effectiveness. Overall, the vaccine is 60% to 70% effective in preventing invasive disease caused by serotypes in the vaccine. PPSV23 shows reduced effectiveness among immunocompromised persons; however, because of their increased risk of IPD, CDC recommends PPSV23 for people in these groups who receive PCV15. There is no consensus regarding the ability of PPSV23 to prevent non-bacteremic pneumococcal pneumonia.

Click here to access the CDC's webpage for the most current information on this subject

Studies comparing patterns of asymptomatic pneumococcal carriage before and after PPSV23 vaccination have not shown decreases in carrier rates among those vaccinated.

Package Inserts

Consult the following package inserts for proper storage and handing details, shelf life, and reconstitution instructions:

- Pneumovax 23®
- Prevnar13®
- Prevnar20®
- Vaxneuvance®

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Related Pages

Pneumococcal Vaccine Information Statements

- PCV (English / Other Languages)
- PPSV23 (English / Other Languages)

Pink Book's Chapter on Pneumococcal Disease

Epidemiology & Prevention of Vaccine-Preventable Diseases

Last Reviewed: January 24, 2022

Pneumococcal Vaccine Timing for Adults

Make sure your patients are up to date with pneumococcal vaccination.

Adults ≥65 years old
Complete pneumococcal vaccine schedules

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 fluid 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

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.

www.cdc.gov/pneumococcal/vaccination.html

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Adults 19–64 years old with specified immunocompromising conditions
Complete pneumococcal vaccine schedules

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.
PCV13 and **1 dose of PPSV23**	≥5 years → **PCV20**	≥5 years† → **PPSV23** Review pneumococcal vaccine recommendations again when your patient turns 65 years old.
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 ▪ Congenital or acquired asplenia ▪ Congenital or acquired immunodeficiency§ ▪ Generalized malignancy ▪ HIV infection ▪ Hodgkin disease ▪ Iatrogenic immunosuppression¶ ▪ Leukemia ▪ Lymphoma ▪ Multiple myeloma ▪ Nephrotic syndrome ▪ Sickle cell disease/other hemoglobinopathies ▪ Solid organ transplant	

* 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
§ 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

Adults 19–64 years old with a cochlear implant or cerebrospinal fluid leak
Complete pneumococcal vaccine schedules

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.
PCV13 and **1 dose of PPSV23**	≥5 years → **PCV20**	**No vaccines** recommended at this time. 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

Adults 19–64 years old with chronic health conditions
Complete pneumococcal vaccine schedules

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

* Also applies to people who received PCV7 at any age and no other pneumococcal vaccines
† Adults with chronic medical conditions were previously not recommended to receive PCV13

Pneumococcal Disease and the 2023 CDC Pneumococcal Vaccine Guidance

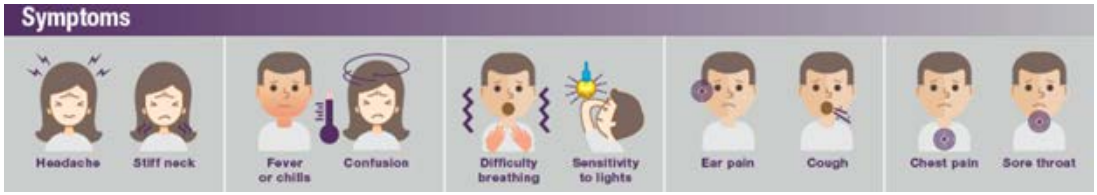
PNEUMOCOCCAL DISEASE

Pneumococcal disease refers to illnesses conferred by the bacteria *Streptococcus pneumoniae* (also known as pneumococcus). *S. pneumoniae* can cause contagious illnesses, including **pneumonia, sinusitis** and **otitis media**. **Invasive Pneumococcal Disease (IPD)** refers to more severe and invasive pneumococcal infections, such as **bacteremia, meningitis,** and **sepsis** (where bacteria can be isolated from normally sterile sites).

Pneumococcal vaccines provide preventative measures against infection from select covered serotypes of *S. pneumoniae* and are particularly focused on preventing **invasive pneumococcal disease (IPD)**.

INFECTION PRESENTATION

Pneumococcal disease can include many different types of infections (see above). Symptoms depend on the part of the body that is infected. Most pneumococcal infections are mild. However, some can be deadly or result in long-term problems.



Visit the CDC's Pneumococcal Disease – Symptoms and Complications webpage for more information on the presentation of each distinct type of infection.

COMPLICATIONS/MORBIDITY/MORTALITY RISK

Pneumonia: Pneumococcal pneumonia kills about 1 in 20 who get it.
Sinusitis: Complications are rare, but include infection of the tissue surrounding the eyes, bone infection, and painful abscesses.
Otitis Media: Ear infections are usually mild and are more common than the more severe forms of pneumococcal disease. However, some children develop repeated ear infections and may need ear tubes.

Bacteremia: About 1 in 30 children with pneumococcal bacteremia die of it. Pneumococcal bacteremia kills about 1 in 8 adults who get it. For those who survive, pneumococcal bacteremia can lead to loss of limb(s).
Meningitis: About 1 in 12 children and 1 in 6 older adults who get pneumococcal meningitis dies of the infection. Those who survive may have long-term problems, such as hearing loss or developmental delay.
Sepsis: Complications of sepsis include kidney failure and damage to the brain, lungs, or heart.

PNEUMOCOCCAL VACCINES

There are currently 4 pneumococcal vaccines available on the US market, divided into two vaccine types:

- Pneumococcal conjugate vaccines (PCV13, PCV15, or PCV20)
- Pneumococcal polysaccharide vaccine (PPSV23)

These vaccines differ by their composition (conjugate vs polysaccharide) and the number of serotypes they protect against (e.g., PCV13 vs PCV20).

Visit the CDC's About Pneumococcal Vaccines webpage for information on these types and compositions, immunogenicity and vaccine efficacy.

The following pages detail the current 2023 CDC Pneumococcal Vaccine Guidance, with recommendations on vaccine selection and timing, based on age, qualifying medical conditions, and vaccine history.

PNEUMOCOCCAL VACCINE TIMING FOR ADULTS

Make sure your patients are up to date with pneumococcal vaccination.

Adults ≥65 years old
Complete pneumococcal vaccine schedules

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 fluid (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

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.

Adults 19–64 years old with a cochlear implant or cerebrospinal fluid leak
Complete pneumococcal vaccine schedules

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.
PCV13 and **1 dose of PPSV23**	≥5 years → **PCV20**	**No vaccines** recommended at this time. 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

www.cdc.gov/pneumococcal/vaccination.html

Adults 19–64 years old with specified immunocompromising conditions
Complete pneumococcal vaccine schedules

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.
PCV13 and **1 dose of PPSV23**	≥5 years → **PCV20**	≥5 years† → **PPSV23** Review pneumococcal vaccine recommendations again when your patient turns 65 years old.
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 • Congenital or acquired asplenia • Congenital or acquired immunodeficiency § • Generalized malignancy • HIV infection • Hodgkin disease • Iatrogenic immunosuppression ¶ • Leukemia • Lymphoma • Multiple myeloma • Nephrotic syndrome • Sickle cell disease/other hemoglobinopathies • Solid organ transplant	

* 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
§ 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

www.cdc.gov/pneumococcal/vaccination.html

Adults 19–64 years old with chronic health conditions
Complete pneumococcal vaccine schedules

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

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

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

www.cdc.gov/pneumococcal/vaccination.html

VACCINE INFORMATION STATEMENT

Pneumococcal Conjugate Vaccine: *What You Need to Know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Pneumococcal conjugate vaccine can prevent **pneumococcal disease**.

Pneumococcal disease refers to any illness caused by pneumococcal bacteria. These bacteria can cause many types of illnesses, including pneumonia, which is an infection of the lungs. Pneumococcal bacteria are one of the most common causes of pneumonia.

Besides pneumonia, pneumococcal bacteria can also cause:

- Ear infections
- Sinus infections
- Meningitis (infection of the tissue covering the brain and spinal cord)
- Bacteremia (infection of the blood)

Anyone can get pneumococcal disease, but children under 2 years old, people with certain medical conditions or other risk factors, and adults 65 years or older are at the highest risk.

Most pneumococcal infections are mild. However, some can result in long-term problems, such as brain damage or hearing loss. Meningitis, bacteremia, and pneumonia caused by pneumococcal disease can be fatal.

2. Pneumococcal conjugate vaccine

Pneumococcal conjugate vaccine helps protect against bacteria that cause pneumococcal disease. There are three pneumococcal conjugate vaccines (PCV13, PCV15, and PCV20). The different vaccines are recommended for different people based on age and medical status. Your health care provider can help you determine which type of pneumococcal conjugate vaccine, and how many doses, you should receive.

Infants and young children usually need 4 doses of pneumococcal conjugate vaccine. These doses are recommended at 2, 4, 6, and 12–15 months of age.

Older children and adolescents might need pneumococcal conjugate vaccine depending on their age and medical conditions or other risk factors if they did not receive the recommended doses as infants or young children.

Adults 19 through 64 years old with certain medical conditions or other risk factors who have not already received pneumococcal conjugate vaccine should receive pneumococcal conjugate vaccine.

Adults 65 years or older who have not previously received pneumococcal conjugate vaccine should receive pneumococcal conjugate vaccine.

Some people with certain medical conditions are also recommended to receive pneumococcal polysaccharide vaccine (a different type of pneumococcal vaccine, known as PPSV23). Some adults who have previously received a pneumococcal conjugate vaccine may be recommended to receive another pneumococcal conjugate vaccine.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

PharMerica

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of any type of pneumococcal conjugate vaccine (PCV13, PCV15, PCV20, or an earlier pneumococcal conjugate vaccine known as PCV7), or to any vaccine containing diphtheria toxoid** (for example, DTaP), or has any **severe, life-threatening allergies**

In some cases, your health care provider may decide to postpone pneumococcal conjugate vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- Redness, swelling, pain, or tenderness where the shot is given, and fever, loss of appetite, fussiness (irritability), feeling tired, headache, muscle aches, joint pain, and chills can happen after pneumococcal conjugate vaccination.

Young children may be at increased risk for seizures caused by fever after a pneumococcal conjugate vaccine if it is administered at the same time as inactivated influenza vaccine. Ask your health care provider for more information.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at **www.cdc.gov/vaccines**.

VACCINE INFORMATION STATEMENT

Pneumococcal Polysaccharide Vaccine (PPSV23): *What You Need to Know*

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Pneumococcal polysaccharide vaccine (PPSV23) can prevent **pneumococcal disease**.

Pneumococcal disease refers to any illness caused by pneumococcal bacteria. These bacteria can cause many types of illnesses, including pneumonia, which is an infection of the lungs. Pneumococcal bacteria are one of the most common causes of pneumonia.

Besides pneumonia, pneumococcal bacteria can also cause:
- Ear infections
- Sinus infections
- Meningitis (infection of the tissue covering the brain and spinal cord)
- Bacteremia (bloodstream infection)

Anyone can get pneumococcal disease, but children under 2 years of age, people with certain medical conditions, adults 65 years or older, and cigarette smokers are at the highest risk.

Most pneumococcal infections are mild. However, some can result in long-term problems, such as brain damage or hearing loss. Meningitis, bacteremia, and pneumonia caused by pneumococcal disease can be fatal.

2 PPSV23

PPSV23 protects against 23 types of bacteria that cause pneumococcal disease.

PPSV23 is recommended for:
- All **adults 65 years or older**,
- Anyone **2 years or older with certain medical conditions that can lead to an increased risk for pneumococcal disease**.

Most people need only one dose of PPSV23. A second dose of PPSV23, and another type of pneumococcal vaccine called PCV13, are recommended for certain high-risk groups. Your health care provider can give you more information.

People 65 years or older should get a dose of PPSV23 even if they have already gotten one or more doses of the vaccine before they turned 65.

3 Talk with your health care provider

Tell your vaccine provider if the person getting the vaccine:
- Has had an **allergic reaction after a previous dose of PPSV23**, or has any **severe, life-threatening allergies**.

In some cases, your health care provider may decide to postpone PPSV23 vaccination to a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting PPSV23.

Your health care provider can give you more information.

U.S. Department of Health and Human Service
Centers for Disease Control and Prevention

4 Risks of a vaccine reaction

- Redness or pain where the shot is given, feeling tired, fever, or muscle aches can happen after PPSV23.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5 What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff do not give medical advice.*

6 How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at **www.cdc.gov/vaccines**

Vaccine Information Statement
PPSV23 Vaccine

Office use only

10/30/2019

PharMerica

SHINGLES (HERPES ZOSTER)

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Centers for Disease Control and Prevention

Vaccines and Preventable Diseases

Shingles Vaccination

What Everyone Should Know about the Shingles Vaccine (Shingrix)

Shingles vaccination is the only way to protect against shingles and postherpetic neuralgia (PHN), the most common complication from shingles.

