



## Guidance for The New York State COVID-19 Vaccination Program for Individuals 12 Years of Age or Older March 17, 2022

**Note:** This guidance document applies specifically to health care providers offering COVID-19 vaccinations to adolescents and adults age 12 and older. Guidance specific to COVID-19 vaccination of children ages 5-11 may be found on the [New York State COVID-19 Vaccine Information for Providers](#) page.

### Purpose and Background:

On February 22, 2022, following a review of current COVID-19 vaccine safety and efficacy data, the U.S. Centers for Disease Control and Prevention (CDC) updated its clinical guidance for the mRNA COVID-19 vaccine primary series to include considerations for an **8-week interval between the first and second doses in the mRNA COVID-19 vaccine primary series for certain persons**. The document summarizes considerations for the mRNA COVID-19 vaccine primary series intervals.

### mRNA COVID-19 Vaccine Primary Series Interval

Since early 2021, several nations have offered mRNA COVID-19 vaccines on extended primary series schedules (i.e., with the first and second doses offered later than the minimum recommended interval), which has enabled an opportunity to study the vaccine effectiveness and adverse events when the primary series is given on different intervals. These data show that persons who received the second dose of an mRNA COVID-19 vaccine 8 weeks after the first dose, compared with persons who received the primary series on the 3-week (Pfizer-BioNTech) or 4-week (Moderna) interval, may have:

- A stronger immune response, leading to improved vaccine effectiveness; and
- A lower risk of myocarditis or pericarditis following receipt of mRNA COVID-19 vaccine.

Certain populations may still benefit from a shorter interval between doses 1 and 2 of the mRNA COVID-19 vaccine primary series. For that reason, a **shorter interval** (3 weeks for Pfizer-BioNTech COVID-19 vaccine or 4 weeks for Moderna COVID-19 vaccine) remains recommended for:

- Children 5-11 years of age (Pfizer-BioNTech COVID-19 vaccine is the only COVID-19 vaccine currently authorized for use in this age group in the U.S.);
- Adults age 65 years and older;
- Persons with moderate or severe immunocompromise (see the “COVID-19 Vaccines for Immunocompromised” section of this document); and
- Others who need rapid protection due to high community transmission or risk of severe disease.

However, an **8-week interval** between mRNA COVID-19 vaccine primary series may be optimal for other persons age 12-64 years, **particularly males age 12-39 years** who have a higher relative risk for myocarditis and pericarditis after mRNA COVID-19 vaccines.

Doses of mRNA COVID-19 vaccines received at the 3-week (Pfizer-BioNTech) or 4-week (Moderna) interval are still valid and do not to be repeated unless otherwise indicated (such as a booster dose or revaccination due to a vaccine administration or storage error).

### COVID-19 Vaccine Schedule for the General Population

Vaccine manufacturer	Age group	Number of doses in primary series	Interval between 1st and 2nd dose	Interval between primary series and booster dose
Pfizer-BioNTech	5-11 years	2	3 weeks	N/A
	12-64 years		3-8 weeks*	≥ 5 months
	≥ 65 years		3 weeks	
Moderna	18-64 years	2	4-8 weeks*	≥ 5 months
	≥ 65 years		4 weeks	
Janssen	≥ 18 years	1	N/A	≥ 2 months

\*A shorter interval between doses 1 and 2 (i.e., 3 weeks for Pfizer-BioNTech COVID-19 vaccine and 4 weeks for Moderna COVID-19 vaccine) remains recommended for persons with moderate or severe immunocompromise and others who need rapid protection due to high community transmission or risk of severe disease.

### Myocarditis after Receipt of an mRNA COVID-19 Vaccine

A rare risk for myocarditis and/or pericarditis has been observed following receipt of mRNA COVID-19 vaccines. Cases have occurred predominantly in males ages 12–29 years within the first week after receiving the second dose of an mRNA COVID-19 vaccine. To date, data suggest the risk for myocarditis and/or pericarditis after mRNA COVID-19 booster doses in young adults appears lower than the risk after the primary mRNA COVID-19 vaccine series. Most patients with myocarditis and/or pericarditis after receipt of an mRNA COVID-19 vaccine were hospitalized, but their hospital courses were generally mild and for short periods, with most achieving resolution of acute symptoms. Estimates of the [frequency of myocarditis among patients with COVID-19](#) and [among mRNA COVID-19 vaccine recipients](#) suggest that the risk of myocarditis following COVID-19 infection greatly exceeds the risk of myocarditis following mRNA vaccination.

After reviewing available data on the risks and benefits, the CDC determined that the benefits (i.e., prevention of COVID-19 cases and its severe outcomes) outweigh the risks of myocarditis and pericarditis after receipt of mRNA COVID-19 vaccines for children, adolescents, and young adults without a history of myocarditis after a previous dose of mRNA COVID-19 vaccine. Extending the interval between the first and second mRNA vaccine dose to 8 weeks might further reduce the risk.

