# STANDING ORDERS FOR

# Administering 2025-2026 Formula Adjuvanted Protein COVID-19 Vaccine to Individuals 12 Years and Older

# **Purpose**

To reduce morbidity and mortality from COVID-19 by vaccinating people 12 years and older.

# **Policy**

Where allowed by state law, standing orders enable eligible nurses, pharmacists, and other healthcare professionals to vaccinate people 12 years and older.

There are four available vaccine options for this age group. This standing order template covers administration of **Nuvaxovid** (Sanofi-Novavax), a protein-based vaccine, which is FDA-licensed for use in ages 12 through 64 years with at least one underlying condition that puts them at risk for severe COVID-19 infection and individuals 65 years and older.

A standing orders template for mRNA COVID-19 vaccines (**Comirnaty** [Pfizer-BioNTech], **mNexspike** or **Spikevax** [Moderna products]) for individuals 12 and older is available at www.immunize.org/wp-content/uploads/catg.d/p3140.pdf, and for those age 6 months through 11 years at www.immunize.org/wp-content/uploads/catg.d/p3140a.pdf.

#### Important information about COVID-19 vaccine recommendations and the use of this template:

The Advisory Committee on Immunization Practices (ACIP) recommends COVID-19 vaccination based on shared clinical decision-making (also known as individual based decision-making), emphasizing use in individuals at increased risk for severe COVID-19 infection, based on the CDC list of risk factors (see pages 2 and 3). Shared clinical decision-making discussions, due to their individualized nature, cannot be incorporated into a standing order. Individuals can self-attest to factors that increase their risk of severe COVID-19 infection and receive COVID-19 vaccination. An individual should not be denied COVID-19 vaccination because of lack of documentation.

The American Academy of Pediatrics (AAP) also issued routine age-based recommendations for those age 6 months through 23 months, as well as routine risk-based recommendations for older children with certain medical conditions or in certain settings. For details, see AAP recommendations: https://publications.aap.org/pediatrics/article/doi/10.1542/peds.2025-073924/203222/Recommendations-for-COVID-19-Vaccines-in-Infants.

The American Academy of Family Physicians (AAFP) has published COVID-19 vaccine recommendations for children and adults. They are consistent with AAP for COVID-19 vaccination of children. For details, see www.aafp.org/family-physician/patient-care/public-health-emergencies/recent-outbreaks/covid-19/covid-19-vaccine.html.

The Infectious Diseases Society of America (IDSA) has issued recommendations for COVID-19 vaccination of immunocompromised individuals. IDSA also recommends vaccination of household members and close contacts of immunocompromised patients. For details, see www.idsociety.org/practice-guideline/idsa-2025-guidelines-on-the-use-of-vaccines-for-the-prevention-of-seasonal-covid-19-influenza-and-rsv-infections-in-immunocompromised-patients/.





The American College of Obstetricians & Gynecologist (ACOG) has issued recommendations for COVID-19 vaccination during pregnancy or while lactating. For details see www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/covid-19-vaccination-considerations-for-obstetric-gynecologic-care.

Because ACIP recommendations are not adaptable to standing orders and professional medical society recommendations differ, this template provides instructions for COVID-19 vaccination of individuals **once a decision to vaccinate them has been made**. Vaccination providers should incorporate the steps of this template with their approach to making COVID-19 vaccination decisions in their practice setting.

This template follows clinical guidance from CDC dated November 4, 2025. For additional details, including comprehensive information about all conditions that increase the risk of severe COVID-19 illness and all other clinical considerations, see Interim Clinical Considerations for Use of COVID-19 Vaccines at www.cdc.gov/covid/hcp/vaccine-considerations/index.html.