CDC recommends that adults 50 years and older get two doses of the shingles vaccine called Shingrix (recombinant zoster vaccine) to prevent shingles and the complications from the disease. Adults 19 years and older who have weakened immune systems because of disease or therapy should also get two doses of Shingrix, as they have a higher risk of getting shingles and related complications.

Your doctor or pharmacist can give you Shingrix as a shot in your upper arm.

Shingrix provides strong protection against shingles and PHN. In adults 50 years and older who have healthy immune systems, Shingrix is more than 90% effective at preventing shingles and PHN. Immunity stays strong for at least the first 7 years after vaccination. In adults with weakened immune systems, studies show that Shingrix is 68%-91% effective in preventing shingles, depending on the condition that affects the immune system.

Who Should Get Shingrix?

Adults 50 years and older should get two doses of Shingrix, separated by 2 to 6 months. Adults 19 years and older who have or will have weakened immune systems because of disease or therapy should also get two doses of Shingrix. If needed, people with weakened immune systems can get the second dose 1 to 2 months after the first.

You should get Shingrix even if in the past you:

- Had shingles
- Received Zostavax*
- Received varicella (chickenpox) vaccine

There is no maximum age for getting Shingrix.

If you had shingles in the past, Shingrix can help prevent future occurrences of the disease. There is no specific length of time that you need to wait after having shingles before you can receive Shingrix, but generally you should make sure the shingles rash has gone away before getting vaccinated.

Chickenpox and shingles are related because they are caused by the same virus (varicella-zoster virus). After a person recovers from chickenpox, the virus stays dormant (inactive) in the body. It can reactivate years later and cause shingles.

- You can get Shingrix whether or not you remember having had chickenpox in the past.

- More than 99% of Americans born on or before 1980 have had chickenpox, even if they don't remember having the disease.
- Adults with weakened immune systems and no documented history of chickenpox disease, chickenpox vaccination, or shingles should talk to their healthcare provider, who can refer to the CDC Clinical Considerations for Use of Recombinant Zoster Vaccine (RZV, Shingrix) in Immunocompromised Adults Aged ≥19 Years | CDC and Chickenpox (Varicella) Vaccination | CDC for further guidance.

Shingrix is available in doctor's offices and pharmacies.

If you have questions about Shingrix, talk with your healthcare provider.

* *A shingles vaccine called zoster vaccine live (Zostavax) is no longer available for use in the United States, as of November 18, 2020. If you had Zostavax in the past, you should still get Shingrix. Talk to your healthcare provider to determine the best time to get Shingrix.*

The side effects of Shingrix are temporary, and usually last 2 to 3 days. While you may experience pain for a few days after getting Shingrix, the pain will be less severe than having shingles and the complications from the disease.

Who Should Not Get Shingrix?

You should not get Shingrix if you:

- Have ever had a severe allergic reaction to any component of the vaccine or after a dose of Shingrix.
- Currently have shingles.
- Currently are pregnant. Women who are pregnant should wait to get Shingrix.

If you have a minor illness, such as a cold, you may get Shingrix. But if you have a moderate or severe illness, with or without fever, you should usually wait until you recover before getting the vaccine.

How Well Does Shingrix Work?

Two doses of Shingrix provide strong protection against shingles and postherpetic neuralgia (PHN), the most common complication of shingles.

- In adults 50 to 69 years old with healthy immune systems, Shingrix was 97% effective in preventing shingles; in adults 70 years and older, Shingrix was 91% effective.
- In adults 50 years and older, Shingrix was 91% effective in preventing PHN; in adults 70 years and older, Shingrix was 89% effective.
- In adults with weakened immune systems, Shingrix was between 68% and 91% effective in preventing shingles, depending on their underlying immunocompromising condition.

In people 70 years and older who had healthy immune systems, Shingrix immunity remained high throughout 7 years following vaccination.

What Are the Possible Side Effects of Shingrix?

Studies show that Shingrix is safe. The vaccine helps your body create a strong defense against shingles. As a result, you are likely to have temporary side effects from getting the shots. The side effects might affect your ability to do normal daily activities for 2 to 3 days.

Most people got a sore arm with mild or moderate pain after getting Shingrix, and some also had redness and swelling where they got the shot. Some people felt tired, had muscle pain, a headache, shivering, fever, stomach pain, or nausea. Some people who got Shingrix experienced side effects that prevented them from doing regular activities. Symptoms went away on their own in about 2 to 3 days. Side effects were more common in younger people.

https://www.cdc.gov/vaccines/vpd/shingles/public/shingrix/index.html

You might have a reaction to the first or second dose of Shingrix, or both doses. If you experience side effects, you may choose to take over-the-counter pain medicine such as ibuprofen or acetaminophen.

Guillain-Barré syndrome (GBS), a serious nervous system disorder, has been reported very rarely after Shingrix. There is also a very small increased risk of GBS after having shingles.

If you experience side effects from Shingrix, you should report them to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS website, or by calling 1-800-822-7967.

If you have any questions about side effects from Shingrix, talk with your doctor.

When Should I See a Doctor Because of the Side Effects I Experience from Shingrix?

Shingrix causes a strong response in your immune system, so it may produce short-term side effects. These side effects can be uncomfortable, but they are expected and usually go away on their own in 2 or 3 days. You may choose to take over-the-counter pain medicine such as ibuprofen or acetaminophen. Contact your healthcare provider if the symptoms are not improving or if they are getting worse.

In clinical trials, Shingrix was not associated with serious adverse events. In fact, serious side effects from vaccines are extremely rare. For example, for every 1 million doses of a vaccine given, only one or two people might have a severe allergic reaction. Signs of an allergic reaction happen within minutes or hours after vaccination and include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness. If you experience these or any other life-threatening symptoms, see a doctor right away.

How Can I Pay for Shingrix?

There are several ways shingles vaccine may be paid for:

Medicare

- Starting in 2023, people with Medicare Part D coverage will pay nothing out-of-pocket for the Shingrix vaccine.

Medicaid

- Medicaid may or may not cover the vaccine. Contact your insurer to find out.

Private health insurance

- Many private health insurance plans will cover the vaccine, but there may be a cost to you depending on your plan. Contact your insurer to find out.

Vaccine assistance programs

- Some pharmaceutical companies provide vaccines to eligible adults who cannot afford them. You may want to check with the vaccine manufacturer, GlaxoSmithKline, about Shingrix.

If you do not currently have health insurance, learn more about affordable health coverage options.

Related Page

Shingles Vaccine Information Statement (Shingrix)

Last Reviewed: May 8, 2023

Centers for Disease Control and Prevention

Vaccines and Preventable Diseases

Vaccines and Preventable Diseases Home

Shingrix Recommendations

For the recommendations of the Advisory Committee on Immunization Practices (ACIP), see Shingrix (recombinant zoster vaccine) Recommendations

Summary of Recommendations

Routine Vaccination of People 50 Years Old and Older

CDC recommends Shingrix (recombinant zoster vaccine, or RZV) for the prevention of herpes zoster (shingles) and related complications. CDC recommends two doses of Shingrix separated by 2 to 6 months for immunocompetent adults aged 50 years and older:

- Whether or not they report a prior episode of herpes zoster.
- Whether or not they report a prior dose of Zostavax, a shingles vaccine that is no longer available for use in the United States.
- It is not necessary to screen, either verbally or by laboratory serology, for evidence of prior varicella.

Recombinant and adjuvanted vaccines, such as Shingrix, can be administered concomitantly, at different anatomic sites, with other adult vaccines, including COVID-19 vaccines. Coadministration of RZV with adjuvanted influenza vaccine (Fluad) and COVID-19 vaccines is being studied.

Vaccination of Immunocompromised Adults 19 Years and Older

CDC recommends two doses of RZV for the prevention of shingles and related complications in adults aged ≥19 years who are or will be immunodeficient or immunosuppressed because of disease or therapy. The second dose of RZV should typically be given 2–6 months after the first. However, for persons who are or will be immunodeficient or immunosuppressed and who would benefit from completing the series in a shorter period, the second dose can be administered 1–2 months after the first. For more detailed clinical guidance see www.cdc.gov/shingles/vaccination/immunocompromised-adults.html.

Timing Considerations for Giving Shingrix

For patients who previously had herpes zoster

There is no specific amount of time you need to wait before administering Shingrix to patients who have had herpes zoster. However, you should not give Shingrix to patients who are experiencing an acute episode of herpes zoster.

For patients who previously received Zostavax

Zostavax is no longer available for use in the United States, as of November 18, 2020. Consider the patient's age and when he or she received Zostavax to determine when to vaccinate with Shingrix. Studies examined the safety of Shingrix vaccination 5 or more years after Zostavax vaccination. Shorter intervals were not studied, but there are no theoretical or data concerns to indicate that Shingrix would be less safe or effective if administered less than 5 years after a patient received Zostavax.

You may consider an interval shorter than 5 years between Zostavax and Shingrix based on the age at which the patient received Zostavax. Differences in efficacy between Shingrix and Zostavax are most pronounced among older patients. Studies have shown that the effectiveness of Zostavax wanes substantially over time, leaving recipients with reduced protection against herpes zoster. For example, the vaccine efficacy among adults aged 70 to 79 years and adults aged 80 years and older is 41% and 18%, respectively, on average during the first 3 years following Zostavax vaccination.

You should wait at least 8 weeks after a patient received Zostavax to administer Shingrix.

For patients who do not report a prior episode of varicella

When vaccinating immunocompetent adults aged 50 years and older, there is no need to screen for a history of varicella (chickenpox) or to conduct laboratory testing for serologic evidence of prior varicella. More than 99% of adults aged 50 years and older worldwide have been exposed to varicella-zoster virus, and the Advisory Committee on Immunization Practices (ACIP) considers people born in the United States prior to 1980 immune to varicella. Therefore, even if a person does not recall having chickenpox, serologic testing for varicella immunity is not recommended. It is often a barrier to herpes zoster vaccination, and false negatives are common. However, if serologic evidence of varicella susceptibility becomes available to the healthcare provider, providers should follow ACIP guidelines for varicella vaccination. Shingrix has not been evaluated in persons who are seronegative to varicella, and it is not indicated for the prevention of varicella.

For adults 19 years of age and older who are or will be immunocompromised, see www.cdc.gov/shingles/vaccination/immunocompromised-adults.html.

Contraindications and Precautions for Herpes Zoster Vaccination

Shingrix should **not** be administered to:

- A person with a history of severe allergic reaction, such as anaphylaxis, to any component of this vaccine.
- A person experiencing an acute episode of herpes zoster. Shingrix is not a treatment for herpes zoster or postherpetic neuralgia (PHN). The general guidance for any vaccine is to wait until the acute stage of the illness is over and symptoms abate.

There is currently no CDC recommendation for Shingrix use in pregnancy; therefore, providers should consider delaying vaccination until after pregnancy. There is no recommendation for pregnancy testing before vaccination with Shingrix. Recombinant vaccines such as Shingrix pose no known risk to people who are breastfeeding or to their infants. Providers may consider vaccination without regard to breastfeeding status if Shingrix is otherwise indicated.

Adults with a minor acute illness, such as a cold, can receive Shingrix. Adults with a moderate or severe acute illness should usually wait until they recover before getting the vaccine.

To learn more, see Contraindications and Precautions, General Best Practice Guidelines for Immunization: Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP).

Related Page

Use of Recombinant Zoster Vaccine in Immunocompromised Adults Aged ≥19 Years: Recommendations of the Advisory Committee on Immunization Practices — United States, 2022.

Recommendations of the Advisory Committee on Immunization Practices for Use of Herpes Zoster Vaccines, 2018.

