Influenza
and
Adult Immunization Guide

PharMerica

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Purpose for this Guide

This guide is for general informational purposes only. 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. Essential documents are included, such as **Vaccine Information Sheets** (VIS), **Consent Forms** and **Declination Forms**.

This year's publication will also comment on *non*-COVID-19 vaccination with respect to COVID-19.

Note: At the time of publication, the authors of this guide are providing current information sourced from national organizations such as the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC). Users are reminded that information around this virus is continually growing, and therefore, recommendations are considered subject-to-change. Users are encouraged to regularly consult the CDC's interim clinical considerations for guidance on COVID-19 related matters, including vaccination schedules and co-administration of COVID-19 vaccines with other immunizations.

As a whole, routine vaccine recommendations for other preventable illnesses remain unchanged throughout the COVID-19 pandemic. The recommendation to administer COVID-19 vaccines alone (minimum interval of 14 days before or after other vaccines) was *previously* made out of an abundance of caution, and no longer stands as consensus expert opinion. CDC currently states that COVID-19 vaccines **may now be administered without regard to timing**. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day, as well as co-administration within 14 days.

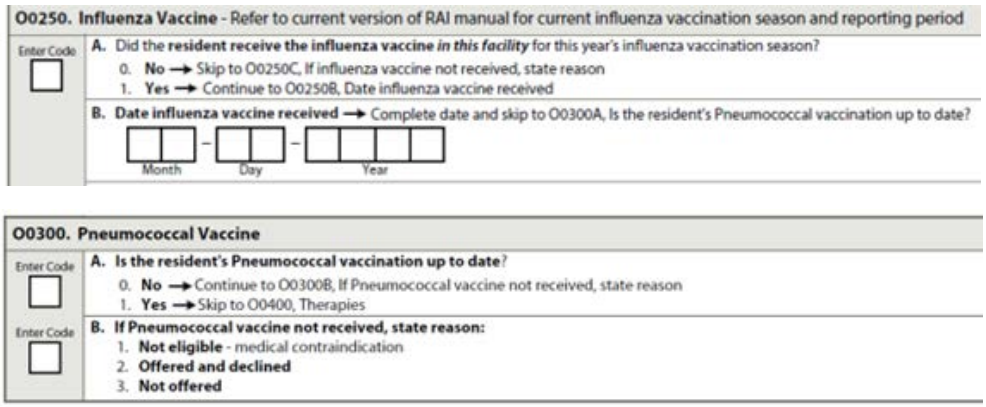
Acknowledgements

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 2022-23 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 Adds COVID-19 Vaccinations to List of Regulated Immunizations to be Offered in Nursing Homes

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 Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff." This IFC called for the novel COVID-19 vaccines to be treated in similar manner to influenza and pneumococcal vaccines, with LTCFs bearing additional responsibility for ensuring all residents and staff receive **appropriate education** and the **opportunity to be vaccinated**.

CMS has lifted the physician signature requirement for administration of COVID-19 vaccines to long-term care facility residents during the federal Public Health Emergency (PHE). Administrators and Healthcare Providers (HCPs) are encouraged to stay apprised of changing regulatory guidance with respect to the PHE.

Specifically, the CMS IFC enumerates the following regulatory criteria:

I. LTC Facilities must develop **policies and procedures** to:
   - **Educate** residents, resident representatives and staff on benefits and potential side effects of COVID-19 vaccines.
   - **Offer** COVID-19 vaccine to all of these individuals unless it is medically contraindicated or they have already been immunized.

II. LTC Facilities must maintain appropriate **documentation** to reflect that the facility has provided the required vaccine education, and whether residents and staff members have received the vaccine.

III. LTC Facilities must **report** additional data to the National Healthcare Safety Network (NHSN), including:
   - COVID-19 vaccine status of residents and staff.
   - Each dose of vaccine received.
   - COVID-19 vaccination adverse events.
   - Therapeutics administered to residents for COVID-19 treatment.

Noncompliance related to the new requirements for **educating** and **offering** COVID-19 vaccination to residents and staff will be cited at F-tag 887, and noncompliance related to COVID-19 vaccination **reporting** will be cited at F-tag 884.