People receiving mRNA COVID-19 vaccines, especially males ages 12–29 years, should be made aware of the rare risk of myocarditis and/or pericarditis following receipt of mRNA COVID-19 vaccines and the benefit of COVID-19 vaccination in reducing the risk of severe outcomes from COVID-19, including the possibility of cardiac sequelae. Counseling should include the need to seek care if symptoms of myocarditis or pericarditis, such as chest pain, shortness of breath, or tachycardia develop after vaccination, particularly in the week after vaccination.

Myocarditis and pericarditis after receipt of an mRNA vaccine are precautions to further doses of COVID-19 vaccine. If myocarditis or pericarditis occurs after receipt of an mRNA COVID-19 vaccine, the individual generally **should not** receive subsequent doses of COVID-19 vaccine. If after a risk assessment it is decided to administer a subsequent dose of COVID-19 vaccine, the person should wait until after the

episode of myocarditis or pericarditis has resolved. Considerations for subsequent COVID-19 vaccine doses may include:

- If the myocarditis or pericarditis was considered unrelated to mRNA COVID-19 vaccine (e.g., due to SARS-CoV-2 or other viruses), especially if the episode occurred more than 3 weeks after the most recent dose of COVID-19 vaccine.
- Personal risk of severe acute COVID-19.
- Level of COVID-19 transmission and personal risk of infection
- Timing of any immunomodulatory therapies.

### **COVID-19 Vaccines for Immunocompromised Persons:**

The CDC recommends administration of an additional primary dose of either the [Pfizer-BioNTech](#) or the [Moderna](#) COVID-19 vaccine at least 28 days after receipt of the second dose for certain people who are **moderately or severely immunocompromised** due to a medical condition or receipt of immunosuppressive medications or treatments. On February 11, 2022, the CDC expanded this recommendation to include people who are moderately or severely immunocompromised who received an initial dose of the Janssen (Johnson & Johnson) COVID-19 vaccine.

#### Eligible persons for an additional primary dose of an mRNA vaccine due to being moderately to severely immunocompromised include:

- Individuals 5 through 17 years who received two doses of the Pfizer-BioNTech COVID-19 vaccine may receive a 3<sup>rd</sup> dose of the Pfizer-BioNTech COVID-19 vaccine at least 28 days after the second dose.
- Individuals who received a primary series of a non-FDA authorized or approved COVID-19 vaccine may receive a 3<sup>rd</sup> dose of the Pfizer-BioNTech COVID-19 vaccine if they are 12 years and older or the Moderna COVID-19 vaccine if they are 18 years and older at least 28 days after the last dose in the primary series.
- Individuals 18 years or older who received two doses of an FDA-approved mRNA vaccine may receive a 3<sup>rd</sup> dose of EITHER the Pfizer-BioNTech or Moderna COVID-19 vaccine at least 28 days after the second dose.
- Individuals 18 years or older who received an initial dose of the Janssen (Johnson & Johnson) COVID-19 vaccine may receive an additional dose of EITHER the Pfizer-BioNTech or Moderna COVID-19 vaccine at least 28 days after the dose of Janssen COVID-19 vaccine.

#### Recommendations for booster doses of COVID-19 vaccine for moderately to severely immunocompromised people:

- Individuals 12 years or older who received a three-dose primary series of an mRNA COVID-19 vaccine due to a moderately to severely immunocompromising condition should get a booster dose at least **three (3) months** after their 3<sup>rd</sup> dose, as illustrated in the chart below.
- Individuals ≥18 years of age who received an initial dose of Janssen COVID-19 vaccine followed by an additional dose of an mRNA COVID-19 vaccine due to a moderately to severely immunocompromising condition should get a booster dose at least **two (2) months** after the additional dose, as illustrated in the chart below.
- In such situations, people who are moderately and severely immunocompromised may receive four or more COVID-19 vaccine doses, including the primary series, additional dose, and booster dose. As noted below, certain immunocompromised individuals may also require additional doses for revaccination.

Attempts should be made to match the additional dose type to the mRNA primary series, however if that is not feasible, a heterologous additional dose is permitted.

**COVID-19 Vaccination Schedule for People Who are Moderately or Severely Immunocompromised**

Vaccine	Vaccination Schedule			
<b>Pfizer-BioNTech</b> (ages 5 years and older)	<b>Dose 1</b>	<b>Dose 2</b> 21 days after dose 1	<b>Dose 3</b> at least 28 days after dose 2	<b>Booster dose*</b> at least 3 months after dose 3
<b>Moderna</b> (ages 18 years and older)	<b>Dose 1</b>	<b>Dose 2</b> 28 days after dose 2	<b>Dose 3</b> at least 28 days after dose 2	<b>Booster dose*</b> at least 3 months after dose 3
<b>Janssen</b> (ages 18 years and older)	<b>Dose 1</b>	<b>Additional dose</b> of an mRNA COVID-19 vaccine at least 28 days after dose 1		<b>Booster dose*</b> at least 2 months after additional dose

\*Children ages 5-11 years are not recommended to receive a booster dose. Pfizer-BioNTech COVID-19 vaccine is the only COVID-19 vaccine authorized as a booster dose for adolescents age 12-17 years. Any FDA-authorized or -approved COVID-19 vaccine can be used for the booster dose in people 18 years and older, although mRNA vaccines are preferred.