Last Reviewed: January 24, 2022

Your Patients Aged 50 Years and Older Are at Increased Risk for Herpes Zoster

Herpes zoster (HZ) is caused by reactivation of the latent **varicella-zoster virus (VZV)**. After initial exposure to VZV, resulting in chickenpox, the virus remains dormant and can reactivate later in life. The HZ rash is typically unilateral, in 1 or 2 adjacent dermatomes, on the torso or body. The rash progresses to form vesicles and usually resolves in 2 to 4 weeks.[1]

Overview of HZ

- **Up to 99.8% of people aged ≥50 years** have been infected with **VZV**[2]
  - In about **1 out of 3** people during their lifetime, the dormant virus reactivates and causes **HZ**—a blistering rash that can be excruciatingly painful[1,3]
- Most people will have HZ only once; although recurrence is possible, that rate is unknown[1]

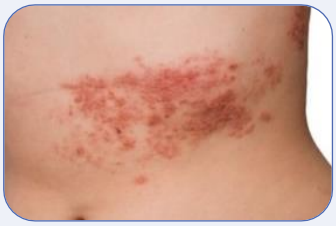


Image source: iStock Photo

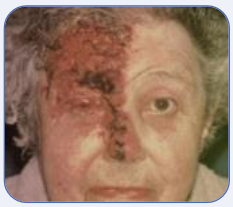
Risk factors for HZ:

- Natural decline in immunity due to[1]:
  - Increasing age (risk for HZ increases significantly after 50 years of age)
  - Immunocompromising conditions or therapies

Postherpetic neuralgia (PHN) is the most common complication of HZ[1,4,5]

- PHN is a pain that can last months to years after the rash has gone
- About 10–18% of patients with HZ develop PHN
- PHN is more common and severe in older patients

Additional complications of HZ[1,4]:



- HZ ophthalmicus (10–25% of patients)
- Possible increased short-term risk of acute cardiovascular events and stroke (based on multiple meta-analyses)[6-8]
- Disseminated HZ (nearly exclusive to immunocompromised patients)

Impact of HZ on Patients

Patients experience financial burden due to HZ[9,10]

- Based on an hourly wage rate of $20.32, a working patient with HZ is estimated to potentially lose approximately **$2,350 in income** on average due to work loss from[9]*:

Presenteeism
(i.e., being unproductive at work; 84.4 hours, on average)

Absenteeism
(31.6 hours, on average)

- Adjusted annual incremental healthcare cost of a HZ episode during a 12-month period was **$1,809** as an overall value for the HZ cohort vs. matched non-HZ controls and as high as **$7,291** for the PHN cohort vs. matched non-HZ controls[10]

Impact of HZ and PHN on Quality of Life

Data suggests that HZ interferes with quality of life[9,11]

- **Approximately 2 out of 3** adult patients with HZ surveyed reported an impact on everyday activities like shopping, work around the house, and socializing[9]*
- Pain during the acute phase of HZ can affect patients' lives across all **4 health domains**: physical, psychological, functional, and social[11]

Refer to the CDC's website to learn more about how you can help protect your patients against the reactivation of VZV.[1]

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Footnote: *Data from a telephone survey of 153 working individuals with mean age of 56.6 ± 4.2 years in the United States estimating absenteeism- and presenteeism-related average work hours lost per episode of herpes zoster.[9]

Abbreviations: HZ=herpes zoster; PHN=postherpetic neuralgia.

References: 1. Centers for Disease Control and Prevention. Shingles (herpes zoster): clinical overview. https://www.cdc.gov/shingles/hcp/clinical-overview.html. Accessed September 29, 2022. **2.** Kilgore PE, et al. *J Med Virol.* 2003;70(Suppl 1):S111-S118. **3.** Kawai K, et al. *BMJ* Open. 2014;4(6):e004833. **4.** Harpaz R, et al. *MMWR Recomm Rep.* 2008;57(RR-5):1-30. **5.** Gudin J, et al. *J Manag Care Spec Pharm.* 2019;25(12):1387-1396. **6.** Erskine N, et al. *PLOS One.* 2017;12(7):e0181565. **7.** Liu X, et al. *PLoS One.* 2016;11(10):e0165203. **8.** Patterson BJ, et al. *Mayo Clin Proc.* 2019;94(5):763-75. **9.** Singhal PK, et al. *J Med Econ.* 2011;14(5):639-645. **10.** Meyers JL, et al. *Hum Vaccin Immunother.* 2017;13(8):1861-1872. **11.** Johnson RW, et al. *BMC Med.* 2010;8:37. **12.** Centers for Disease Control and Prevention. Vaccine needs assessment. https://www.cdc.gov/vaccines/hcp/adults/downloads/standards-immz-practice-assessment.pdf. Accessed September 29, 2022.

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Vaccines and Preventable Diseases

Vaccines and Preventable Diseases Home

About the Vaccine

Shingrix Vaccine Composition

Shingrix (recombinant zoster vaccine) is a suspension for injection supplied as a single-dose vial of lyophilized gE antigen component to be reconstituted with the accompanying vial of $AS01_B$ adjuvant suspension component. A single dose after reconstitution is 0.5 mL. The shingles vaccine does not contain thimerosal (a preservative containing mercury).

Shingrix Vaccine Efficacy and Duration of Protection

Among immunocompetent adults 50 years and older, the efficacy of two doses of Shingrix for the prevention of herpes zoster (shingles) was high among all age groups. In a clinical trial of more than 30,000 participants, vaccine efficacy was 96.6% in adults aged 50 to 59 years, 97.4% in adults aged 60 to 69 years, and 91.3% in adults aged 70 years and older.

The efficacy of two doses of Shingrix for the prevention of postherpetic neuralgia (PHN) was high: 91.2% in adults aged 50 years and older, and 88.8% in adults aged 70 years and older.

Vaccine efficacy was estimated among several immunocompromised groups:

- 68.2% among adult autologous hematopoietic cell transplant recipients.
- 87.2% in a post hoc efficacy analysis of adult patients with hematologic malignancies.
- 90.5% in a post hoc efficacy analysis of adult patients with immune-mediated diseases who were not taking immunosuppressive medication.

In immunocompetent adults 70 years and older, vaccine efficacy remained high, at or above 84% in all 7 years after vaccination.

Side Effects and Counseling for Reactogenicity

In eight clinical trials of more than 10,000 immunocompetent participants 50 years or older, grade 3 reactions (vaccination-related reactions severe enough to prevent normal activities) were common after patients received Shingrix. About 1 out of 10 adults who received Shingrix reported grade 3 injection-site symptoms such as pain, redness, and swelling. Also, about 1 out of 10 reported grade 3 systemic reactions such as myalgia, fatigue, headache, shivering, fever, and gastrointestinal illness. Most people (78%) who got Shingrix reported at least some pain at the injection site.

Local and systemic grade 3 reactions among immunocompromised adults were evaluated in six studies in five immunocompromised groups. Local grade 3 reactions occurred in 10.7% to 14.2% of RZV recipients, and systemic grade 3 reactions occurred in 9.9% to 22.3% of RZV recipients, compared with 0% to 0.3% and 6.0% to 15.5%, respectively, among placebo recipients. The most commonly reported systemic symptoms were fatigue and myalgia.

Healthcare providers should counsel patients about expected reactogenicity before administering Shingrix.

What to tell patients about the side effects of Shingrix:

Most people have a sore arm after they get Shingrix. Many people have redness and swelling on their arm spanning several inches where they got the shot. Many people also feel tired or have muscle pain, a headache, shivering, fever, stomach pain, or nausea.

About 1 out of 6 people had symptoms severe enough to prevent them from doing regular activities. Vaccine recipients should plan to avoid strenuous activities, such as yardwork or swimming, for a few days after vaccination.

Strongly recommend your patients get the second dose of the vaccine even if they experience these side effects to ensure maximum protection from shingles.

- If they have a reaction to the first dose of Shingrix, it does not necessarily mean they will have a reaction to the second dose.
- If they don't have a reaction to the first dose, they might or might not have a reaction to the second dose.
- Remind your patients that the pain from shingles can last a lifetime, and these side effects should only last 2 to 3 days.

Vaccine recipients may take over-the-counter pain medicine like ibuprofen or acetaminophen to ease discomfort from these side effects. It is not recommended to take these medications before vaccination.

Severe Allergic Reactions

Severe allergic reactions to Shingrix are very rare. Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

Any adverse events following vaccination can be reported to the Vaccine Adverse Event Reporting System (VAERS). Reporting is encouraged for any clinically significant adverse event even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at VAERS website , or by calling 1-800-822-7967.

Considerations for Patients Who Previously Received Zostavax

Studies have not examined the safety and immunogenicity of Shingrix administered less than 5 years following Zostavax (zoster vaccine live) vaccination. However, there are no data or theoretical concerns to indicate that Shingrix would be less safe or less effective when given at an interval shorter than 5 years following Zostavax. Since the risk of herpes zoster increases with age, providers should weigh a patient's risk of herpes zoster with the age-specific protection expected from Zostavax to determine when to vaccinate with Shingrix.

Related Pages

Use of Recombinant Zoster Vaccine in Immunocompromised Adults Aged ≥19 Years: Recommendations of the Advisory Committee on Immunization Practices — United States, 2022.

Clinical Considerations for Use of Recombinant Zoster Vaccine (RZV, Shingrix) in Immunocompromised Adults Aged ≥19 Years | CDC

Recommendations of the Advisory Committee on Immunization Practices for Use of Herpes Zoster Vaccines, 2018.

Package insert for Shingrix, U.S. Food and Drug Administrationpdf iconexternal icon

Shingles Clinical Overview

Shingles Vaccine Information Statement (Shingrix)

Shingles Vaccine (Shingrix) Safety

Last Reviewed: January 24, 2022

VACCINE INFORMATION STATEMENT

Recombinant Zoster (Shingles) Vaccine: *What You Need to Know*

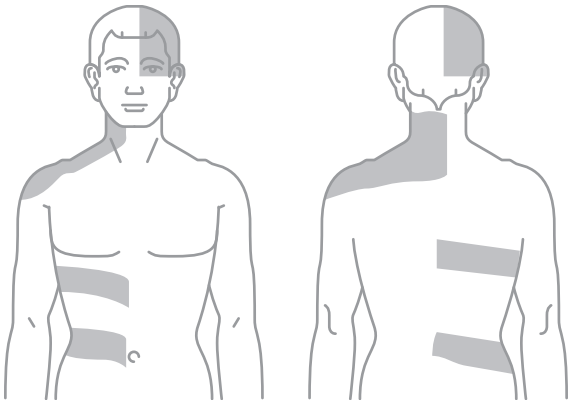
Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Recombinant zoster (shingles) vaccine can prevent **shingles**.

Shingles (also called herpes zoster, or just zoster) is a painful skin rash, usually with blisters. In addition to the rash, shingles can cause fever, headache, chills, or upset stomach. Rarely, shingles can lead to complications such as pneumonia, hearing problems, blindness, brain inflammation (encephalitis), or death.



The risk of shingles increases with age. The most common complication of shingles is long-term nerve pain called postherpetic neuralgia (PHN). PHN occurs in the areas where the shingles rash was and can last for months or years after the rash goes away. The pain from PHN can be severe and debilitating.

The risk of PHN increases with age. An older adult with shingles is more likely to develop PHN and have longer lasting and more severe pain than a younger person.

People with weakened immune systems also have a higher risk of getting shingles and complications from the disease.

Shingles is caused by varicella-zoster virus, the same virus that causes chickenpox. After you have chickenpox, the virus stays in your body and can cause shingles later in life. Shingles cannot be passed from one person to another, but the virus that causes shingles can spread and cause chickenpox in someone who has never had chickenpox or has never received chickenpox vaccine.

2. Recombinant shingles vaccine

Recombinant shingles vaccine provides strong protection against shingles. By preventing shingles, recombinant shingles vaccine also protects against PHN and other complications.

Recombinant shingles vaccine is recommended for:

- **Adults 50 years and older**
- **Adults 19 years and older who have a weakened immune system** because of disease or treatments

Shingles vaccine is given as a two-dose series. For most people, the second dose should be given 2 to 6 months after the first dose. Some people who have or will have a weakened immune system can get the second dose 1 to 2 months after the first dose. Ask your health care provider for guidance.

People who have had shingles in the past and people who have received varicella (chickenpox) vaccine are recommended to get recombinant shingles vaccine. The vaccine is also recommended for people who have already gotten another type of shingles vaccine, the live shingles vaccine. There is no live virus in recombinant shingles vaccine.

Shingles vaccine may be given at the same time as other vaccines.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of recombinant shingles vaccine**, or has any **severe, life-threatening allergies**
- Is **currently experiencing an episode of shingles**
- Is **pregnant**

In some cases, your health care provider may decide to postpone shingles vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting recombinant shingles vaccine.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- A sore arm with mild or moderate pain is very common after recombinant shingles vaccine. Redness and swelling can also happen at the site of the injection.
- Tiredness, muscle pain, headache, shivering, fever, stomach pain, and nausea are common after recombinant shingles vaccine.

These side effects may temporarily prevent a vaccinated person from doing regular activities. Symptoms usually go away on their own in 2 to 3 days. You should still get the second dose of recombinant shingles vaccine even if you had one of these reactions after the first dose.

Guillain-Barré syndrome (GBS), a serious nervous system disorder, has been reported very rarely after recombinant zoster vaccine.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

6. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at **www.cdc.gov/vaccines**.

Vaccine Information Statement
Recombinant Zoster Vaccine 2/04/2022

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RESPIRATORY SYNCYTIAL VIRUS (RSV)

Centers for Disease Control and Prevention

Respiratory Syncytial Virus Infection (RSV)

Respiratory Syncytial Virus Infection (RSV) Home

RSV in Older Adults and Adults with Chronic Medical Conditions

RSV infections can be dangerous for certain adults. Each year, it is estimated that between 60,000-160,000 older adults in the United States are hospitalized and 6,000-10,000 die due to RSV infection. Adults at highest risk for severe RSV infection include:

- Older adults
- Adults with chronic heart or lung disease
- Adults with weakened immune systems
- Adults with certain other underlying medical conditions
- Adults living in nursing homes or long-term care facilities

An RSV vaccine protects against serious disease

RSV vaccine can help protect adults aged 60 years and older from RSV. Talk to your healthcare provider to see if vaccination is right for you.