Shingles: Additional Vaccine Preventable Disease with Impact to Older Adults

Shingles (Herpes Zoster) presents an additional Vaccine Preventable Disease (VPD) with impact to older adults. While vaccination against shingles is not an explicit CMS requirement, preventing and mitigating shingles outbreaks in Long Term Care Facilities (LTCFs) may have significant health and cost benefits.

Who can develop Herpes Zoster (HZ) Infections?

- Anyone who has had natural infection with Varicella Zoster Virus (VZV) or had varicella vaccination can develop HZ[1]
- 99.5% of adults in the US born before 1980 were infected with VZV and are at risk for developing HZ[2]
- In 1 out of 3 people, the dormant VZV reactivates and causes shingles[3]

What factors increase an individual's risk of developing HZ infection?

- Age and/or reduced immune function

What complications can occur?

- Postherpetic neuralgia
  - Most common complication; more common and severe in older adults[4]
  - Nerve pain that lasts for 3 months (≥90 days) and can sometimes last for years[3,5]
- Herpes Zoster Ophthalmicus (HZO)
  - Can lead to ophthalmic complications (e.g. keratitis, uveitis, optic neuritis), including, in rare cases, vision loss[4]
  - Affects between 10%-25% of adults with shingles
- Cardiovascular Complications
  - HZ is associated with increased short-term risk of cerebrovascular and cardiac events[6,7,8]
  - HZO associated with even greater risk of stroke[6,7,8]
- Other Complications
  - Bacterial superinfection
  - Meningoencephalitis
  - Disseminated HZ: HZ with lesions involving > 2 dermatomes or any visceral or CNS involvement

Shingrix (Zoster Vaccine Recombinant, Adjuvanted [RZV])[5]

Indications: Shingrix is a vaccine indicated for prevention of HZ:

- In adults aged 50 years and older
- In adults aged 18 years and older who are or will be at increased risk of HZ due to immunodeficiency or immunosuppression caused by known disease or therapy

Limitations of use: Shingrix is not indicated for prevention of primary varicella infection (chickenpox).

Contraindications: History of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or after a previous dose of Shingrix.

Dosing: Two doses (0.5 mL each) administered intramuscularly according to the following schedules:

- A first dose at month 0 followed by a second dose administered 2 to 6 months later
- For individuals who are or will be immunodeficient or immunosuppressed and who would benefit from a shorter vaccination schedule: a first dose at month 0 followed by a second dose administered 1 to 2 months later

Warnings and Precautions:

- Prior to administration, the HCP should review the immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of Shingrix.
- In a postmarketing observational study, an increased risk of Guillain-Barré syndrome was observed during the 42 days following vaccination with Shingrix.
- Syncope (fainting) can be associated with the administration of injectable vaccines, including Shingrix. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope.

CDC Recommendations

Routine Vaccination of People 50 Years Old and Older: CDC recommends Shingrix® (RZV) to prevent HZ and related complications whether or not they report a prior episode of herpes zoster or if they report a prior dose of Zostavax.

Vaccination of Immunocompromised Adults 19 Years and Older: CDC recommends Shingrix® (RZV) for the prevention of HZ and related complications in adults aged ≥19 years who are or will be immunodeficient or immunosuppressed because of disease or therapy. The 2nd 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.

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Medicare Coverage of Vaccinations

	Vaccine Preventable Disease	Products Covered
Part B	Influenza	Quadrivalent, High Dose, Adjuvant
	Pneumococcal	Prevnar 13, Vaxneuvance, Prevnar 20, Pneumovax 23
	Hepatitis B[1]	Energix-B, Recombivax HB, Heplisav-B
	COVID-19[2]	Pfizer, Moderna, Janssen, Novavax (and other COVID-19 vaccines under EUA/BLA)
	[1] Patients at Medium to High Risk for infection as designated by Medicare	
	[2] CARES ACT requires COVID-19 vaccine coverage under Part B with no beneficiary cost-sharing	
Part D	Hep A/ Hep B	Twinrix
	Herpes Zoster	Shingrix
	HPV	Gardasil
	Tdap	Adacel, Boostrix
	Meningococcal	Menactra, Menveo
	Others	All commercially available vaccines (not otherwise covered by Part B) when they are reasonable and necessary to prevent illness; co-pays may apply
Part B with Clinical Review[3]	Rabies	Imovax, RabAvert
	Hep A	Havrix, VAQTA
	Tetanus Toxoid	Tetanus Toxoid
	Anthrax	BioThrax
	[3] Vaccines directly related to the treatment of an injury or direct exposure to a disease or condition, such as rabies and tetanus	

Vaccine Recommendations: What's New?