# Conditions in this age group that increase the risk of severe COVID-19 disease (not moderately or severely immunocompromising)

In general, being unvaccinated or not up to date on COVID-19 vaccination increases the risk of severe COVID-19 illness compared to people who are up to date. The following conditions have been demonstrated (with conclusive or suggestive evidence) to increase the risk of severe COVID-19 illness but are not moderately or severely immunocompromising. People with these conditions (self-attestation is sufficient; documentation not required) follow the routine COVID-19 vaccine dose schedule:

Higher risk of severe COVID-19 illness (conclusive evidence)

- Age 65 years or older
- Residence in a long-term care facility
- Asthma
- Cancer, including hematologic malignancies (not meeting criteria for moderate or severe immunocompromise)
- Cerebrovascular disease
- Chronic kidney disease, including people receiving dialysis
- Chronic liver disease: cirrhosis, non-alcoholic fatty liver disease, alcoholic liver disease, and autoimmune hepatitis
- Chronic lung disease: bronchiectasis, chronic obstructive pulmonary disease, interstitial lung disease, pulmonary embolism, pulmonary hypertension
- Cystic fibrosis
- Diabetes (type 1 and type 2)
- Disabilities: people with any type of disability that makes it more difficult to do certain activities
  or interact with the world around them, including people who need help with self-care or daily
  activities including but not limited to: people with attention-deficit/hyperactivity disorder, cerebral
  palsy, congenital abnormalities, chromosomal abnormalities, intellectual and developmental
  disabilities, learning disabilities, spinal cord injuries, neuromuscular disorders, Down syndrome,
  visual impairment/blindness or wheelchair use
- Heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies
- HIV (controlled, not meeting the criteria for moderate or severe immunocompromise)
- Mental health conditions, such as mood disorders, including depression and schizophrenia spectrum disorders



- Neurologic conditions limited to dementia and Parkinson's disease
- Obesity (BMI 30 kg/m² or greater, or 95% or higher weight percentile in children)
- Physical inactivity
- Pregnancy and recent pregnancy
- Smoking: former or current
- Tuberculosis

Higher risk of severe COVID-19 illness (suggestive evidence, meaning published studies demonstrate risk but further evaluation through meta-analysis or systematic review has not been done)

- Children with certain underlying conditions: obesity; diabetes; cardiac, lung, neurologic disorders.
   Medical complexity increases the risk of severe outcomes from COVID-19. Having more than one pre-existing comorbidity is associated with an increased risk of severe illness.
- Epilepsy
- Hemophilia
- Overweight (BMI 25 through 29 kg/m²)
- Sickle cell disease
- Substance use disorders

Some people may be at increased risk of SARS-CoV-2 infection, including healthcare workers and residents and employees in long-term care facilities and other residential congregate settings.

**NOTE:** This list is not exhaustive. Health care provider determination of increased risk as part of shared clinical decision making is sufficient. Age is the strongest risk factor for severe COVID-19 outcomes. Patients with one or more underlying medical conditions are also at higher risk.

#### Moderate or severe immunocompromising conditions:

People with moderate or severe immunocompromise are at increased risk for severe COVID-19 illness and are recommended to receive additional doses of vaccine for adequate protection. People with the following conditions (self-attestation is sufficient; documentation not required) should follow the moderate or severe immunocompromise schedule for the relevant brand described in the vaccine schedule section. These conditions may be attributable to a medical condition or receipt of immunosuppressive medications or treatment. They include, but are not limited to, the following:

- Active treatment for solid tumor and hematologic malignancies
- Hematologic malignancies associated with poor responses to COVID-19 vaccines regardless of current treatment status (e.g., chronic lymphocytic leukemia, non-Hodgkin lymphoma, multiple myeloma, acute leukemia)
- Receipt of solid-organ transplant or an islet transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic cell transplant (HCT) (within 2 years of transplantation or taking immunosuppressive therapy)
- Moderate or severe primary immunodeficiency (e.g., common variable immunodeficiency disease, severe combined immunodeficiency, DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced HIV infection (people with HIV and CD4 cell counts less than 200/mm3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV) or untreated HIV infection



Active treatment with high-dose corticosteroids (i.e., 20 mg or more of prednisone or equivalent per
day when administered for 2 or more weeks), alkylating agents, antimetabolites, transplant-related
immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor necrosis factor (TNF) blockers, and other biologic agents that are immunosuppressive or
immunomodulatory (e.g., B-cell-depleting agents)

NOTE: Revaccination (beginning a new initial COVID-19 series) is recommended for people who received who received HCT or CAR-T-cell therapy after vaccination. Revaccination may also be considered for patients who received 1 or more doses of COVID-19 vaccine during treatment with B-cell-depleting therapies (e.g., rituximab, ocrelizumab). Refer such patients for clinical evaluation.