Severe RSV Infection

When an adult gets RSV infection, they typically have mild cold-like symptoms, but some may develop a lung infection or pneumonia.

RSV can sometimes also lead to worsening of serious conditions such as:

- Asthma
- Chronic obstructive pulmonary disease (COPD) – a chronic disease of the lungs that makes it hard to breathe
- Congestive heart failure – when the heart can't pump enough blood and oxygen through the body

Older adults who get very sick from RSV may need to be hospitalized. Some may even die. Older adults are at greater risk than young adults for serious complications from RSV because our immune systems weaken when we are older.

What you should do if you or a loved one is at high risk for severe RSV disease

RSV season in most regions of the U.S. starts in the fall and peaks in winter. If you are at high risk for severe RSV infection, or if you interact with an older adult, you should take extra care to keep them healthy:

- **Wash your hands often**
  Wash your hands often with soap and water for at least 20 seconds. If soap and water are not available, use an alcohol-based hand sanitizer. Washing your hands will help protect you from germs.
- **Keep your hands off your face**
  Avoid touching your eyes, nose, and mouth with unwashed hands. Germs spread this way.
- **Avoid close contact with sick people**
  Avoid close contact, such as kissing, and sharing cups or eating utensils with people who have cold-like symptoms.
- **Cover your coughs and sneezes**
  Cover your mouth and nose with a tissue or your upper shirt sleeve when coughing or sneezing. Throw the tissue in the trash afterward.
- **Clean and disinfect surfaces**
  Clean and disinfect surfaces and objects that people frequently touch, such as toys, doorknobs, and mobile devices. When people infected with RSV touch surfaces and objects, they can leave behind germs. Also, when they cough or sneeze, droplets containing germs can land on surfaces and objects.
- **Stay home when you are sick**
  If possible, stay home from work, school, and public areas when you are sick. This will help protect others from catching your illness.

Last Reviewed: October 28, 2022

https://www.cdc.gov/rsv/high-risk/older-adults.html

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Respiratory Syncytial Virus Infection (RSV)

Respiratory Syncytial Virus Infection (RSV) Home

Symptoms and Care

Symptoms

People infected with RSV usually show symptoms within 4 to 6 days after getting infected. Symptoms of RSV infection usually include

- Runny nose
- Decrease in appetite
- Coughing
- Sneezing
- Fever
- Wheezing

These symptoms usually appear in stages and not all at once. In very young infants with RSV, the only symptoms may be irritability, decreased activity, and breathing difficulties.

Almost all children will have had an RSV infection by their second birthday.

Call your healthcare professional if you or your child is having difficulty breathing, not drinking enough fluids, or experiencing worsening symptoms.

Care

Antiviral medication is not routinely recommended to fight infection. Most RSV infections go away on their own in a week or two. However, RSV can cause severe illness in some people.

Take steps to relieve symptoms

- **Manage fever and pain** with over-the-counter fever reducers and pain relievers, such as acetaminophen or ibuprofen. (Never give aspirin to children.)
- **Drink enough fluids.** It is important for people with RSV infection to drink enough fluids to prevent dehydration (loss of body fluids).
- **Talk to your healthcare provider** before giving your child nonprescription cold medicines. Some medicines contain ingredients that are not good for children.

RSV can cause more serious health problems

RSV can also cause more severe infections such as bronchiolitis, an inflammation of the small airways in the lung, and pneumonia, an infection of the lungs. It is the most common cause of bronchiolitis and pneumonia in children younger than 1 year of age.

Healthy adults and infants infected with RSV do not usually need to be hospitalized. But some people with RSV infection, especially older adults and infants younger than 6 months of age, may need to be hospitalized if they are having trouble breathing or are dehydrated. In the most severe cases, a person may require additional oxygen, or IV fluids (if they can't eat or drink enough), or intubation (have a breathing tube inserted through the mouth and down to the airway) with mechanical ventilation (a machine to help a person breathe). In most of these cases, hospitalization only lasts a few days.

Learn more about people at high risk for severe RSV infection.

Transmission

How this virus spreads

Prevention

Ways to help stop RSV from spreading

Last Reviewed: October 24, 2022

https://www.cdc.gov/rsv/about/symptoms.html

Centers for Disease Control and Prevention

Respiratory Syncytial Virus Infection (RSV)

Respiratory Syncytial Virus Infection (RSV) Home

RSV Transmission

RSV can spread when

- An infected person coughs or sneezes
- You get virus droplets from a cough or sneeze in your eyes, nose, or mouth
- You have direct contact with the virus, like kissing the face of a child with RSV
- You touch a surface that has the virus on it, like a doorknob, and then touch your face before washing your hands

People infected with RSV are usually contagious for 3 to 8 days and may become contagious a day or two before they start showing signs of illness. However, some infants, and people with weakened immune systems, can continue to spread the virus even after they stop showing symptoms, for as long as 4 weeks. Children are often exposed to and infected with RSV outside the home, such as in school or childcare centers. They can then transmit the virus to other members of the family.

RSV can survive for many hours on hard surfaces such as tables and crib rails. It typically lives on soft surfaces such as tissues and hands for shorter amounts of time.

People are typically infected with RSV for the first time as an infant or toddler and nearly all children are infected before their second birthday. However, repeat infections may occur throughout life, and people of any age can be infected. Infections in healthy children and adults are generally less severe than among infants and older adults with certain medical conditions. People at highest risk for severe disease include

- Premature infants
- Young children with congenital (from birth) heart or chronic lung disease
- Young children with compromised (weakened) immune systems due to a medical condition or medical treatment
- Children with neuromuscular disorders
- Adults with compromised immune systems
- Older adults, especially those with underlying heart or lung disease

In most regions of the United States and other areas with similar climates, RSV season generally starts during fall and peaks in the winter. The timing and severity of RSV season in a given community can vary from year to year.

Prevention

Ways to help stop RSV from spreading

Symptoms and Care

Symptoms of RSV and how to care for someone sick with RSV

Last Reviewed: April 26, 2023

Español | Other Languages

Centers for Disease Control and Prevention

Respiratory Syncytial Virus Infection (RSV)

Respiratory Syncytial Virus Infection (RSV) Home

RSV Prevention

How to Protect Yourself and Others

There are steps you can take to help prevent the spread of RSV. Specifically, if you have cold-like symptoms you should:

- Cover your coughs and sneezes with a tissue or your upper shirt sleeve, not your hands
- Wash your hands often with soap and water for at least 20 seconds
- Avoid close contact, such as kissing, shaking hands, and sharing cups and eating utensils, with others
- Clean frequently touched surfaces such as doorknobs and mobile devices

RSV Vaccine

RSV vaccine helps protect adults 60 years and older from RSV disease. Older adults are at greater risk than young adults for serious complications from RSV because immune systems weaken with age. In addition, certain underlying medical conditions may increase the risk of getting very sick from RSV and older adults with these conditions may especially benefit from getting RSV vaccine. If you are 60 years and older, talk to your healthcare provider to see if RSV vaccination is right for you.

View Infographic

Prevention for Children at High Risk for Severe RSV

A drug called palivizumab (pah-lih-VIH-zu-mahb) is available to prevent severe RSV illness in certain infants and children who are at high risk for severe disease. This could include, for example, infants born prematurely or with congenital (present from birth) heart disease or chronic lung disease. The drug can help prevent serious RSV disease, but it cannot help cure or treat children already suffering from serious RSV disease, and it cannot prevent infection with RSV. If your child is at high risk for severe RSV disease, talk to your healthcare provider to see if palivizumab can be used as a preventive measure.

Ideally, people with cold-like symptoms should not interact with children at high risk for severe RSV disease, including premature infants, children younger than 2 years of age with chronic lung or heart conditions, children with weakened immune systems, or children with neuromuscular disorders. If this is not possible, they should carefully follow the prevention steps mentioned above and wash their hands before interacting with such children. They should also refrain from kissing high-risk children while they have cold-like symptoms.

Parents of children at high risk for developing severe RSV disease should help their child, when possible, do the following:

- Avoid close contact with sick people
- Wash their hands often with soap and water for at least 20 seconds
- Avoid touching their face with unwashed hands
- Limit the time they spend in childcare centers or other potentially contagious settings during periods of high RSV activity. This may help prevent infection and spread of the virus during the RSV season

Symptoms and Care

Symptoms of RSV and how to care for someone sick with RSV

Transmission

How this virus spreads

Last Reviewed: July 12, 2023

Español | Other Languages

Centers for Disease Control and Prevention

Respiratory Syncytial Virus Infection (RSV)

Respiratory Syncytial Virus Infection (RSV) Home

For Healthcare Providers

Healthcare providers should consider RSV in patients with respiratory illness, particularly during the RSV season.

Respiratory syncytial virus (RSV) is recognized as one of the most common causes of childhood illness. It causes annual outbreaks of respiratory illnesses in all age groups. In most regions of the United States, RSV season starts in the fall and peaks in the winter, but the timing and severity of RSV season in a given community can vary from year to year.

Clinical Description and Diagnosis

In Infants and Young Children

RSV infection can cause a variety of respiratory illnesses in infants and young children. It most commonly causes a cold-like illness but can also cause lower respiratory infections like bronchiolitis and pneumonia. One to two percent of children younger than 6 months of age with RSV infection may need to be hospitalized. Severe disease most commonly occurs in very young infants. Additionally, children with any of the following underlying conditions are considered at high risk:

- Premature infants
- Infants, especially those 6 months and younger
- Children younger than 2 years old with chronic lung disease or congenital heart disease
- Children with suppressed immune systems
- Children who have neuromuscular disorders, including those who have difficulty swallowing or clearing mucus secretions

Infants and young children with RSV infection may have rhinorrhea and a decrease in appetite before any other symptoms appear. Cough usually develops one to three days later. Soon after the cough develops, sneezing, fever, and wheezing may occur. In very young infants, irritability, decreased activity, and/or apnea may be the only symptoms of infection.

Most otherwise healthy infants and young children who are infected with RSV do not need hospitalization. Those who are hospitalized may require oxygen, intubation, and/or mechanical ventilation. Most improve with supportive care and are discharged in a few days.

In Older Adults and Adults with Chronic Medical Conditions

Adults who get infected with RSV usually have mild or no symptoms. Symptoms are usually consistent with an upper respiratory tract infection which can include rhinorrhea, pharyngitis, cough, headache, fatigue, and fever. Disease usually lasts less than five days.

Some adults, however, may have more severe symptoms consistent with a lower respiratory tract infection, such as pneumonia. Epidemiologic evidence indicates that people 60 and older who are at highest risk of severe RSV disease include those with any of the following chronic conditions:

- Lung disease (such as chronic obstructive pulmonary disease [COPD] and asthma)
- Chronic cardiovascular diseases (such as congestive heart failure and coronary artery disease)
- Diabetes mellitus

- Neurologic conditions
- Kidney disorders
- Liver disorders
- Hematologic disorders
- Immune compromise
- Other underlying conditions that a health care provider determines might increase the risk for severe respiratory disease

Other underlying factors that the provider determines might increase the risk of severe RSV-associated respiratory illness

- Frailty
- Advanced age
- Residence in a nursing home or other long-term care facility
- Other underlying factors that a health care provider determines might increase the risk for severe respiratory disease

RSV can sometimes also lead to exacerbation of serious conditions such as:

- Asthma
- Chronic obstructive pulmonary disease (COPD)
- Congestive heart failure

Clinical Laboratory Testing

Clinical symptoms of RSV are nonspecific and can overlap with other viral respiratory infections, as well as some bacterial infections. Several types of laboratory tests are available for confirming RSV infection. These tests may be performed on upper and lower respiratory specimens.

The most commonly used types of RSV clinical laboratory tests are

- Real-time reverse transcriptase-polymerase chain reaction (rRT-PCR), which is more sensitive than culture and antigen testing
- Antigen testing, which is highly sensitive in children but not sensitive in adults

Less commonly used tests include:

- Viral culture
- Serology, which is usually only used for research and surveillance studies

Some tests can differentiate between RSV subtypes (A and B), but the clinical significance of these subtypes is unclear. Consult your laboratorian for information on what type of respiratory specimen is most appropriate to use.

For Infants and Young Children

Both rRT-PCR and antigen detection tests are effective methods for diagnosing RSV infection in infants and young children. The RSV sensitivity of antigen detection tests generally ranges from 80% to 90% in this age group. Healthcare providers should consult experienced laboratorians for more information on interpretation of results.

For Older Children, Adolescents, and Adults

Healthcare providers should use highly sensitive rRT-PCR assays when testing older children and adults for RSV. rRT-PCR assays are now commercially available for RSV. The sensitivity of these assays often exceeds the sensitivity of virus isolation and antigen detection methods. Antigen tests are not sensitive for older children and adults because they may have lower viral loads in their respiratory specimens. Healthcare providers should consult experienced laboratorians for more information on interpretation of results.

https://www.cdc.gov/rsv/clinical/index.html

New Vaccines

Two new vaccines against RSV will be available in late July 2023 for adults 60 and older. CDC recommends that adults 60 and older may receive RSV vaccination, using shared clinical decision-making. The decision to vaccinate an individual patient should be based on a discussion between the healthcare provider and the patient, and may be informed by the patient's risk of severe RSV disease and their characteristics, values, and preferences; the healthcare provider's clinical discretion; and the characteristics of the vaccine.