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Introduction

Vaccinations markedly decrease the burden of certain infectious diseases and are responsible for preventing nearly 2.5 million deaths annually.[1,2] The Centers for Disease Control and Prevention (CDC) update recommendations for vaccination use every year based on guidance from the Advisory Committee on Immunization Practices (ACIP). ACIP is comprised of public health and medical experts that meet at least three times a year to discuss the safety and efficacy of vaccinations. There is generally a discussion of disease severity and impact. ACIP assesses vaccinations for people of different ages when determining practicality of recommending certain vaccinations.[3]

ACIP revisions are submitted to and evaluated by the CDC.[3] Recommendations are published in CDC's Morbidity and Mortality Weekly Report (MMWR) annually. This year, the published recommendations were released in the updated vaccine schedule in February.[4]

The updated vaccination schedule includes recommendations that impact the geriatric population and patients residing in long term care facilities. This includes changes to pneumococcal, shingles and hepatitis B vaccination schedules.

Pneumococcal

What is Pneumococcal Disease?

Pneumococcal infections are caused by the bacterium *Streptococcus pneumoniae*. This bacterium can cause pneumonia, otitis media, sinusitis, meningitis, and bacteremia upon infection.[5] Pneumococcal vaccines help prevent illnesses caused by the bacterium *Streptococcus pneumoniae*. Vaccinations also aid in lowering severity of disease.[6]

Currently, there are three conjugate and one polysaccharide pneumococcal vaccinations available in the United States. These vaccines not only differ in how they are made, but also the serotypes they cover as shown in Table 1.[8] Pneumococcal conjugate vaccines are made by linking a polysaccharide antigen to a protein molecule which produces lasting immunity to the polysaccharide antigen. PCV13, PCV15, and PCV20 are the three subtypes of available pneumococcal conjugate vaccines. Pneumococcal polysaccharide vaccines contain a polysaccharide antigen only. PPSV23 is the only available pneumococcal polysaccharide vaccine.[7]

Recommendations:

PCV13 is given as a routine vaccination to children under the age of 2. It is recommended that all adults 65 years or older receive a pneumococcal conjugate vaccine (PCV15 or PCV20) if they have never received a conjugate vaccine or if vaccine history is unknown. If PCV15 is used, it should be followed by a dose of PPSV23 one year later. If a patient has an immunocompromising condition, cochlear implant(s), or a history of cerebrospinal fluid leak and has received a PCV15, a shorter interval of 8 weeks before PPSV23 is given can be considered. The minimum interval between PCV15 and PPSV23 is 8 weeks. If PCV20 is used, a dose of PPSV23 is not needed one year later.[9]

CDC also recommends that patients ages 19-64 with certain medical conditions or risk factors receive the pneumococcal vaccination. These conditions are summarized in Table 2 on the next page. It is recommended to give one dose of PCV15 or PCV20 to these individuals.

If PCV15 is given, PPSV23 should be given one year later. If a patient has received PPSV23, a dose of PCV15 or PCV20 should be given a year later.[9]

The potential additional health benefits of providing PCV15 or PCV20 to adults who have received PCV13 only or both PCV13 and PPSV23 have not yet been studied.[9]

Table 1. Comparison of serotypes in pneumococcal vaccines[8]

PCV13 (Prevnar 13)	PCV15 (Vaxneuvance)	PCV20 (Prevnar 20)	PPSV23 (Pneumovax 23)
1	1	1	1
–	–	–	2
3	3	3	3
4	4	4	4
5	5	5	5
6A	6A	6A	6A
6B	6B	6B	6B
7F	7F	7F	7F
–	–	8	8
–	–	–	9N
9V	9V	9V	9V
–	–	10A	10A
–	–	11A	11A
–	–	12A	12A
14	14	14	14
–	–	15B	15B
–	–	–	17F
18C	18C	18C	18C
19A	19A	19A	19A
19F	19F	19F	19F
–	–	–	20
–	–	22F	22F
23F	23F	23F	23F
–	33F	33F	33F

Table 2. Medical conditions or risk factors for receiving pneumococcal vaccine(s)[9]