Considerations for COVID-19 revaccination of certain immunocompromised persons:

Recipients of hematopoietic stem cell transplant, CAR-T-cell or other B-cell depleting therapies who received doses of COVID-19 vaccine prior to or during treatment should be revaccinated with doses received prior to or during treatment, at least 3 months (12 weeks) after completing treatment. Based on clinical judgment, revaccination may also be considered once immune competence is regained for people who received COVID-19 vaccine doses during chemotherapy or radiation treatment.

On a case-by-case basis, providers of moderately or severely immunocompromised patients may administer mRNA COVID-19 vaccines outside of the FDA and CDC dosing intervals based on clinical judgment when the benefits of vaccination are deemed to outweigh the potential and unknown risks for the recipient. However, providers should not routinely administer additional doses of COVID-19 vaccine beyond those recommended in this guidance. Providers should consult [treatment guidelines](#) for use of monoclonal antibodies as pre-exposure prophylaxis for moderately or severely immunocompromised people who may not mount an immune response to COVID-19 vaccination.

Due to the risk of COVID-19 infection in this population, immunocompromised people should continue to be counseled regarding the potential for a reduced immune response after vaccination and the importance of additional protective measures, regardless of the decision to receive an additional dose of the COVID-19 vaccine. Prevention measures include wearing a mask, staying six feet apart from others they don't live with, and avoiding crowds and poorly ventilated indoor spaces until advised otherwise by their health care provider. Close contacts of immunocompromised people should be strongly encouraged to be vaccinated against COVID-19.

The Emergency Use Authorization (EUA) amendment for additional doses is not intended for persons with chronic conditions such as diabetes or heart disease, for which there might be mild associated immunosuppression, nor for residents of long-term care facilities who do not otherwise meet the moderate to severe immunocompromised criteria.

A patient's clinical team is best positioned to determine the degree of immune compromise and appropriate timing of vaccination. However, there is no requirement for proof or prescription from the individual's health care provider. This is to prevent additional barriers to vaccination for this vulnerable population. The mandatory [New York State COVID-19 Vaccine Form](#), discussed below under "Vaccine Provider Responsibilities," includes a self-attestation regarding eligibility for vaccination and must be completed prior to vaccination.

The [utility of serologic testing](#) or cellular immune testing to assess immune response to vaccination and guide clinical care (e.g., as part of need assessment for an additional dose) has not been established. Serologic testing or cellular immune testing outside of the context of research studies is **not recommended at this time**.

Additional information about the level of immune suppression associated with a range of medical conditions and treatments can be found in [general best practices for vaccination of people with altered immunocompetence](#), the [CDC Yellow Book](#), and the [Infectious Diseases Society of America policy statement, 2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host](#).

Whenever possible, mRNA COVID-19 vaccination doses (including the primary series and an additional dose) should be completed at least two weeks before initiation or resumption of immunosuppressive therapies, but timing of COVID-19 vaccination should take into consideration current or planned immunosuppressive therapies and optimization of both the patient's medical condition and response to vaccine.

#### **Booster Dose Eligibility:**

All persons aged 12 years and older should receive a booster dose of COVID-19 vaccine. Persons age 18 years or older may receive any FDA-approved or -authorized COVID-19 vaccine as the booster dose, however, use of an mRNA COVID-19 vaccine for a booster dose is preferred even for those who received Janssen COVID-19 vaccine for their single dose primary series as described in the "Clinical Preference for mRNA COVID-19 Vaccine" section of this document. Adolescents ages 12 to 17 should receive a booster dose of the Pfizer-BioNTech COVID-19 vaccine.

The interval for booster vaccination should follow the interval recommended for the primary series. Persons aged 18 years and older who received Janssen primary vaccination should receive a COVID-19 vaccine booster dose at least 2 months (8 weeks) later. Recipients of an mRNA COVID-19 vaccine primary series ages 12 and older who are not moderately to severely immunocompromised should receive a single booster dose at least **5 months** after the last dose administered. The vaccine schedule for persons who are moderately to severely immunocompromised is discussed earlier in this document. If the booster dose is given more than 4 days before the dose is due, the booster dose does not need to be repeated.