Healthcare providers should be aware of underlying conditions that may increase the risk of severe RSV illness, and who might be most likely to benefit from these new vaccines.

RSV vaccine is recommended as a single dose. Studies are ongoing to determine whether (and if so, when) revaccination may be needed.

Prophylaxis and High-Risk Infants and Young Children

Palivizumab is a monoclonal antibody recommended by the American Academy of Pediatrics (AAP) to be administered to high-risk infants and young children likely to benefit from immunoprophylaxis based on gestational age and certain underlying medical conditions. It is given in monthly intramuscular injections during the RSV season.

For the latest palivizumab guidance, please consult the AAP policy statement . An accompanying AAP technical report provides additional context and rationale for the guidance. Interim guidance addressing the disruption in typical RSV seasonal patterns during the pandemic has also been provided: Updated Guidance: Use of Palivizumab Prophylaxis to Prevent Hospitalization From Severe Respiratory Syncytial Virus Infection During the 2022-2023 RSV Season (aap.org)

Related Links

Red Book® Online

Last Reviewed: July 12, 2023

First Two Approved RSV Vaccines Anticipated for 2023-24 Season: Information for HCPs

AREXVY approved as 1st RSV Vaccine on 5.3.23

INDICATION:
Active immunization for the prevention of LRTD caused by RSV in individuals ≥60 years of age.

ABRYSVO approved as 2nd RSV Vaccine on 5.31.23

Brand Name	Generic Name	Dosage Form	Labeled Indication
Arexvy	Respiratory syncytial virus vaccine, adjuvanted	Single dose vial of lyophilized antigen; reconstituted with accompanying adjuvant suspension	Active immunization for the prevention of LRTD caused by RSV in individuals 60 years old
Abrysvo	Respiratory syncytial virus vaccine	Single dose vial of lyophilized antigen; reconstituted with accompanying prefilled syringe of sterile water diluent	

Arexvy (respiratory syncytial virus vaccine, adjuvanted) – New vaccine approval

- On May 3, 2023, the FDA announced the approval of GSK's Arexvy (respiratory syncytial virus vaccine, adjuvanted), as the 1st vaccine approved for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by RSV in adults ≥60 years old.
- RSV is a highly contagious virus that causes infections of the lungs and breathing passages in individuals of all age groups.
    - RSV circulation is seasonal, typically starting during the fall and peaking in the winter. In older adults, RSV is a common cause of LRTD, which affects the lungs and can cause life-threatening pneumonia and bronchiolitis.
    - According to the CDC, each year in the U.S., RSV leads to approximately 60,000 to 160,000 hospitalizations and 6,000 to 10,000 deaths among adults ≥60 years old.
- The efficacy of Arexvy was established in an ongoing randomized, placebo-controlled, observer-blind clinical study in adults ≥60 years old.
    - The primary population for efficacy analysis included 24,960 participants randomized equally to receive 1 dose of Arexvy or placebo. At the time of the primary efficacy analysis, participants had been followed for the development of RSV-associated LRTD for up to 10 months.
    - The primary objective was to demonstrate the efficacy of Arexvy in the prevention of a first episode of confirmed RSV-A and/or B-associated LRTD during the first RSV season.
        - Compared with placebo, Arexvy significantly reduced the risk of developing RSV-associated LRTD by 82.6% (96.95% CI: 57.9, 94.1), which met the pre-specified success criterion for the primary study objective.
        - Also, Arexvy significantly reduced the risk of developing severe RSV-associated LRTD by 94.1% (95% CI: 62.4, 99.9).
- In a separate concomitant administration, open-label study, patients 60 years of age and older received 1 dose of Arexvy and Fluarix Quadrivalent (FDA-approved influenza vaccine) at month 0 (n = 442) or 1 dose of Fluarix Quadrivalent at month 0 followed by a dose of Arexvy at month 1 (n = 443).
- There was no evidence for interference in the immune response to any of the antigens contained in both concomitantly administered vaccines.
    - Data are not available for concomitant administration with other vaccines.
- Warnings and precautions for Arexvy include preventing and managing allergic vaccine reactions; syncope; and altered immunocompetence.
- The most commonly reported solicited local adverse reaction (≥ 10%) with Arexvy use was injection site pain.

- The most commonly reported solicited systemic adverse reactions (≥ 10%) with Arexvy use were fatigue, myalgia, headache, and arthralgia.
- The FDA is requiring GSK to conduct a post-marketing study to assess the signals of serious risks for Guillain-Barré syndrome and acute disseminated encephalomyelitis.
- Arexvy is administered as a single dose (0.5 mL) via intramuscular injection.
- GSK plans to launch Arexvy before the 2023/2024 RSV season.
- Arexvy will be available as a single dose vial of lyophilized antigen component to be reconstituted with the accompanying vial of adjuvant suspension component.

Abrysvo™ (respiratory syncytial virus vaccine) – New vaccine approval

- On May 31, 2023, Pfizer announced the FDA approval of Abrysvo (respiratory syncytial virus vaccine), 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.
- Abrysvo is the second vaccine approved for RSV in this patient population.
    - The FDA approved GSK's Arexvy (respiratory syncytial virus vaccine, adjuvanted), on May 3, 2023.
- The efficacy of Abrysvo was established in a randomized, double-blind, placebo-controlled study in individuals 60 years of age and older.
    - Participants were randomized to receive Abrysvo or placebo.
    - The evaluable efficacy population included 32,614 patients.
    - Vaccine efficacy against RSV-LRTD, defined as the relative risk reduction of first episode of RSV-LRTD in the Abrysvo group compared to the placebo group in the first RSV season, was assessed.
        - The study met the pre-specified success criteria for demonstration of efficacy of Abrysvo for the primary objectives of prevention of RSV-LRTD with ≥ 2 symptoms and prevention of RSV-LRTD with ≥ 3 symptoms.
- Warnings and precautions for Abrysvo include management of acute allergic reactions; syncope; altered immunocompetence; and limitations of vaccine effectiveness.
- The most commonly reported solicited local and systemic adverse reactions (≥ 10%) with Abrysvo use were fatigue, headache, pain at the injection site, and muscle pain.
- The recommended dose of Abrysvo is a single dose (approximately 0.5 mL) administered intramuscularly.
- The CDC's Advisory Committee on Immunization Practices (ACIP) met on June 21, 2023, to discuss recommendations for the appropriate use of RSV vaccines in older adults.
- Pfizer anticipates supply availability in 3Q 2023 ahead of the anticipated RSV season this fall
- CDC provides the following current recommendation for RSV vaccination (not product specific):
    - Per 6-29-23 media release – CDC Director Rochelle P. Walensky, M.D., M.P.H., endorsed the CDC Advisory Committee on Immunization Practices' (ACIP) recommendations for use of new Respiratory Syncytial Virus (RSV) vaccines from GSK and Pfizer for people ages 60 years and older, using ***shared clinical decision-making***.
    - This means these individuals may receive a single dose of the vaccine based on discussions with their healthcare provider about whether RSV vaccination is right for them.
    - Adults at the highest risk for severe RSV illness include older adults, adults with chronic heart or lung disease, adults with weakened immune systems, and adults living in nursing homes or long-term care facilities.

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Respiratory Syncytial Virus (RSV) and Vaccination for Older Adults

WHAT IS RSV

Respiratory syncytial virus (RSV) is a common and contagious pathogen known to affect the lungs.
RSV causes cold-like symptoms that can cause significant morbidity and mortality, especially in infants and older adults.
The virus is spread via aerosolization of respiratory droplets or contact with contaminated surfaces.
RSV infections are typically seen in the fall, and peak during the winter months.

IMPACT OF RSV

- CDC estimates between 60,000-160,000 older adults in the United States are hospitalized and 6,000-10,000 of them die due to RSV infection each year. [1]
- Annually, RSV is estimated to cause over 1 billion dollars in hospitalization costs in older, high-risk adults.[2]
- 10-31% of older adults hospitalized with RSV are admitted into the ICU.[2,3,4]
- For those admitted into the hospital with RSV, mortality rate is close to 8%.[2,3,4]

SIGNS AND SYMPTOMS OF RSV IN OLDER ADULTS AND ADULTS WITH CHRONIC MEDICAL CONDITIONS[1]

Adults who get infected with RSV typically have mild or no symptoms. Disease usually lasts less than 5 days.
When disease is symptomatic, symptoms are usually consistent with an upper respiratory tract infection, including **rhinorrhea, pharyngitis, cough, headache, fatigue, and fever**.

Some adults, however, may have more severe symptoms consistent with a lower respiratory tract infection, such as pneumonia. Epidemiologic evidence indicates that people 60 years and older who are at highest risk of severe RSV disease include those with any of the chronic conditions and risk factors below.

THOSE AT INCREASED RISK[5]

Chronic medical conditions associated with increased risk

- Chronic lung disease (Asthma, COPD)
- Chronic cardiovascular disease (CHF, CAD)
- Moderate to severe immunocompromise
- Neurologic or neuromuscular conditions
- Kidney or liver disorders
- Hematologic disorders
- Diabetes Mellitus

Other associated risk factors

- Frailty
- Advanced age
- Residence in a long-term care facility

AVAILABLE VACCINATIONS[5]

There are currently two FDA vaccines approved for the prevention of RSV in adults 60 years old or older. These vaccines are expected to be available Q3 2023.

Arexvy (RSV Vaccine, Adjuvanted)

- Manufacturer: GlaxoSmithKline
- Adjuvanted recombinant stabilized prefusion F protein vaccine (RSVPreF3)
- Single dose of 0.5mL
- Ongoing phase 3 trial for efficacy and phase 1/2 trial for safety
- Efficacy of 1 dose in preventing symptomatic RSV lower respiratory tract disease is 82.6%

Abrysvo (RSV Vaccine)

- Manufacturer: Pfizer
- Recombinant stabilized preF vaccine (bivalent RSVpreF)
- Single dose of 0.5mL
- Ongoing phase 3 trial for efficacy and phase 1/2 trial for safety
- Efficacy of 1 dose in preventing symptomatic RSV lower respiratory tract disease is 88.9%

Please see page two for current CDC recommendations on RSV immunization.

RECOMMENDATIONS FROM THE CDC[5]

> On June 21, 2023, the Advisory Committee on Immunization Practices (ACIP) voted to recommend that adults aged 60 years old and older may receive a single dose of **either** RSV vaccine, utilizing shared clinical decision making based upon patient specific risk factors and patient preferences.

Coadministration of the RSV vaccine with other adult vaccines during the same visit is acceptable, however it may increase the risk of local or systemic reactogenicity. Vaccination should be delayed for those experiencing moderate to severe acute illness with or without fever as a precaution.

Until further post marketing surveillance is completed, there is no further guidance available on the necessity of revaccination.

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RSV (Respiratory Syncytial Virus) Vaccine: *What You Need to Know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

RSV vaccine can prevent lower respiratory tract disease caused by **respiratory syncytial virus (RSV)**. RSV is a common respiratory virus that usually causes mild, cold-like symptoms.

RSV is usually spread through direct contact with the virus, such as droplets from another person's cough or sneeze contacting your eyes, nose, or mouth. It can also be spread by touching a surface that has the virus on it, like a doorknob, and then touching your face before washing your hands.

RSV can cause illness in people of all ages but may be especially serious for infants and older adults. Infants and older adults with chronic medical conditions like heart or lung disease, weakened immune systems, or who live in nursing homes or long-term care facilities, are at highest risk of serious illness and complications from RSV.

Symptoms of RSV infection may include runny nose, decrease in appetite, coughing, sneezing, fever, or wheezing. Most people recover in a week or two, but RSV can be serious, resulting in shortness of breath and low oxygen levels. RSV can also sometimes lead to worsening of other medical conditions such as asthma, chronic obstructive pulmonary disease (a chronic disease of the lungs that makes it hard to breathe), or congestive heart failure (when the heart can't pump enough blood and oxygen through the body).

Older adults and infants who get very sick from RSV may need to be hospitalized. Some may even die.

2. RSV vaccine

CDC recommends **adults 60 years and older** may receive a single dose of RSV vaccine, based on discussions between the patient and health care provider.

RSV vaccine may be given at the same time as other vaccines.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of RSV vaccine**, or has any **severe, life-threatening allergies**

In some cases, your health care provider may decide to postpone RSV vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting RSV vaccine.

Your health care provider can give you more information.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

4. Risks of a vaccine reaction

- Pain, redness, and swelling where the shot is given, fatigue (feeling tired), fever, headache, nausea, diarrhea, and muscle or joint pain can happen after RSV vaccination.