Condition or risk factor
- Alcoholism - Cerebrospinal fluid leak - Chronic heart disease (CHF and cardiomyopathies) - Chronic liver disease - Chronic lung disease (COPD, emphysema, and asthma) - Chronic renal failure - Cigarette smoking - Cochlear implant(s) - Congenital/acquired asplenia - B or T-lymphocyte deficiency - Complement deficiency (especially C1, C2, C3, or C4 deficiency) - Phagocytic disorder (minus chronic granulomatous disease) - Diabetes mellitus - Malignancy - HIV - Hodgkin's disease - Iatrogenic immunosuppression (long-term systemic corticosteroids and radiation therapy) - Leukemia - Lymphoma - Multiple myeloma - Nephrotic syndrome - Sickle cell disease/hemoglobinopathies - Solid organ transplant

Shingles

What is Shingles?

Shingles, also known as herpes zoster, is an infection that is caused by the reactivation of a latent virus, varicella-zoster. It is the same virus that causes chickenpox. After an individual recovers from chickenpox, the virus can lay dormant within the body for years. Reactivation of the virus causes the infection known as shingles. Common signs and symptoms include blister-like sores which can be itchy and painful. These blisters typically appear unilaterally on the face, neck, shoulder, or rib region.[10] Individuals may experience postherpetic neuralgia that lasts months to years after resolution of an active shingles infection.[11]

Recommendations:

The recombinant zoster vaccine (RZV) was approved by the FDA in 2017 for the prevention of in individuals aged 50 years and older. The vaccination is comprised of two doses of 0.5 mL each administered intramuscularly two to six months apart.[12] Previously, RZV was recommended for the prevention of herpes zoster in immunocompetent adults aged ≥50 years.[13] However, there has been unmet need with RVZ in immunocompromised adults. It has been recognized that those who are immunocompromised may be susceptible to a higher incidence of infection and experience more complications to herpes zoster. In the late fall of 2021, ACIP updated its recommendation for RZV as a preventative measure in individuals ≥18 years with immunodeficiency or immunosuppression due to a known cause.[6] Current recommendations for shingles vaccination are shown in Table 3. There is currently no recommendation by the CDC for shingles vaccination in pregnancy.[14]

Table 3. Recommendations for shingles vaccination[14]

Criteria	Dosing regimen	Comments
Age ≥ 50 years OR Age ≥18 years at increased risk due to immunodeficiency or immunosuppression*	RZV (2 doses) 0.5mL IM, 2-6 months apart	*Immunocompromising conditions include:* Chronic heart disease Chronic lung disease Cirrhosis Diabetes mellitus Cerebrospinal fluid leak Cochlear implant Current cigarette smoking Alcohol use disorder Sickle cell disease History of invasive pneumonia

Hepatitis B

What is Hepatitis B?

Hepatitis is described as the inflammation of the liver. Inflammation of the liver may occur due to numerous factors, including a viral etiology. It is estimated that 296 million individuals are living with hepatitis B and approximately 1.5 million new infections occur annually worldwide.[15] This virus may initially present as an acute infection over a period of weeks to months. The acute phase may be symptomatic or asymptomatic and some individuals are able to recover without treatment. Symptoms may include lack of appetite, fatigue, muscle or joint pain, dark urine, or jaundice.[16] An acute hepatitis B infection can progress into a chronic condition that renders health complications such as cirrhosis or hepatic cancer.

Recommendations:

Hepatitis B can be prevented by receiving a full series of hepatitis B vaccinations. There are four different hepatitis vaccinations available in the United States. Depending on age and product, an individual may receive a two, three, or four dose series with one of the four vaccinations. Infants are typically vaccinated at birth and complete the hepatitis B series by 18 months of age. Recently, hepatitis B recommendations have expanded from a risk-based approach to a more universal approach. This change includes a recommendation for all adults 19 to 59 years and adults 60 years or older with risk factors for hepatitis B. Adults age 60 or older without known risk factor for hepatitis B may receive vaccination, as well.[17]

Heplisav-B is a recombinant, adjuvanted vaccine indicated for the prevention of hepatitis B. It is a two-dose series of 0.5 mL intramuscularly with at least four weeks between doses.[18] Engerix-B and Recombivax HB are also recombinant vaccines.[19,20] Twinrix is unique in that it is indicated for active immunization against disease caused by hepatitis A virus and infection by hepatitis B.[21] Table 4 outlines the recommendations for the different hepatitis B vaccines.