#### **Procedure**

Once a decision to vaccinate has been made following the procedures below:

**NOTE:** COVID-19 vaccination history refers to all doses of COVID-19 vaccine from any manufacturer received before the availability of the 2025–2026 COVID-19 vaccines.

#### 1a Routine Vaccination Schedule

#### Age 12 through 64 years, routine schedule: Nuvaxovid (Sanofi-Novavax)

COVID-19 VACCINATION HISTORY BEFORE 2025-2026 VACCINE	NUMBER OF 2025-2026 NUVAXOVID DOSES INDICATED	INTERVAL BETWEEN DOSES
Unvaccinated	1 dose	Administer now
Previously vaccinated with 1 or more doses of any COVID-19 vaccine	1 dose	At least 8 weeks after most recent dose of Comirnaty, Spikevax, or Nuvaxovid, or 3 months after mNexspike*

<sup>\*</sup> The recommended interval for mNexspike is 3 months; however, a dose administered at least 2 months after the last dose should not be repeated.

#### Age 65 years and older, routine schedule: Nuvaxovid (Sanofi-Novavax)

COVID-19 VACCINATION HISTORY BEFORE 2025-2026 VACCINE	NUMBER OF 2025-2026 NUVAXOVID DOSES INDICATED	INTERVAL BETWEEN DOSES
Unvaccinated	2 doses	Dose #1: administer now Dose #2: 6 months after dose #1 (minimum interval of 2 months)+
Previously vaccinated with 1 or more doses of any COVID-19 vaccine	2 doses	Dose #1: at least 8 weeks after most recent dose Dose #2: 6 months after dose #1  (minimum interval of 2 months)+

<sup>&</sup>lt;sup>+</sup> Any licensed, age-appropriate COVID-19 vaccine product may be used for this dose. The recommended interval for mNexspike is 3 months; however, a dose administered at least 2 months after the last dose should not be repeated.

#### 1b Moderate or Severe Immunocompromise Vaccine Schedule

Once a decision to vaccinate has been made following the procedures below:

**NOTE ABOUT PRODUCT CHOICE:** When administering the initial series of COVID-19 vaccine to a person with moderate or severe immunocompromise, use the same manufacturer for all initial series doses when feasible. It is not necessary for all initial series doses to be the same season's formulation.



# Age 12 years and older, moderate or severe immunocompromise schedule: Nuvaxovid (Sanofi-Novavax) See page 3 for list of moderate or severe immunocompromising conditions and treatments.

COVID-19 VACCINATION HISTORY BEFORE 2025-2026 VACCINE	NUMBER OF 2025-2026 NUVAXOVID DOSES INDICATED	INTERVAL BETWEEN DOSES
Unvaccinated	3 doses	Dose #1: administer now Dose #2: 3 weeks after dose #1 Dose #3: 6 months after dose #2 (minimum interval of 2 months)+
Initiated but did not complete the vaccine complete series:  • Received 1 prior dose of Novavax vaccine	2 doses	Dose #1: at least 3 weeks after most recent dose Dose #2: 6 months after dose #2 (minimum interval of 2 months)+
Previously completed an initial vaccine series:  • 3 or more doses of mRNA vaccine  • 2 or more doses of Novavax vaccine	2 doses	Dose #1: at least 8 weeks after most recent dose Dose #2: 6 months after dose #1  (minimum interval of 2 months)+

<sup>&</sup>lt;sup>†</sup> Any licensed, age-appropriate COVID-19 vaccine may be used for this dose. The recommended interval for mNexspike is 3 months; however, a dose administered at least 2 months after the last dose should not be repeated.

#### 2 Screen for Contraindications and Precautions

#### **Contraindications**

 Do not give any COVID-19 vaccine to an individual who has experienced a serious reaction (e.g., anaphylaxis) to any of its components. For a list of vaccine components for each product, refer to the manufacturer's package insert) at www.immunize.org/fda or www.fda.gov/vaccines-blood-biologics/ vaccines/vaccines-licensed-use-united-states.

#### **Precautions**

Moderate or severe acute illness with or without fever (defer until recovering)

Refer for clinical evaluation before vaccination decision, if:

- A diagnosed non-severe allergy to a component of the COVID-19 vaccine
- Non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of one COVID-19 vaccine type, if receiving the same vaccine type
- History of multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A)
- Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine

#### 3 Provide Vaccine Information Statement (VIS)

Because COVID-19 vaccine is not covered under the Vaccine Injury Compensation Program, use of the VIS is recommended, but not required, by CDC.