Serious neurologic conditions, including Guillain-Barré syndrome (GBS), have been reported very rarely after RSV vaccination in clinical trials. It is unclear whether the vaccine caused these events.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

6. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at **www.cdc.gov/vaccines**.

ESSENTIAL RESOURCES

PharMerica

Influenza (Flu) Vaccine (Inactivated or Recombinant): *What you need to know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Influenza vaccine can prevent **influenza (flu)**.

Flu is a contagious disease that spreads around the United States every year, usually between October and May. Anyone can get the flu, but it is more dangerous for some people. Infants and young children, people 65 years and older, pregnant people, and people with certain health conditions or a weakened immune system are at greatest risk of flu complications.

Pneumonia, bronchitis, sinus infections, and ear infections are examples of flu-related complications. If you have a medical condition, such as heart disease, cancer, or diabetes, flu can make it worse.

Flu can cause fever and chills, sore throat, muscle aches, fatigue, cough, headache, and runny or stuffy nose. Some people may have vomiting and diarrhea, though this is more common in children than adults.

In an average year, **thousands of people in the United States die from flu**, and many more are hospitalized. Flu vaccine prevents millions of illnesses and flu-related visits to the doctor each year.

2. Influenza vaccines

CDC recommends everyone 6 months and older get vaccinated every flu season. **Children 6 months through 8 years of age** may need 2 doses during a single flu season. **Everyone else** needs only 1 dose each flu season.

It takes about 2 weeks for protection to develop after vaccination.

There are many flu viruses, and they are always changing. Each year a new flu vaccine is made to protect against the influenza viruses believed to be likely to cause disease in the upcoming flu season.

Even when the vaccine doesn't exactly match these viruses, it may still provide some protection.

Influenza vaccine **does not cause flu**.

Influenza vaccine may be given at the same time as other vaccines.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of influenza vaccine**, or has any **severe, life-threatening allergies**
- Has ever had **Guillain-Barré Syndrome** (also called "GBS")

In some cases, your health care provider may decide to postpone influenza vaccination until a future visit.

Influenza vaccine can be administered at any time during pregnancy. People who are or will be pregnant during influenza season should receive inactivated influenza vaccine.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting influenza vaccine.

Your health care provider can give you more information.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

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4. Risks of a vaccine reaction

- Soreness, redness, and swelling where the shot is given, fever, muscle aches, and headache can happen after influenza vaccination.
- There may be a very small increased risk of Guillain-Barré Syndrome (GBS) after inactivated influenza vaccine (the flu shot).

Young children who get the flu shot along with pneumococcal vaccine (PCV13) and/or DTaP vaccine at the same time might be slightly more likely to have a seizure caused by fever. Tell your health care provider if a child who is getting flu vaccine has ever had a seizure.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at **www.cdc.gov/flu**.

Pneumococcal Conjugate Vaccine: *What You Need to Know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Pneumococcal conjugate vaccine can prevent **pneumococcal disease**.

Pneumococcal disease refers to any illness caused by pneumococcal bacteria. These bacteria can cause many types of illnesses, including pneumonia, which is an infection of the lungs. Pneumococcal bacteria are one of the most common causes of pneumonia.

Besides pneumonia, pneumococcal bacteria can also cause:

- Ear infections
- Sinus infections
- Meningitis (infection of the tissue covering the brain and spinal cord)
- Bacteremia (infection of the blood)

Anyone can get pneumococcal disease, but children under 2 years old, people with certain medical conditions or other risk factors, and adults 65 years or older are at the highest risk.

Most pneumococcal infections are mild. However, some can result in long-term problems, such as brain damage or hearing loss. Meningitis, bacteremia, and pneumonia caused by pneumococcal disease can be fatal.

2. Pneumococcal conjugate vaccine

Pneumococcal conjugate vaccine helps protect against bacteria that cause pneumococcal disease. There are three pneumococcal conjugate vaccines (PCV13, PCV15, and PCV20). The different vaccines are recommended for different people based on age and medical status. Your health care provider can help you determine which type of pneumococcal conjugate vaccine, and how many doses, you should receive.

Infants and young children usually need 4 doses of pneumococcal conjugate vaccine. These doses are recommended at 2, 4, 6, and 12–15 months of age.

Older children and adolescents might need pneumococcal conjugate vaccine depending on their age and medical conditions or other risk factors if they did not receive the recommended doses as infants or young children.

Adults 19 through 64 years old with certain medical conditions or other risk factors who have not already received pneumococcal conjugate vaccine should receive pneumococcal conjugate vaccine.

Adults 65 years or older who have not previously received pneumococcal conjugate vaccine should receive pneumococcal conjugate vaccine.

Some people with certain medical conditions are also recommended to receive pneumococcal polysaccharide vaccine (a different type of pneumococcal vaccine, known as PPSV23). Some adults who have previously received a pneumococcal conjugate vaccine may be recommended to receive another pneumococcal conjugate vaccine.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of any type of pneumococcal conjugate vaccine (PCV13, PCV15, PCV20, or an earlier pneumococcal conjugate vaccine known as PCV7), or to any vaccine containing diphtheria toxoid** (for example, DTaP), or has any **severe, life-threatening allergies**

In some cases, your health care provider may decide to postpone pneumococcal conjugate vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- Redness, swelling, pain, or tenderness where the shot is given, and fever, loss of appetite, fussiness (irritability), feeling tired, headache, muscle aches, joint pain, and chills can happen after pneumococcal conjugate vaccination.

Young children may be at increased risk for seizures caused by fever after a pneumococcal conjugate vaccine if it is administered at the same time as inactivated influenza vaccine. Ask your health care provider for more information.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at **www.cdc.gov/vaccines**.

Pneumococcal Polysaccharide Vaccine (PPSV23): *What You Need to Know*

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Pneumococcal polysaccharide vaccine (PPSV23) can prevent **pneumococcal disease**.

Pneumococcal disease refers to any illness caused by pneumococcal bacteria. These bacteria can cause many types of illnesses, including pneumonia, which is an infection of the lungs. Pneumococcal bacteria are one of the most common causes of pneumonia.

Besides pneumonia, pneumococcal bacteria can also cause:
- Ear infections
- Sinus infections
- Meningitis (infection of the tissue covering the brain and spinal cord)
- Bacteremia (bloodstream infection)

Anyone can get pneumococcal disease, but children under 2 years of age, people with certain medical conditions, adults 65 years or older, and cigarette smokers are at the highest risk.

Most pneumococcal infections are mild. However, some can result in long-term problems, such as brain damage or hearing loss. Meningitis, bacteremia, and pneumonia caused by pneumococcal disease can be fatal.

2 PPSV23

PPSV23 protects against 23 types of bacteria that cause pneumococcal disease.

PPSV23 is recommended for:
- All **adults 65 years or older**,
- Anyone **2 years or older with certain medical conditions that can lead to an increased risk for pneumococcal disease**.

Most people need only one dose of PPSV23. A second dose of PPSV23, and another type of pneumococcal vaccine called PCV13, are recommended for certain high-risk groups. Your health care provider can give you more information.

People 65 years or older should get a dose of PPSV23 even if they have already gotten one or more doses of the vaccine before they turned 65.

3 Talk with your health care provider

Tell your vaccine provider if the person getting the vaccine:
- Has had an **allergic reaction after a previous dose of PPSV23**, or has any **severe, life-threatening allergies**.

In some cases, your health care provider may decide to postpone PPSV23 vaccination to a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting PPSV23.

Your health care provider can give you more information.

U.S. Department of Health and Human Service
Centers for Disease Control and Prevention

4 Risks of a vaccine reaction

- Redness or pain where the shot is given, feeling tired, fever, or muscle aches can happen after PPSV23.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5 What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff do not give medical advice.*

6 How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at **www.cdc.gov/vaccines**

Vaccine Information Statement
PPSV23 Vaccine

Office use only

10/30/2019

Recombinant Zoster (Shingles) Vaccine: *What You Need to Know*

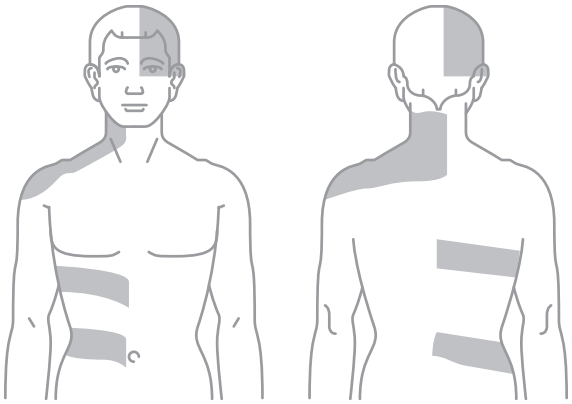
Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Recombinant zoster (shingles) vaccine can prevent **shingles**.

Shingles (also called herpes zoster, or just zoster) is a painful skin rash, usually with blisters. In addition to the rash, shingles can cause fever, headache, chills, or upset stomach. Rarely, shingles can lead to complications such as pneumonia, hearing problems, blindness, brain inflammation (encephalitis), or death.



The risk of shingles increases with age. The most common complication of shingles is long-term nerve pain called postherpetic neuralgia (PHN). PHN occurs in the areas where the shingles rash was and can last for months or years after the rash goes away. The pain from PHN can be severe and debilitating.

The risk of PHN increases with age. An older adult with shingles is more likely to develop PHN and have longer lasting and more severe pain than a younger person.

People with weakened immune systems also have a higher risk of getting shingles and complications from the disease.

Shingles is caused by varicella-zoster virus, the same virus that causes chickenpox. After you have chickenpox, the virus stays in your body and can cause shingles later in life. Shingles cannot be passed from one person to another, but the virus that causes shingles can spread and cause chickenpox in someone who has never had chickenpox or has never received chickenpox vaccine.

2. Recombinant shingles vaccine

Recombinant shingles vaccine provides strong protection against shingles. By preventing shingles, recombinant shingles vaccine also protects against PHN and other complications.

Recombinant shingles vaccine is recommended for:

- **Adults 50 years and older**
- **Adults 19 years and older who have a weakened immune system** because of disease or treatments

Shingles vaccine is given as a two-dose series. For most people, the second dose should be given 2 to 6 months after the first dose. Some people who have or will have a weakened immune system can get the second dose 1 to 2 months after the first dose. Ask your health care provider for guidance.

People who have had shingles in the past and people who have received varicella (chickenpox) vaccine are recommended to get recombinant shingles vaccine. The vaccine is also recommended for people who have already gotten another type of shingles vaccine, the live shingles vaccine. There is no live virus in recombinant shingles vaccine.

Shingles vaccine may be given at the same time as other vaccines.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

PharMerica

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of recombinant shingles vaccine**, or has any **severe, life-threatening allergies**
- Is **currently experiencing an episode of shingles**
- Is **pregnant**

In some cases, your health care provider may decide to postpone shingles vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting recombinant shingles vaccine.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- A sore arm with mild or moderate pain is very common after recombinant shingles vaccine. Redness and swelling can also happen at the site of the injection.
- Tiredness, muscle pain, headache, shivering, fever, stomach pain, and nausea are common after recombinant shingles vaccine.

These side effects may temporarily prevent a vaccinated person from doing regular activities. Symptoms usually go away on their own in 2 to 3 days. You should still get the second dose of recombinant shingles vaccine even if you had one of these reactions after the first dose.

Guillain-Barré syndrome (GBS), a serious nervous system disorder, has been reported very rarely after recombinant zoster vaccine.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

6. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at **www.cdc.gov/vaccines**.

RSV (Respiratory Syncytial Virus) Vaccine: *What You Need to Know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

RSV vaccine can prevent lower respiratory tract disease caused by **respiratory syncytial virus (RSV)**. RSV is a common respiratory virus that usually causes mild, cold-like symptoms.

RSV is usually spread through direct contact with the virus, such as droplets from another person's cough or sneeze contacting your eyes, nose, or mouth. It can also be spread by touching a surface that has the virus on it, like a doorknob, and then touching your face before washing your hands.

RSV can cause illness in people of all ages but may be especially serious for infants and older adults. Infants and older adults with chronic medical conditions like heart or lung disease, weakened immune systems, or who live in nursing homes or long-term care facilities, are at highest risk of serious illness and complications from RSV.

Symptoms of RSV infection may include runny nose, decrease in appetite, coughing, sneezing, fever, or wheezing. Most people recover in a week or two, but RSV can be serious, resulting in shortness of breath and low oxygen levels. RSV can also sometimes lead to worsening of other medical conditions such as asthma, chronic obstructive pulmonary disease (a chronic disease of the lungs that makes it hard to breathe), or congestive heart failure (when the heart can't pump enough blood and oxygen through the body).

Older adults and infants who get very sick from RSV may need to be hospitalized. Some may even die.

2. RSV vaccine

CDC recommends **adults 60 years and older** may receive a single dose of RSV vaccine, based on discussions between the patient and health care provider.