The following vaccine-specific booster dose and volume should be administered regardless of whether the vaccine is homologous (same dose as primary series) or heterologous (different than primary series):

- Pfizer-BioNTech: 30 ug in a volume of 0.3 mL (same dose as the primary series dose and additional primary dose).
- Moderna: 50 ug in a volume of 0.25 mL. This is a different dose than what is used for the primary series dose and the additional primary dose.

- Janssen:  $5 \times 10^{10}$  viral particles in a volume of 0.5 mL (same dose as the primary series dose).

#### **Timing of Vaccination for Persons Receiving Passive Antibody Products:**

On February 11, 2022, following review of the antibody response to COVID-19 vaccines among individuals who had received passive antibody products prior to vaccination, the CDC updated clinical guidance to recommend **no minimum interval** between receipt of passive antibody products and subsequent COVID-19 vaccine administration. A study among nursing home residents and staff demonstrated that recipients of bamlanivimab mounted a robust immune response to mRNA vaccination regardless of age, risk category, or vaccine type. Additionally, there was no correlation between the interval to COVID-19 vaccination and neutralizing titers in recent monoclonal antibody recipients. This guidance applies to individual who have received passive antibody products as treatment, post-exposure prophylaxis or pre-exposure prophylaxis prior to COVID-19 vaccination.

However, among individuals who receive COVID-19 vaccine before tixagevimab/cilgavimab (EVUSHELD™), subsequent doses of EVUSHELD™ should be deferred for at least two weeks after COVID-19 vaccination.

#### **No Minimum Interval Between COVID-19 Vaccine and Other Vaccines:**

The CDC's [Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States](#) current recommendations state that "COVID-19 vaccines **may be administered without regard to timing of other vaccines**. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day."

#### **Special Considerations for Individuals Receiving COVID-19 Vaccine Outside the United States:**

The [CDC's Interim Clinical Considerations for Use of COVID-19 Vaccine](#) states as follows:

- People who were vaccinated outside the United States with a currently FDA-approved or FDA-authorized COVID-19 vaccine:
  - Those who received all of the recommended doses of an FDA-approved or FDA-authorized primary COVID-19 vaccine series are considered fully vaccinated 2 weeks after completion of the series and should also follow U.S. guidance for additional doses for persons with moderate-to-severe immunocompromise and for booster doses.
  - Those who received the first dose of Pfizer-BioNTech or Moderna COVID-19 vaccine outside the U.S. do not need to restart the vaccine series in the United States. They should complete the series with an mRNA vaccine as close to the recommended time as possible and are considered fully vaccinated upon completion of the primary series. People who were vaccinated in countries where only a single mRNA dose is recommended in certain populations are not considered fully vaccinated in the United States until after completion of the primary series.
- People who completed all of the recommended doses of a COVID-19 vaccine listed for emergency use by the World Health Organization (WHO) but not approved or authorized by FDA, or people who completed a heterologous (mix and match) series composed of doses of a COVID-19 vaccine listed for emergency use by WHO, at least one of which is a non-FDA-approved or authorized vaccine, are considered fully vaccinated 2 weeks after completion of the series.

- People who are not moderately or severely immunocompromised should receive a single booster dose of Pfizer-BioNTech COVID-19 vaccine if they are 12 years and older or Moderna COVID-19 vaccine if they are 18 years and older at least 5 months after completing their primary series.
- Moderately or severely immunocompromised people should receive an additional primary dose of Pfizer-BioNTech COVID-19 vaccine if they are 12 years and older or Moderna COVID-19 vaccine if they are 18 years and older at least 28 days after receiving the second vaccine dose of their primary series and a single booster dose at least 3 months after their additional dose.
- People who received incomplete series of a WHO COVID-19 vaccine listed for emergency use that is not FDA-approved or FDA-authorized do not need to restart a primary vaccination series in the United States.
  - They should receive a single dose of Pfizer-BioNTech COVID-19 vaccine if they are 12 years and older or Moderna COVID-19 vaccine if they are 18 years and older at least 28 days after receipt of their most recent dose, after which they are considered fully vaccinated.
  - Moderately or severely immunocompromised people who received an mRNA COVID-19 vaccine to complete the initial series should receive an additional primary dose of Pfizer-BioNTech COVID-19 vaccine if they are 12 years and older or Moderna COVID-19 vaccine if they are 18 years and older at least 28 days later and a booster dose at least 3 months after their additional dose.
  - People who are not moderately or severely immunocompromised should also receive a single Pfizer-BioNTech COVID-19 vaccine booster dose if they are 12 years and older or Moderna COVID-19 vaccine if they are 18 years and older, at least 5 months after completing their primary series.
- People who received all or some of the recommended doses of a COVID-19 vaccine primary series that is not listed for emergency use by WHO:
  - Should be offered primary vaccination with an FDA-approved or FDA-authorized COVID-19 vaccine (i.e., Pfizer-BioNTech, Moderna or Janssen vaccine), preferably with an mRNA COVID-19 vaccine, with a minimum interval of at least 28 days since after receipt of the last dose of a vaccine not listed for emergency use by WHO.
  - Moderately or severely immunocompromised people who received an mRNA COVID-19 Vaccine to complete the initial series should receive an additional primary dose of Pfizer-BioNTech COVID-19 Vaccine if they are 12 years and older or Moderna COVID-19 vaccine if they are 18 years and older at least 28 days later and a booster dose at least 3 months after their additional dose.
  - People who are not moderately or severely immunocompromised, should also receive a single booster dose of Pfizer-BioNTech COVID-19 vaccine if they are 12 years and older or Moderna COVID-19 vaccine if they are 18 years and older, at least 5 months after completing their primary series.