If a VIS is used, provide all patients (or, in the case of minors, their parent or legal representative) with a copy of the current VIS. Provide non-English speaking patients with a copy of the VIS in their preferred language, if one is available and desired. The VIS and all translations are available at www.immunize.org/vaccines/vis/covid-19/.

(For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

#### 4 Prepare to Administer Vaccine

Prepare the vaccine according to manufacturer's instructions. For manufacturer instructions, see:

• Nuvaxovid package insert (www.fda.gov/vaccines-blood-biologics/coronavirus-covid-19-cber-regu-



lated-biologics/novavax-covid-19-vaccine-adjuvanted)

Choose the needle gauge, needle length and injection site according to the following chart:

BIOLOGICAL SEX AND WEIGHT OF PATIENT	NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
Female or male less than 130 lbs	22-25	5%"*-1"	Deltoid muscle of arm
Female or male 130-152 lbs	22-25	1"	Deltoid muscle of arm
Female 153-200 lbs	22-25	1-1½"	Deltoid muscle of arm
Male 153-260 lbs	22-25	1-1½"	Deltoid muscle of arm
Female 200+ lbs	22-25	1½"	Deltoid muscle of arm
Male 260+ lbs	22-25	1½"	Deltoid muscle of arm
Female or male, any weight	22-25	1"*-1½"	Anterolateral thigh muscle

<sup>\*</sup> Alternative needle lengths may be used for IM injections if the skin is stretched tightly, the subcutaneous tissues are not bunched, and the injection is made at a 90° angle to the skin as follows: a) a 5/8" needle for adults weighing less than 130 lbs (<60 kg) or b) a 1" needle for administration in the thigh muscle for adults of any weight.

#### 5 Administer Nuvaxovid 2025-2026 COVID-19 Vaccine

2025-2026 COVID-19 ADJUVANTED PROTEIN VACCINE	AGES	DILUENT	DOSE/INJECTION AMOUNT	ROUTE
Nuvaxovid (Sanofi-Novavax) manufacturer-filled syringe (MFS)	12+ years	None	0.5 mL/5 mcg antigen+50 mcg Matrix-M adjuvant	Intramuscular (IM) injection

#### Notes about coadministration with other vaccines:

COVID-19 vaccine may be given at the same visit or at any time before or after other recommended vaccines using different anatomic sites (e.g., at least 1 inch apart in the same limb or in different limbs).

If considering simultaneous administration of an orthopoxvirus vaccine (Jynneos, Bavarian Nordic) and COVID-19 vaccine, refer patient for clinical evaluation to determine whether to coadminister or separate the doses.

#### **6 Document Vaccination**

Document each patient's vaccine administration information and follow up in the following places:

Medical record: Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and address and, if appropriate, the title of the person administering the vaccine. If a VIS was given, document in the patient's medical record or office log the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal); discuss the need for vaccine with the patient (or, in the case of a minor, their parent or legal representative) at the next visit.

**Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.

*Immunization Information System (IIS) or "registry"*: Report the vaccination to the appropriate state/local IIS.

#### 7 Be Prepared to Manage Medical Emergencies

Be prepared for management of a medical emergency related to the administration of vaccine by



having a written emergency medical protocol available, as well as equipment and medications. For Immunize.org's "Medical Management of Vaccine Reactions in Adults in a Community Setting," go to www.immunize.org/catg.d/p3082.pdf. For Immunize.org's "Medical Management of Vaccine Reactions in Children and Teens in a Community Setting," go to www.immunize.org/catg.d/p3082a.pdf.

Consider a 30-minute observation period for persons with:

- A history of a non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of one COVID-19 vaccine type, if receiving the same vaccine type
- A history of a diagnosed non-severe allergy to a component of the COVID-19 vaccine, if receiving the same vaccine type

To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

### 8 Report All Adverse Events to VAERS

Report all adverse events following the administration of COVID-19 vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

# **Standing Orders Authorization**

This policy and procedure shall remain in effect for all patients of the	
effective until rescinded or until	
Medical Director/	DATE