RSV vaccine may be given at the same time as other vaccines.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of RSV vaccine**, or has any **severe, life-threatening allergies**

In some cases, your health care provider may decide to postpone RSV vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting RSV vaccine.

Your health care provider can give you more information.

U.S. Department of Health and Human Service
Centers for Disease Control and Prevention

4. Risks of a vaccine reaction

- Pain, redness, and swelling where the shot is given, fatigue (feeling tired), fever, headache, nausea, diarrhea, and muscle or joint pain can happen after RSV vaccination.

Serious neurologic conditions, including Guillain-Barré syndrome (GBS), have been reported very rarely after RSV vaccination in clinical trials. It is unclear whether the vaccine caused these events.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

6. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at **www.cdc.gov/vaccines**.

Vaccine Consent Form

Resident: _____Birth Date:_____

ID Number: _____ Nursing Care Center: _____

Living Unit: _____ Physician:_____

SPECIAL PRECAUTIONS:

- Consult with a prescriber for use in children under 3 years of age and pregnant women.
- Consult with a prescriber for use in individuals who are allergic to eggs, chicken feather, or chicken dander.
  Note: Beginning with the 2023-24 influenza season, The ACIP voted that people with egg-allergy may receive any flu vaccine (egg-based or non-egg based) that is otherwise appropriate for their age and health status. Additional safety measures are no longer recommended beyond those recommended for receipt of any vaccine.
- Persons with fever should not receive this vaccine.
- Persons who have received another type of vaccine within the past fourteen days should see their prescriber before receiving this vaccine.
- If you have a reaction, see your prescriber immediately. If you have any questions, please ask.

Has the person receiving the vaccine ever had a severe allergic (hypersensitivity) reaction to eggs, latex, thimerosal, or any vaccine component?
*Specify_____ ____*YES ____NO

Does the person receiving the vaccine have a history of Guillain-Barre syndrome or a persistent neurological illness? ____YES ____NO

Has the person received a live vaccine within the past 30 days (i.e. MMR, Rotarix, Zostavax) ____*YES ____NO
*If YES - recommended to space live vaccines by ≥ 4 weeks for full efficacy

Is the person receiving the vaccine currently sick with a fever? ____YES ____NO

Is the person receiving the vaccine currently receiving radiation, chemotherapy, or immunosuppressive therapy? ____YES ____NO

I have read the above information and VIS for my requested vaccination and have had an opportunity to ask questions. I understand the benefits and risks of my requested vaccination(s) as described. I request that the vaccine be given to me or to the person named below for whom I am authorized to sign.

__ _Influenza

__ _PPSV23 (Pneumovax) _ __PCV13 (Prevnar13) _ __PCV15 (Vaxneuvance) __ _PCV20 (Prevnar20)

__ _RZV (Shingrix)

____RSV (Arexvy or Abrysvo)

____ COVID-19 (Pfizer, Moderna, Other)

Resident Name (please print) Date of birth Age

Address City State Zip Code

Signature of person to receive vaccine (or authorized guardian)

----------FOR OFFICE USE ONLY----------

Date/Time of Administration: _____

Immunizer:_____

- Right arm
- Left arm
- Other:_____

Lot #:_____

Expiration Date: _____

Vaccine Name:_____

Vaccine Administration Record (VAR)/Informed Consent for Vaccination at LTCF

****Recipient/Caregiver: Please print clearly and complete the below information in its entirety****

☐ **Resident** ☐ **Staff** ☐ **Other**

First name: _____ **Last name:** _____

Gender: ☐ Female ☐ Male ☐ Unk/Undftd

Date of birth: _____ **Age:** _____ **Phone:** _____

Race: _____ ☐ Unknown **Ethnicity:** _____ ☐ Unknown

LTCF Name: _____ **Address:** _____

City: _____ **State:** _____ **ZIP code:** _____ ***(Home Address if non-Resident)***

Please ensure to record BOTH pharmacy AND medical insurance information since there are multiple ways immunizations can be billed.

Though insurance is being billed to offset administration costs, individuals will not be charged any copay or co-insurance.

Non-Medicare:	Pharmacy Card	Medical Card
Plan Name:		
Insurance Plan/Plan ID:		
Member/Recipient ID #:		
RX BIN:		
RX PCN:		
Group Number:		
Plan Phone Number:		

Medicare:	Medicare Part B
Medicare Number*:	

*Medicare Claim Number for cards distributed earlier than 2018.

Please provide a photocopy of both sides of your insurance cards and identification.

For residents - Please provide a Face Sheet with relevant demographics and insurance information.

☐ **Uninsured**

Is the patient the cardholder? ☐ Yes ☐ No

If no, please provide cardholders name, date of birth (MM/DD/YYY) and relationship: _____

I want to receive the following vaccination(s): ☐ **COVID-19 Vaccination** ☐ **Influenza Vaccination** ☐ **Other:** _____

I certify that I am: (a) the patient and at least 18 years of age; (b) the legal guardian of the patient; or (c) a person authorized to consent on behalf of the patient where the patient is not otherwise competent or unable to consent for themselves. Further, I hereby give my consent to PharMerica Corporation and the licensed healthcare professional administering the vaccine, as applicable (each an "applicable Provider"), to administer the vaccine(s)) I have requested above. I understand that it is not possible to predict all possible side effects or complications associated with receiving vaccine(s). I understand the risks and benefits associated with the above vaccine(s) and have received, read and/or had explained to me the Vaccine Information Sheet (VIS) or EUA Fact Sheet on the vaccine(s) I have elected to receive. I also acknowledge that I have had a chance to ask questions and that such questions were answered to my satisfaction. Further, I acknowledge that I have been advised that the patient should remain near the vaccination location for observation for approximately 15 minutes after administration. On behalf of the patient, the patient's heirs and personal representatives, I hereby release and hold harmless each applicable Provider, its staff, agents, successors, divisions, affiliates, subsidiaries, officers, directors, contractors and employees from any and all liabilities or claims whether known or unknown arising out of, in connection with, or in any way related to the administration of the vaccine(s) listed above.

I acknowledge that: (a) I understand the purposes/benefits of my state's vaccination registry ("State Registry") and my state's health information exchange ("State HIE"); and (b) the applicable Provider may disclose my vaccination information to the State Registry, to the State HIE, or through the State HIE to the State Registry, or to any state or federal governmental agencies or authorities ("Government Agencies"), such as state, county, or local Departments of Health or the federal Department of Health and Human Services, the Center for Disease Control and Prevention, or their respective designees as may be required by law, for purposes of public health reporting, or to my healthcare providers enrolled in the State Registry and/or State HIE for purposes of care coordination. I acknowledge that, depending upon my state's law, I may prevent, by using a state-approved opt-out form or, as permitted by my state law, an opt-out form ("Opt-Out Form") furnished by the applicable Provider: (a) the disclosure of my vaccination information by the applicable Provider to the State HIE and/or State Registry; or (b) the State HIE and/or State Registry from sharing my vaccination information with any of my other healthcare providers enrolled in the State Registry and/or State HIE. The applicable Provider will, if my state permits, provide me with an Opt-Out Form. I understand that, depending on my state's law, I may need to specifically consent, and, to the extent required by my state's law, by signing below, I hereby do consent to the applicable Provider reporting my vaccination information to the Government Agencies, State HIE, or through the State HIE and/or State Registry to the entities and for the purposes described in this Informed Consent form. Unless I provide the applicable Provider with a signed Opt-Out Form, I understand that my consent will remain in effect until I withdraw my permission and that I may withdraw my consent by providing a completed Opt-Out Form to the applicable Provider and/or my State HIE, as applicable.

I understand that even if I do not consent or if I withdraw my consent, my state's laws or federal law may permit certain disclosures of my vaccination information to or through the State HIE or to Government Agencies as required or permitted by law. I further authorize the applicable Provider to: (a) release my medical or other information, including any communicable disease (including HIV), and mental health information, to, or through, the State HIE or Government Agencies to my healthcare professionals, Medicare, Medicaid, or other third-party payer as necessary to effectuate care or payment; (b) submit a claim to my insurer for the above requested items and services; and (c) request payment of authorized benefits be made on my behalf to the applicable Provider with respect to the above requested items and services. I further agree to be fully financially responsible for any cost-sharing amounts, including copays, coinsurance and deductibles, for the requested items and services, as well as for any requested items and services not covered by my insurance benefits. I understand that any payment for which I am financially responsible is due at the time of service or, if the applicable Provider invoices me after the time of service, upon receipt of such invoice. PharMerica Corporation may disclose your vaccination information from this visit for public health purposes and will send this information to the Medical Director or Administrator of the LTCF identified above. If you are an employee of the LTCF, PharMerica Corporation will send your vaccination information to your employer as required. I hereby acknowledge that I have received PharMerica's Notice of Privacy Practices.

Print Name: _____ **Patient/Authorized Person signature:** _____ **Dat**

PharMerica

Recipient Name: _____

These sections to be completed day of clinic by vaccinator/support staff

Complete immediately PRIOR to vaccine administration

SCREENING QUESTIONS. The following questions will help us determine your eligibility to be vaccinated today.

1. Have you received a previous dose of COVID-19 vaccine? ☐ Yes ☐ No ☐ Don't know
2. Do you feel sick today? ☐ Yes ☐ No ☐ Don't know
3. Have you had thrombocytopenia syndrome (TTS), myocarditis, or pericarditis after COVID-19 vaccination? ☐ Yes ☐ No ☐ Don't know
4. Do you have allergies to latex, medications, food, vaccines or any component of vaccines (examples: Polyethylene glycol (PEG) or polysorbate). If yes, please list: _____ ☐ Yes ☐ No ☐ Don't know
5. Have you ever had a reaction after receiving a vaccination, including fainting or feeling dizzy? ☐ Yes ☐ No ☐ Don't know
6. Do you have a bleeding disorder or are you on a blood thinner? ☐ Yes ☐ No ☐ Don't know
7. **For women of childbearing age**: Are you pregnant or considering becoming pregnant in the next month? ☐ Yes ☐ No ☐ Don't know

Complete AFTER vaccine administration

COVID-19 Vaccine Manufacturer	Expiration	Lot Number	Dosage	Site of administration	EUA Fact Sheet/VIS date
				☐ **L** Deltoid ☐ **R** Deltoid ☐ Other:	

☐ Dose 1 ☐ Dose 2 ☐ Dose 3 - Immunocompromised ☐ Booster 1 ☐ Booster 2

Clinician's name (print): _____ **Clinician's signature:** _____ **Title:** _____

If applicable, intern/tech name (print): _____ **Administration date:** _____ **Date EUA Fact Sheet/VIS given to patient:** _____

Influenza Vaccine Manufacturer	Expiration	Lot Number	Dosage	Site of administration	VIS published date
				☐ **L** Deltoid ☐ **R** Deltoid ☐ Other:	

Clinician's name (print): _____ **Clinician's signature:** _____ **Title:** _____

If applicable, intern/tech name (print): _____ **Administration date:** _____ **Date VIS given to patient:** _____

Other Vaccine:	Expiration	Lot Number	Dosage	Site of administration	VIS published date
Manufacturer:				☐ **L** Deltoid ☐ **R** Deltoid ☐ Other:	

Clinician's name (print): _____ **Clinician's signature:** _____ **Title:** _____

If applicable, intern/tech name (print): _____ **Administration date:** _____ **Date VIS given to patient:** _____

1. Update the patient's record with any new allergy, health condition or primary care provider information.
2. Enter vaccine lot #, expiration date and site of administration, then scan the VAR form into the patient's record.

Declination of Influenza or Pneumococcal Vaccination

My health facility,_____, has recommended that I receive an **influenza** and/or **pneumococcal vaccination** to protect myself and other residents or employees in the facility.

I acknowledge that I am aware of the following facts:

Influenza

- Influenza is a serious respiratory disease that kills thousands of people in the US each year.
- Influenza vaccination is recommended for me to protect this facility's patients from influenza, its complications, and death.
- If I contract influenza, I can shed the virus for 24 hours before influenza symptoms appear.
- My shedding the virus can spread influenza to patients in this facility.
- If I become infected with influenza, even if my symptoms are mild or non-existent, I can spread it to others and they can become seriously ill.
- I understand that I cannot get influenza from the influenza vaccine.
- The consequences of my refusing to be vaccinated could have life-threatening consequences to my health and the health of those with whom I have contact.
- Influenza vaccination is recommended by the Centers for Disease Control and Prevention.

Pneumococcal

- Pneumococcal disease kills more people in the US each year than all other vaccine preventable diseases combined.
- Those >65 years, the very young, and people with special health problems (alcoholism, heart or lung disease, kidney failure, HIV, certain cancers) are at greater risk.
- Pneumococcal disease can lead to serious infections of the lungs (pneumonia), the blood (bacteremia), and the covering of the brain (meningitis).
- The bacteria causing pneumococcal disease have become more resistant to antibiotics used today, making prevention even more important.
- Pneumococcal vaccination is recommended by the Centers for Disease Control and Prevention

I was offered a vaccination of (please check):

☐ **Influenza Vaccine**

☐ **Pneumococcal Conjugate Vaccine (PCV13, PCV15, PCV20)**

☐ **Pneumococcal Polysaccharide Vaccine (PPSV23)**

Despite these facts, I am choosing to decline vaccination right now for the following reasons:

_____

_____

I understand that I can change my mind at any time and accept this vaccination if it is still available.
I have read and fully understand the information on this declination form.