Conclusion

The schedule for the use of vaccines in standard practice is updated annually to reflect the most current guidance. The 2022 immunization schedule for adults aged ≥19 years of age includes changes and updates to the pneumococcal, shingles and hepatitis B vaccinations.[3] Because vaccine specific changes may occur throughout the year, it is suggested to check respective ACIP vaccine recommendations to ensure best practices. Pharmacists can provide a valuable role in promoting, supporting, and administering vaccinations. Screening patients for vaccines, making recommendations, and counseling are among the important contributions pharmacists make to positively impact public health.[22]

Table 4. Recommendations for hepatitis B vaccination in adults[18-21]

Vaccine	Age Group / Condition	Dosage	*Risk Factors
Engerix-B	≤19 yrs (3 doses)	0.5 mL	*Sexual Exposure* Sexually active with multiple partners Sexually active with a partner who has a positive HBsAg Patient seeking treatment for STDs Men who have sex with other men *Exposure to blood* Recent or current injection drug use Household contact with those who test positive for HBsAg Health care personnel with risk for exposure to blood or bodily fluids Those receiving dialysis Those with diabetes *Others* Traveling to countries with high prevalence People with hepatitis C infection People with chronic liver disease People with HIV infection
	≥20 yrs (3 doses)	1 mL	
	Persons receiving dialysis (4 doses)	2 mL	
Recombivax HB	≤19 yrs (3 doses)	0.5 mL	
	11 - 15 yrs (2 or 3 doses)	2 dose series: 1 mL 3 dose series: 0.5 mL	
	≥20 yrs (3 doses)	1 mL	
	Persons receiving dialysis (3 doses)	1 mL	
Heplisav-B	≥18 yrs (2 doses)	0.5 mL	
Twinrix	≥18 yrs (3 or 4 doses)	1 mL	

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Summary of Recent Changes to Influenza Vaccines

On June 23, 2022, the CDC's Advisory Committee on Immunization Practices (ACIP) offered the first ever preferential recommendation for the use of specific flu vaccines for adults ages 65 years and older, including **higher dose (high dose** and **recombinant)** and **adjuvanted** vaccine products.

On June 30, 2022, the CDC Director adopted this ACIP recommendation into official CDC policy, stating preferential recommendation for **Fluzone® High-Dose Quadrivalent, Flublok® Quadrivalent,** and **Fluad® Quadrivalent** flu vaccines in older adults ≥65 years of age.

Historically, the CDC recommends annual influenza vaccination for everyone 6 months and older with *any* licensed age-appropriate flu vaccine, not withstanding applicable precautions and contraindications. There is still no preferential recommendations for people younger than 65. People 65 and older should try to get one of the three preferentially recommended vaccines; 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.**[1]

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

Preservative-free single-use syringes are available to accommodate patient allergies/intolerances to preservatives. Vaccine formulations are now manufactured to be latex-free. Egg-free formulations, including Flublok®, are also available for patients with egg allergies. The CDC publishes guidance for flu vaccination of persons with egg allergy here.

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 that does not use the flu virus or chicken eggs in its manufacturing process. It is licensed for persons 18 years and older and is a higher-dose vaccine preferentially recommended in adults ages 65 and older.

High Dose Quadrivalent Vaccine

FLUZONE® HD QUADRIVALENT pre-filled syringe is a high-dose quadrivalent vaccine that contains four times the amount of antigen, indicated specifically for persons 65 years of age and older due to their weakened immune systems. This vaccine has replaced the previously licensed trivalent high-dose vaccine.[3]

Adjuvanted Quadrivalent Vaccine

FLUAD® QUADRIVALENT pre-filled syringe is a non-high dose quadrivalent flu vaccine licensed specifically for adults 65 years of age and older that contains both an adjuvant (MF59) designed to elicit a greater immune response to vaccination and the maximal 4 flu strains.[4]

A previous edition erroneously included FLUBLOK® under the Standard Quadrivalent Vaccine section. A correction has been issued to note that FLUBLOK® is a distinct, higher-dose vaccine than standard quadrivalent formulations. November 8, 2022.