### **COVID-19 Vaccines Listed for Emergency Use by the WHO:**

As of March 9, 2022, the WHO has listed the following COVID-19 vaccines for emergency use:

- Pfizer-BioNTech COVID-19 vaccines (e.g., COMIRNATY, Tozinameran)\*
- Janssen (Johnson & Johnson) COVID-19 vaccine\*
- Moderna COVID-19 vaccine (Spikevax)\*



- AstraZeneca-Oxford COVID-19 vaccines (e.g., Covishield, Vaxzevria)
- Sinopharm Beijing Institute of Biological Products (BIBP) COVID-19 vaccine
  - Sinopharm Wuhan Institute of Biological Products (WIBP) is a separate vaccine from Sinopharm BIBP and has not been listed for emergency use by the WHO as of January 12, 2022.
- Sinovac-Coronavac COVID-19 vaccine
- Bharat Biotech BBV152 COVID-19 Vaccine (COVAXIN)
- Novavax (Covovax, Nuvaxovid)

\*Also authorized by the FDA for Emergency Use in the United States

The WHO maintains a list of COVID-19 vaccines listed for emergency use at <https://extranet.who.int/pgweb/vaccines/vaccinescovid-19-vaccine-eul-issued>.

### **Clinical Preference for mRNA COVID-19 Vaccine:**

On December 16, 2021, the CDC endorsed the recommendations of its Advisory Committee on Immunization Practices (ACIP) for a clinical preference for individuals aged 18 years and older to receive an mRNA COVID-19 vaccine over the Janssen (also known as Johnson & Johnson) COVID-19 vaccine.

As part of a pre-vaccination discussion with a vaccination provider, all persons who elect to receive a Janssen COVID-19 Vaccine primary series or booster dose should be informed about the risk and symptoms of thrombosis with thrombocytopenia syndrome (TTS), and the need to seek immediate medical care should TTS symptoms develop. The highest rates of TTS occur among females 30-49 years. The FDA also added a contraindication for people who experienced TTS after their first shot of the Janssen COVID-19 vaccine, or from other COVID-19 vaccines based on a similar adenovirus vector technology such as the one developed by AstraZeneca, from getting a booster shot from the same type of vaccine. Current recommendations are for urgent medical evaluation for TTS if any of the following symptoms develop 4 to 30 days after vaccination:

- severe headache,
- visual changes,
- abdominal pain,
- nausea and/or vomiting,
- backache,
- shortness of breath,
- leg pain or swelling, or
- petechiae or easy bruising.

In limited, exceptional situations where an individual received the first dose of an mRNA COVID-19 vaccine but is unable to complete the series with either the same or different mRNA COVID-19 vaccine (e.g., due to contraindication), a single dose of Janssen COVID-19 Vaccine may be considered at a minimum interval of 28 days from the mRNA COVID-19 vaccine dose if the person is aged  $\geq 18$  years.

The CDC also noted: “Given the current state of the pandemic both here and around the world, the ACIP reaffirmed that receiving any vaccine is better than being unvaccinated. Individuals who are unable or unwilling to receive an mRNA vaccine will continue to have access to Johnson & Johnson’s COVID-19 vaccine. The benefits of using the Ad26.COVS vaccine still outweigh the risks involved with COVID-19



infection. Previous studies suggest that thrombotic complications are far more likely following infection with COVID-19.”

### **“Gray Cap” Pfizer Adult/Adolescent Formulation:**

On December 23, 2021 a new formulation of Pfizer adult/adolescent vaccine was introduced. This formulation is being referred to as Pfizer Adult/Adolescent Tris (Gray Cap, age 12+, no diluent). This formulation contains the Tris Sucrose buffer, **does not require dilution** at administration sites, may be stored at refrigerated temperature (2-8° C) for up to 10 weeks, and can be used on individuals 12 years of age and older. The vials will have a gray cap and label with gray border. Individuals who received a previous dose or doses of the Pfizer 12+ “purple cap” vials may receive the Pfizer Adult/Adolescent Tris (Gray Cap, age 12+, no diluent) formulation for primary, additional, or booster doses.