Signature: _____Date: _____

Name (print): _____

Developed using references published by the Immunization Action Coalition (IAC) www.immunize.org

DECLINATION OF COVID-19 VACCINATION

Name: _____

My health facility/employer,_____, has offered the opportunity for me to receive a COVID-19 vaccination to protect myself and other residents or employees in the facility.

I acknowledge that I am aware of the following facts:

COVID-19

- COVID-19 is a serious respiratory disease that has infected millions and killed hundreds of thousands of people in the US in 2020 alone.
- The Advisory Committee on Immunization Practices (ACIP) identifies Long-Term Care residents as some of the nation's most vulnerable individuals, and has prioritized my access to this vaccination.
- Accordingly, the Centers for Disease Control and Prevention (CDC) recommends that I receive any authorized and age-appropriate COVID-19 vaccine to protect myself and this facility's patients from COVID-19, its complications, and death.
- If I contract COVID-19, I can shed the virus even without presenting symptoms.
- My shedding the virus can spread COVID-19 to other patients and staff in this facility.
- If I become infected with COVID-19, even if my symptoms are mild or non-existent, I can spread it to others and they can become seriously ill.
- I understand that I cannot get COVID-19 from any currently authorized or proposed COVID-19 vaccine.
- The consequences of my refusing to be vaccinated could have life-threatening consequences to my health and the health of those with whom I have contact.

Despite these facts, I am choosing to decline Coronavirus Vaccination right now for the following reasons:

_____

_____

_____

I understand that I can change my mind at any time and accept this vaccination if it is still available. I understand that current vaccine supply and demand dynamics may preclude me from receiving timely administration at a later date.

I have read and fully understand the information on this declination form.

Signature:_____ Date: _____

Name (print): _____

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

Adverse events are possible reactions or problems that occur during or after vaccination. Items **2, 3, 4, 5, 6, 17, 18** and **21** are **ESSENTIAL** and should be completed. Patient identity is kept confidential. Instructions are provided on the last two pages.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE (Use **Continuation Page** if needed).

1. Patient name: (first) _____ (last) _____
Street address: _____
City: _____ State: _____ County: _____
ZIP code: _____ Phone: ( ) _____ Email: _____

2. Date of birth: (mm/dd/yyyy) _____ 3. Sex: ☐ Male ☐ Female ☐ Unknown

4. Date and time of vaccination: (mm/dd/yyyy) _____ Time: hh:mm ☐AM ☐PM

5. Date and time adverse event started: (mm/dd/yyyy) _____ Time: hh:mm ☐AM ☐PM

6. Age at vaccination: ____ Years ____ Months 7. Today's date: (mm/dd/yyyy) _____

8. Is the report about vaccine(s) given to a pregnant woman?: ☐ No ☐ Unknown ☐ Yes
(If yes, describe the event, any pregnancy complications, and estimated due date if known in item 18).

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:

10. Allergies to medications, food, or other products:

11. Other illnesses at the time of vaccination and up to one month prior:

12. Chronic or long-standing health conditions:

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) _____
Relation to patient: ☐ Healthcare professional/staff ☐ Patient (yourself) ☐ Parent/guardian/caregiver ☐ Other:
Street address: _____ ☐ Check if same as item 1.
City: _____ State: _____ ZIP code: _____
Phone: ( ) _____ Email: _____

14. Best doctor/healthcare professional to contact about the adverse event: Name: _____ Phone: ( ) _____ Ext: _____

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: _____
Fax: ( ) _____
Street address: ☐ Check if same as item 13.
_____
_____
City: _____
State: _____ ZIP code: _____
Phone: ( ) _____

16. Type of facility: (Check one).
☐ Doctor's office or hospital
☐ Pharmacy or drug store
☐ Workplace clinic
☐ Public health clinic
☐ Nursing home or senior living facility
☐ School/student health clinic
☐ Other:
☐ Unknown

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given). Use **Continuation Page** if needed.

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose no. in series
select			select	select	select
select			select	select	select
select			select	select	select
select			select	select	select

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Use **Continuation Page** if needed.

19. Medical tests and laboratory results related to the adverse event(s): (include dates)
Use **Continuation Page** if needed.

20. Has the patient recovered from the adverse event(s)?: ☐ Yes ☐ No ☐ Unknown

21. Result or outcome of adverse event(s): (Check all that apply).
☐ Doctor or other healthcare professional office/clinic visit
☐ Emergency room or emergency department visit
☐ Hospitalization: Number of days (if known)
Hospital name:
City: State:
☐ Prolongation of existing hospitalization (vaccine received during existing hospitalization)
☐ Life threatening illness (immediate risk of death from the event)
☐ Disability or permanent damage
☐ Patient died: Date of death (mm/dd/yyyy)
☐ Congenital anomaly or birth defect
☐ None of the above

ADDITIONAL INFORMATION (Use **Continuation Page** if needed).

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose no. in series
select			select	select	select
select			select	select	select

23. Has the patient ever had an adverse event following any previous vaccine?: (If yes, describe adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name).
☐ No ☐ Unknown ☐ Yes

24. Patient's race: (Check all that apply). ☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander ☐ White ☐ Unknown ☐ Other:

25. Patient's ethnicity: ☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown

26. Immuniz. proj. report no.: (Health Dept use only). _____

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at vaccination: ☐ Active duty ☐ Reserve ☐ National Guard ☐ Beneficiary ☐ Other:

28. Vaccinated at Military/DoD site: ☐ Yes ☐ No

FORM FDA VAERS-2.0 (6/17)

SAVE

17. Enter all vaccines given on the date listed in item 4 (continued):					Dose no. in series
Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	
select			select	select	select
select			select	select	select
select			select	select	select
select			select	select	select

22. Any other vaccines received within one month prior to the date listed in item 4 (continued):					Dose no. in series
Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	
select			select	select	select
select			select	select	select
select			select	select	select
select			select	select	select
select			select	select	select
select			select	select	select

Use the space below to provide any additional information (indicate Item number): RETURN TO PAGE 1

COMPLETING THE VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS) FORM

GENERAL INSTRUCTIONS

- Submit this form electronically using the Internet. For instructions, visit www.vaers.hhs.gov/uploadfile/.
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366.
- If you need additional help submitting a report you may call the VAERS toll-free information line at 1-800-822-7967, or send an email to info@vaers.org.
- Fill out the VAERS form as completely as possible and use the **Continuation Page** if needed. Use a separate VAERS form for each individual patient.
- If you do not know exact numbers, dates, or times, please provide your best guess. You may leave these spaces blank if you are not comfortable guessing.
- You can get specific information on the vaccine and vaccine lot number by contacting the facility or clinic where the vaccine was administered.
- Please report all significant adverse events that occur after vaccination of adults and children, even if you are not sure whether the vaccine caused the adverse event.
- Healthcare professionals should refer to the VAERS Table of Reportable Events at www.vaers.hhs.gov/reportable.html for the list of adverse events that must be reported by law (42 USC 300aa-25).
- Healthcare professionals treating a patient for a suspected vaccine adverse event may need to contact the person who administered the vaccine in order to exchange information and decide how best to complete and submit the VAERS form.

SPECIFIC INSTRUCTIONS

Items 2, 3, 4, 5, 6, 17, 18 and 21 are **ESSENTIAL** and should be completed.

- **Items 4 and 5**: Provide dates and times as specifically as you can and enter as much information as possible (e.g., enter the month and year even if you don't know the day). If you do not know the exact time, but know it was in the morning ("AM") or afternoon or evening ("PM"), please provide that information.
- **Item 6**: If you fill in the form by hand, provide age in years. If a child is less than 1 year old, provide months of age. If a child is more than 1 year old but less than 2 years old, provide year and months (e.g., 1 year and 6 months). If a child is less than 1 month of age when vaccinated (e.g., a birth dose of hepatitis B vaccine) then answer 0 years and 0 months, but be sure to include the patient's date of birth (Item 2) and date and time of vaccination (Item 4).
- **Item 8:** If the report is about a vaccine given to a pregnant woman, select "Yes" and describe the event, any pregnancy complications, and estimated due date if known in item 18. Otherwise, select "No" or "Unknown."
- **Item 9:** List any prescriptions, over-the-counter medications, dietary supplements, herbal remedies, or other non-traditional/ alternative medicines being taken by the patient when the vaccine(s) was given.
- **Item 10:** List any allergies the patient has to medications, foods, or other products.
- **Item 11:** List any short-term or acute illnesses the patient had on the date of vaccination AND up to one month prior to this date (e.g., cold, stomach flu, ear infection, etc.). This does **NOT** include the adverse event you are reporting.
- **Item 12:** List any chronic or long-standing health conditions the patient has (e.g., asthma, diabetes, heart disease).
- **Item 13:** List the name of the person who is completing the form. Select the "Check if same as item 1" box if you are the patient or if you live at the same address as the patient. The contact information you provided in item 1 will be automatically entered for you. Otherwise, please provide new contact information.
- **Item 14:** List the doctor or other healthcare professional who is the best person to contact to discuss the clinical details of the adverse event.
- **Item 15:** Select the "Check if same as item 13" box if the person completing the form works at the facility that administered the vaccine(s). The contact information provided in item 13 will be automatically entered for you. Otherwise, provide new contact information.
- **Item 16:** Select the option that best describes the type of facility where the vaccine(s) was given.

- **Item 17:** Include only vaccines given on the date provided in item 4. The vaccine route options include:

  - Injection/shot (intramuscular, subcutaneous, intradermal, jet injection, and unknown)
  - By mouth/oral
  - In nose/intranasal
  - Other (specify)
  - Unknown

  For body site, the options include:

  - Right arm
  - Left arm
  - Arm (side unknown)
  - Right thigh
  - Left thigh
  - Thigh (side unknown)
  - Nose
  - Mouth
  - Other (specify)
  - Unknown

  For vaccines given as a series (i.e., 2 or more doses of the same vaccine given to complete a series), list the dose number for the vaccine in the last column named "Dose no. in series."

- **Item 18:** Describe the adverse event(s), treatment, and outcome(s). Include signs and symptoms, when the symptoms occurred, diagnosis, and treatment. Provide specific information if you can (e.g., if patient had a fever, provide the temperature).
- **Item 19:** List any medical tests and laboratory results related to the adverse event(s). Include abnormal findings as well as normal or negative findings.
- **Item 20:** Select "Yes" if the patient's health is the same as it was prior to the vaccination or "No" if the patient has not returned to the same state of health prior to the vaccination, and provide details in item 18. Select "Unknown" if the patient's present condition is not known.
- **Item 21:** Select the result(s) or outcome(s) for the patient. If the patient did not have any of the outcomes listed, select "None of the above." Prolongation of existing hospitalization means the patient received a vaccine during a hospital stay and an adverse event following vaccination occurred that resulted in the patient spending extra time in the hospital. Life threatening illness means you believe this adverse event could have resulted in the death of the patient.
- **Item 22:** List any other vaccines the patient received within one month prior to the vaccination date listed in item 4.
- **Item 23:** Describe the adverse event(s) following any previous vaccine(s). Include patient age at vaccination, dates of vaccination, vaccine type, and brand name.
- **Item 24:** Check all races that apply.
- **Item 25:** Check the single best answer for ethnicity.
- **Item 26:** For health department use only.
- **Items 27 and 28:** Complete only for U.S. Military or Department of Defense related reports. In addition to active duty service members, Reserve and National Guard members, beneficiaries include: retirees, their families, survivors, certain former spouses, and others who are registered in the Defense Enrollment Eligibility Reporting System (DEERS).

GENERAL INFORMATION

- VAERS (www.vaers.hhs.gov) is a national vaccine safety monitoring system that collects information about adverse events (possible reactions or problems) that occur during or after administration of vaccines licensed in the United States.
- VAERS protects patient identity and keeps patient identifying information confidential.
- The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule permits reporting of protected health information to public health authorities including the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) (45 CFR § 164.512(b)).
- VAERS accepts all reports without judging the importance of the adverse event or whether a vaccine caused the adverse event.
- Acceptance of a VAERS report by CDC and FDA does not constitute admission that the vaccine or healthcare personnel caused or contributed to the reported event.
- The National Vaccine Injury Compensation Program (VICP) is administered by the Health Resources and Services Administration (HRSA). The VICP is separate from the VAERS program and reporting an event to VAERS does not constitute filing a claim for compensation to the VICP (see www.hrsa.gov/vaccinecompensation/index.html).
- Knowingly filing a false VAERS report with the intent to mislead the Department of Health and Human Services is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.