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

NOTE: This interim guidance was published and current for the 2020-2021 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
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, 2020-2021 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 by 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 health care workers 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, any age-appropriate IIV formulation (standard-dose or high-dose, trivalent or quadrivalent, unadjuvanted or adjuvanted) or quadrivalent recombinant influenza vaccine are acceptable options. 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.

Health Care 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, health care 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 health care 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 health care 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 health care 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 health care 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, or those who have progressive illness, or those who are at high risk for complications of influenza. (https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm)

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 12 years and older who are otherwise healthy or at high-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. Longer antiviral treatment courses for hospitalized patients who remain severely ill after 5 days of treatment can be considered. 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 pre-approved 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 on units or wards with influenza cases in the long-term care facility (currently impacted wards) should receive antiviral chemo-prophylaxis 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 chemo-prophylaxis 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 chemo-prophylaxis 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 chemo-prophylaxis 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 chemo-prophylaxis 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 chemo-prophylaxis is not 100% effective in preventing influenza illness.

CDC recommends antiviral chemo-prophylaxis 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 chemo-prophylaxis 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 chemo-prophylaxis 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 high risk of influenza complications.

While CDC recommends judicious use of antiviral medications for chemo-prophylaxis to reduce the possibility of development and spread of antiviral resistant influenza viruses, chemo-prophylaxis 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 chemo-prophylaxis 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 chemo-prophylaxis 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 health-care provider immediately for evaluation and possible early initiation of antiviral treatment if clinical signs or symptoms develop.

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

chemo-prophylaxis should not receive live attenuated influenza virus vaccine (LAIV), and persons receiving LAIV should not receive antiviral treatment or chemo-prophylaxis 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 chemo-prophylaxis might have an infection with an antiviral-resistant influenza virus. Persons receiving chemo-prophylaxis 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 chemo-prophylaxis.

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 chemo-prophylaxis.

Consider the following additional measures to reduce transmission among residents and health care 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.

*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 17, 2020

Influenza Antiviral Medications: Summary for Clinicians

Priority Groups for Antiviral Treatment of Influenza

The information on this page should be considered current for the 2021-2022 influenza season for clinical practice regarding the use of influenza antiviral medications. This CDC resource was last updated on June 13, 2022. Users are encouraged to check the primary resource here for more recent updates.

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 Table 3), SARS-CoV-2 testing, or multiplex molecular assays that detect influenza A and B viruses and SARS-CoV-2 (view 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 the Algorithm to Assist in Medical Office Telephone Evaluation of Patients with Possible Influenza.
- 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) are recommended for use in the United States during the 2020-2021 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 chemo-prophylaxis 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.

Table 1. Antiviral Medications Recommended for Treatment of Chemo-prophylaxis 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	2 yrs 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	12 yrs and older[6]	N/A	**Adverse events:** none more common than placebo in clinical trials
		Chemo-prophylaxis[5]	Approved for post-exposure prophylaxis in persons 12 yrs and older[5]		

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 2 years 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 for use of peramivir for chemo-prophylaxis of influenza. On November 23, 2020, FDA approved baloxavir for post-exposure prophylaxis of influenza in persons aged 12 years and older. One study of baloxavir post-exposure prophylaxis (PEP) of influenza in household members aged 12 years and older (73% received baloxavir within 24 hours of onset of symptoms in the index household case who received antiviral treatment) reported that the risk of laboratory-confirmed influenza was significantly lower, 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).

[6] Oral baloxavir marboxil is approved by the FDA for treatment of acute uncomplicated influenza within 2 days of illness onset in people 12 years and older who are otherwise healthy, or at high risk of developing influenza-related complications. The safety and efficacy of baloxavir for the treatment of influenza have been established in pediatric patients 12 years and older weighing at least 40 kg. 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; Baloxavir marboxil (Xofluza) pdf icon [package insert]. U.S. Food and Drug Administration website; 2019). 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. There are no available data from clinical trials for baloxavir treatment of hospitalized patients with influenza.