Pfizer Adult/Adolescent Tris (Gray Cap, age 12+, no diluent) is a multiple dose vial that contains a volume of 2.25 mL and is supplied as a frozen suspension that does not contain preservative. Each vial must be thawed prior to administration. **DO NOT DILUTE** prior to use. One vial contains 6 doses of 0.3 mL. Even though the vaccine does not require dilution, the vial must be mixed by gently inverting the vial 10 times before puncture.

Vaccination providers should maximize using inventory of all Pfizer 12+ purple cap vials prior to using Pfizer Adult/Adolescent Tris (Gray Cap, age 12+, no diluent) vials and should ideally carry only one Pfizer adult formulation at a time. Provider sites utilizing the Pfizer thermal shipping containers for temporary storage must prepare for use of an ULT freezer or refrigerator moving forward; the shipping containers used for this formulation are single use and cannot be used for temporary storage with dry ice or for vaccine transport. **To avoid mistakes during this period of transition when both adult formulation products may be in circulation, these products should not be offered/administered at the same time.**

### **EUAs, FDA Vaccine Approval Status, and Appropriate Use of Vaccines in New York State:**

All authorized COVID-19 vaccine providers in New York State, including those located in the City of New York and those participating in federal programs, must follow New York State Department of Health (NYSDOH) guidance regarding vaccine prioritization, as well as any other relevant directives. Providers are responsible for adhering to all requirements outlined in the COVID-19 Vaccination Program agreement. Specifically, providers must administer COVID-19 vaccines in accordance with all [program requirements and recommendations](#) of NYSDOH and the CDC, the [Advisory Committee on Immunization Practices](#), and the U.S Food and Drug Administration (FDA). This applies to vaccines administered in accordance with an EUA or Emergency Use Instruction (EUI), as well as FDA approved COVID-19 vaccines. Accordingly, use of these products outside of those that have been approved and authorized by FDA or in accordance with a CDC EUI (often referred to as “**off-label use**”) **is not recommended**. It would violate the provider agreement and could expose providers to the following risks:

- Administration of the product off label may not be covered under the Public Readiness and Emergency Preparedness (PREP) Act or the PREP Act declaration; therefore, providers may not have immunity from claims.
- Individuals who receive an off-label dose may not be eligible for compensation under the Countermeasures Injury Compensation Program after a possible adverse event.
- CDC has defined the scope of the CDC COVID-19 Vaccination Program in terms of how the USG-provided vaccines may be used in the program. Providers giving off-label doses would be in

violation of the CDC Program provider agreement potentially impacting their ability to remain a provider in the CDC program.

- Administration fees may not be reimbursable by payers.

Accurate and timely reporting to NYSIIS/CIR is critical, as this information can be used to allow individuals to display proof of vaccination, such as the Excelsior Pass or Excelsior Pass Plus.

### COVID-19 Vaccine Expiration and Beyond Use Dates:

#### Expiration Dates:

Determining when a vaccine expires is a critical step in proper storage and handling. The expiration date should always be checked prior to preparing or administering vaccine. Expired vaccine or diluent should NEVER be used. As additional stability data become available, the expiration dates for some products may change. Follow the instructions below to determine the expiration date:

- Pfizer-BioNTech COVID-19 vaccine for ages 12 and older (vials have purple caps): FDA approved an amendment to the EUA for Pfizer-BioNTech COVID-19 vaccine extending the expiration dates of COVID-19 vaccine from six to nine months. Cartons and vials of Pfizer-BioNTech COVID-19 vaccine with an expiry date of August 2021 through February 2022 printed on the label may remain in use for 3 months beyond the printed date as long as authorized storage conditions between -90°C to -60°C (-130°F to -76°F) have been maintained. Please note: the ultra-cold temperature range has been broadened to include -90° C (-130°F). Frozen vials stored at -25°C to -15°C and refrigerated vials (2°C to 8°C) are NOT eligible for a three-month use extension. Updated expiry dates for vaccine maintained in ultra-cold storage are shown below. The extended expiration date is effective immediately for all currently available batches that have not yet expired.

The extension of Pfizer-BioNtech COVID-19 vaccine expiration applies to any vaccine that has been stored in a manner consistent with the storage guidelines that have been in place to this point. Specifically:

- Vaccine moved from ultra-cold storage to standard frozen storage and back once to ultra-cold storage.
- Vaccine in a standard freezer for a total of up to 14 days.
- Vaccine in a refrigerator for a total of up to 31 days, including vaccine that was previously in a standard freezer for 14 days.

All of the above conditions are consistent with the existing storage guidance. **Vaccine stored under these conditions can be used until the [correct beyond-use date](#), based on the vaccine storage conditions, or the updated expiration date, whichever occurs first.** Vaccine cannot be used after the new expiration date, even if the storage-determined beyond-use date would be after the updated expiration date.