Abridged Summary of Influenza Antiviral Treatment Recommendations

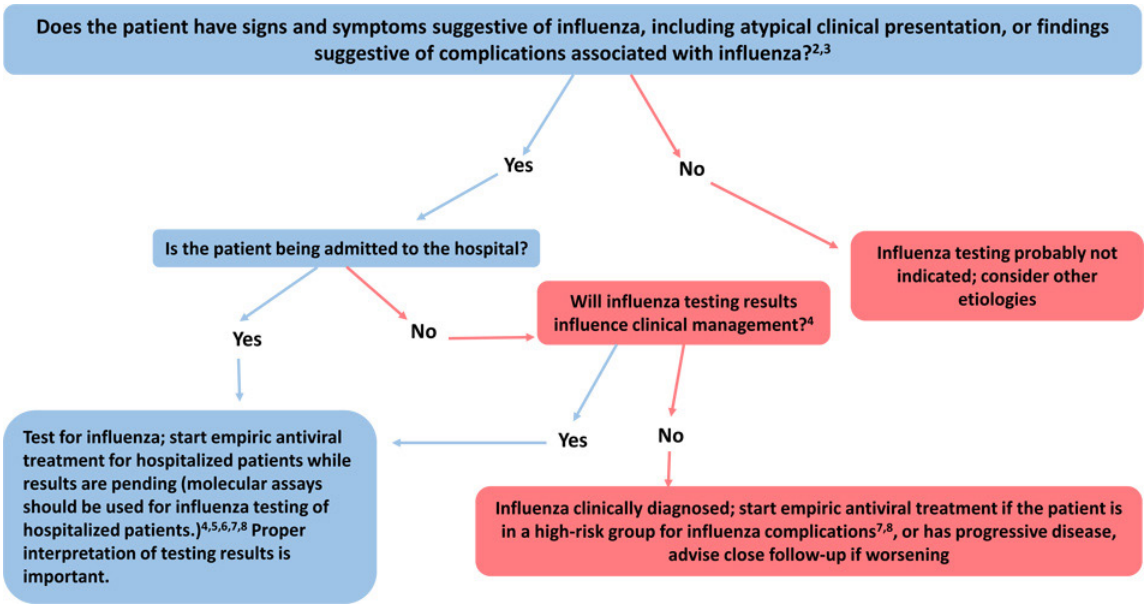
Antiviral treatment is recommended ***as soon as possible*** for any patient with suspected or confirmed influenza who:

- 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: 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 high-risk outpatients.
- 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 high risk 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 women***
  - Baloxavir is not recommended for the treatment of influenza in pregnant women, 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.

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
	Chemoprophylaxis (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
	Chemoprophylaxis (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]	(2 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 2 yrs or older)	(13 yrs and older) One 600 mg dose, via intravenous infusion for a minimum of 15 minutes
	Chemoprophylaxis[8]	Not recommended	N/A
Oral Baloxavir[9]	Treatment (1 day)[1]	FDA approved and recommended for use in children 12 yrs or older. See adult dosage.	(12 yrs and older) weight <80 kg: One 40 mg dose; weight ≥80 kg: One 80 mg dose[9]
	Chemoprophylaxis[8]	FDA-approved for post-exposure prophylaxis for persons aged 12 years and older. See adult dosage."	(12 yrs and older) weight <80 kg: One 40 mg dose; weight ≥80 kg: One 80 mg dose[8]

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 chemo-prophylaxis 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 chemo-prophylaxis in infants 3 months to 1 year of age, is recommended by the CDC and the American Academy of Pediatrics (Committee on Infectious Diseases, 2018).

[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 chemo-prophylaxis 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 7 years and older, and for chemo-prophylaxis with once-daily dosing in people 5 years and older.

[7] Intravenous peramivir is approved for treatment of acute uncomplicated influenza within 2 days of illness onset with a single dose in people 2 years and older. 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 chemo-prophylaxis of influenza. One study of baloxavir post-exposure prophylaxis (PEP) of influenza in household members aged 12 years and older (73% received baloxavir within 24 hours of onset of symptoms in the index household case who received antiviral treatment) reported that the risk of laboratory-confirmed influenza was significantly lower, 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) (Ikematsu, 2020).

[9] Oral baloxavir marboxil is approved by the FDA for treatment of acute uncomplicated influenza within 2 days of illness onset in people 12 years and older who are otherwise healthy, or at high risk of developing influenza-related complications. (Baloxavir marboxil (Xofluza) pdf icon [package insert]. U.S. Food and Drug Administration website; 2019). 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 patients who are pregnant, immunocompromised, have severe disease, or in hospitalized patients. A randomized clinical trial of baloxavir treatment of influenza in hospitalized patients 12 years and older is in progress.

Last Reviewed: May 06, 2021

VACCINE INFORMATION STATEMENT

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.

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 their age and medical status.

PCV13

- **Infants and young children** usually need 4 doses of PCV13, at ages 2, 4, 6, and 12–15 months.
- **Older children (through age 59 months)** may be vaccinated with PCV13 if they did not receive the recommended doses.
- **Children and adolescents 6–18 years of age** with certain medical conditions should receive a single dose of PCV13 if they did not already receive PCV13.

PCV15 or PCV20

- **Adults 19 through 64 years old** with certain medical conditions or other risk factors who have not already received a pneumococcal conjugate vaccine should receive either:
  - a single dose of PCV15 followed by a dose of pneumococcal polysaccharide vaccine (PPSV23), or
  - a single dose of PCV20.
- **Adults 65 years or older** who have not already received a pneumococcal conjugate vaccine should receive either:
  - a single dose of PCV15 followed by a dose of PPSV23, or
  - a single dose of PCV20.

Your health care provider can give you more information.

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 PCV13 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.

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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 Services
Centers for Disease Control and Prevention

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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

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VACCINE INFORMATION STATEMENT

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

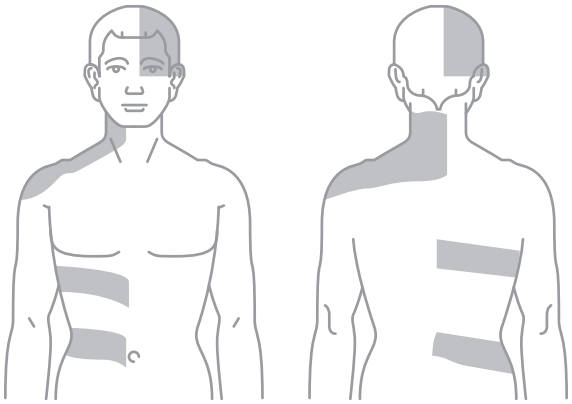
Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

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.

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Centers for Disease Control and Prevention

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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.

Consent for Flu, Pneumococcal, and Shingles Vaccines

Resident: _____Birth Date:_____

ID Number: _____ Nursing Care Center: _____

Living Unit: _____ Physician:_____

INFORMATION:
It is not possible to estimate the risk of an individual getting the flu this year, but for the elderly and for people with diabetes or heart, lung or kidney diseases, flu may be especially serious. An injection of flu vaccine will not give you the flu, because the vaccine is made from killed viruses. The vaccine is made from viruses selected by the Office of Biologics, Food and Drug Administration and the Public Health Service. Side effects of influenza vaccine are generally mild in adults and occur at low frequency. These reactions consist of tenderness at the injection site, fever, chills, headaches, or muscular aches. These symptoms last up to 48 hours.

Gullian-Barre Syndrome (GBS) is typically characterized by a paralysis that begins in the hands or feet and then moves up the arms or legs or both. GBS is usually self-limiting, and most persons with GBS recover without permanent weakness. In approximately 5% of the cases a permanent or even fatal form of paralysis may occur. In 1976, GBS appeared with excess frequency among persons who had received the 1976 Swine Vaccine. For the ten weeks following vaccination, the risk of GBS was found to be approximately ten cases for every one million persons vaccinated. This represents a five to six times higher risk than in unvaccinated persons.

Data on the occurrence of GBS have been collected during three influenza seasons since the surveillance began in 1978. These data suggests that, in contrast to the 1976 situation, the risk of GBS in recipients of influenza vaccine was not significantly higher than that in non-vaccines. Nonetheless, persons who receive influenza vaccines should be aware of this possible risk as compared with the risk of influenza and its complications.

SPECIAL PRECAUTIONS:

- Consult with a prescriber for use in children under 3 years of age and pregnant women.
- Persons who are allergic to eggs, chicken feather, or chicken dander should not receive this vaccine until they have consulted their prescriber.
- 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)

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: _____ Lot #:_____

Immunizer:_____ Expiration Date: _____

Vaccine Name:_____

- Right arm
- Left arm
- Other:_____

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:** _____ **Date:** _____

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 circle)

Influenza PCV 15 (Vaxneuvance) PCV 20 (Prevnar 20) PPSV23 (Pneumovax) PCV13 (Prevnar 13)

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

SAVE

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.