Printed Expiry Date	Updated Expiry Date
October 2021	January 2022
November 2021	February 2022
December 2021	March 2022
January 2022	April 2022
February 2022	May 2022

- Pfizer Adult/Adolescent Tris (Gray Cap, age 12+, no diluent): The date printed on the Pfizer Adult/Adolescent Tris (Gray Cap, age 12+, no diluent) vaccine vials indicate the manufacture date and NOT the expiration date. Originally, the expiration date was 6 months from the manufacture date, when stored in ultra-cold freezer temperatures (-90 to -60° C). **The expiration date for Pfizer gray cap vaccine has now been extended to 9 months (while held at ULT frozen.)** Vials may also be stored up to 10 weeks in the refrigerator (2-8° C). **No standard freezer storage is approved for the Pfizer Adult/Adolescent Tris (Gray Cap, age 12+, no diluent) formulation.** Once thawed, vials CANNOT be refrozen.

The Fact Sheet for the Pfizer Adult/Adolescent Tris (Gray Cap, age 12+, no diluent) provided by the FDA now reads “regardless of storage conditions, vaccines should not be used after 9 months from the date of manufacture printed on the vial and cartons.” Therefore, vaccine must be used by the expiration date, or [the 10-week beyond use date](#) for refrigerator storage, whichever comes first. The updated expiry dates for the gray cap vials based on 9 months from the date of manufacture are provided below:

Printed Manufacturing Date	9-Month Expiry Date*
06/2021	Feb. 28, 2022
07/2021	Mar. 31, 2022
08/2021	Apr. 30, 2022
09/2021	May 31, 2022
10/2021	Jun. 30, 2022
11/2021	July. 31, 2022
12/2021	Aug. 31, 2022
01/2022	Sept. 30, 2022
02/2022	Oct. 31, 2022

\*Date of expiration always falls on the last day of the month

- Moderna COVID-19 vaccine: The expiration date is NOT printed on the vaccine vial or carton. To obtain the expiration date of the lot number received, providers can scan the QR code located on the vial or carton or access the manufacturer’s [website](#) directly, enter the lot number and the expiration date will be displayed.
  - In September 2021, Moderna submitted data to support the extension of certain lot number expiration dates. Prior to discarding expired lots of Moderna vaccine, it is important to re-check the manufacturer’s website to determine if the lot number’s expiration date has been extended. If an extension was made, providers need to ensure the expiration date on the vials/packages and in NYSIS/CIR are updated.
- Janssen/Johnson & Johnson COVID-19 vaccine: The expiration date is NOT printed on the vaccine vial or carton.
  - In March 2022, the FDA announced the approval of a shelf-life extension for an additional three months. This decision is based on data from ongoing stability assessment studies, which have demonstrated that the vaccine is stable at 9 months when refrigerated at temperatures of 36° – 46° Fahrenheit (2° – 8° Celsius). This shelf-life extension applies to all inventory previously dated to expire on March 7, 2022, or later.

To determine the most current expiration date:

- Scan the QR code located on the outer carton, or
- Call 1-800-565-4008, or
- Go to <https://vaxcheck.jnj/>, enter the lot number and the expiration date will be displayed.

For Moderna and Janssen/J&J COVID-19 vaccines it is important to write the expiration date on the carton or vials since it is not printed. Orders of Moderna and Janssen/J&J received in NYSIIS or CIR will contain a placeholder date of 12/31/2069. The actual expiration date must be updated in NYSIIS or CIR, as well as part of inventory management. Vaccines should always follow a first in, first out process in which vials that have the earliest expiration date are used first. CDC's <https://www.cdc.gov/vaccines/covid-19/downloads/expiration-tracker.pdf> can help providers keep track of the expiration date by lot number. Vaccine inventory should be managed using a "first in first out" tracking process to limit the potential for wastage.

#### Beyond Use Dates (BUDs):

All vaccines have expiration dates, and some routinely recommended vaccines have a beyond use date (BUD), which is calculated based on the date the vial is first punctured and the storage information in the package insert. Whenever a vial of COVID-19 vaccine is moved to storage conditions that affect BUD or a multidose vial is punctured, label the vial(s) with the beyond use date/time. The BUD must never exceed the labeled expiration date. Once the vaccine has reached its expiration or beyond use date/time, unused doses must be disposed of as medical waste and [reported as wastage in NYSIIS or CIR](#). A summary of COVID-19 vaccine beyond use dates and resources are listed below:

- Pfizer age 12 and older (vials have purple caps): [Pfizer-BioNTech COVID-19 Vaccine Beyond-Use Date \(BUD\) Tracking Labels for Vaccine During Freezer or Refrigerator Storage](#)
  - Freezer (-25° C to -15° C): Two weeks
  - Refrigerator (2° C to 8° C): 31 days
  - After Puncture: 2° C to 25° C for up to 6 hours
- Pfizer Adult/Adolescent Tris (Gray Cap, age 12+, no diluent): [Beyond-Use Date \(BUD\) Tracking Labels for Vaccine During Refrigerator Storage](#)
  - Refrigerator (2° C to 8° C): 10 weeks
  - **NOTE: NO standard freezer (-25° C to -15° C) storage allowed**
  - Room temperature (8° C to 25° C): 12 hours prior to first puncture
  - After Puncture: 2° C to 25° C for up to 12 hours. Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. The information in the EUA Fact Sheet (12 hours) supersedes the number of hours printed on vial labels and cartons.
- Moderna: [Moderna COVID-19 Vaccine Beyond-Use Date \(BUD\) Tracking Label for Vaccine During Refrigerator Storage](#)
  - Refrigerator (2° C to 8° C): 30 days
  - After Puncture: 2° C to 25° C for up to 12 hours
- Janssen/J&J: [Janssen COVID-19 Vaccine Preparation and Administration Summary](#)

- After Puncture: 2° C to 8° C up to 6 hours OR 9° C to 25° C for up to 2 hours. These times are NOT cumulative (i.e., you cannot store a punctured vial for 6 hours at refrigerated temperatures and then another 2 hours at room temperature).

### **Moderna Booster Dose Inventory Considerations:**

It is important to note that the volume of a Moderna booster dose is **0.25 mL** (half the volume of a primary dose). The Moderna COVID-19 vaccine is supplied in two multiple-dose vial presentations:

- A multiple-dose vial containing 5.5 mL (i.e., Moderna 10-dose)
- A multiple-dose vial containing 7.5 mL (i.e., Moderna 14-dose)

**Reporting:** Despite the volume of the booster dose being **0.25 mL**, providers must still **report a full dose as administered in NYSIIS**. Reporting of half doses is not allowed and **inventory must only be reported in whole doses**. Half doses in NYSIIS inventory will prevent a provider from entering new vaccine orders.

**Maximum vial puncture:** Providers may extract both primary series doses (0.5mL) and booster doses (0.25 mL) from the same vial. When extracting only booster doses or a combination of primary series and booster doses, **the maximum number of doses that may be extracted from either vial presentation should not exceed 20 doses. Do not puncture the vial stopper more than 20 times.**

- When ordering vaccine for booster doses, consider that an order of 140 doses (ten 14-dose vials) can support a maximum of 200 booster and/or primary doses.
- After the vial has been punctured 20 times, the vial must be discarded, even if there is vaccine remaining in the vial and the beyond use date/time has not been reached (see more info below on when to report wastage in NYSIIS).
- The use of vial adapters, dispensing pins, or strategies where a needle is inserted into the vial septum for multiple medication withdraws is not allowed due to contamination risk.

**NYSIIS inventory:** Due to the reporting of full doses for boosters and the maximum of 20 punctures for each vial, the number of doses reported may exceed the number of doses recorded in NYSIIS inventory (i.e., 140 dose order = up to 200 booster doses). This means NYSIIS inventory may be depleted before physical inventory. Best practice would be to [modify inventory](#) to add doses to the lot number BEFORE ADMINISTRATION. Do a vial count of physical inventory at the end of the day and multiply your full, unopened vials times the number of labeled doses in the vial (10 or 14 doses) and manually modify your NYSIIS inventory to reflect this count. If you report vaccine administration data via data exchange, additional doses beyond the NYSIIS doses on hand will go to the Inventory Not Deducted module. If this happens, manually add doses to the lot number and then [update non-deducted inventory](#).

NYSIIS inventory is used to populate Vaccine Finder product availability through a daily data upload. If you have physical inventory and you do not modify inventory to add doses once it is depleted in NYSIIS, your location will not show as having Moderna vaccine available on Vaccine Finder.

**Ancillary Supplies:** Current Moderna inventory may be used for booster doses and is encouraged to be used. Please be aware that there is no mechanism to provide additional ancillary supplies for existing inventory. Providers may need to purchase additional supplies. Ancillary kits for Moderna 14 (140 doses) that were sent for existing inventory contain a combination of 1 mL and 3 mL syringes. While the 3 mL syringes are adequate for extracting a primary series dose (0.5 mL), they do not support extraction of the booster dose (0.25 mL). The 1 mL syringes allow for better visualization and extraction of the smaller 0.25 mL booster dose. To assure providers have an adequate supply of 1 mL syringes to support

extraction of booster doses (0.25 mL) from a Moderna 14 vial, CDC will ship an additional ancillary kit that contains all 1 mL syringes with all Moderna 14 orders. **When possible, please use 3 mL syringes for extraction of primary series doses to ensure you have an adequate supply of 1 mL syringes to support extraction of booster doses from a Moderna vial.**

Wastage: Continue to maintain reporting of wastage in whole doses. Wastage should only be reported if the total doses administered from a vial, regardless of volume or series, is less than the vial dose count (i.e., 1 primary and 5 booster doses from a 14-dose vial would be reported as 6 doses used and 8 doses wasted). Once 14 doses are given from a 14-dose vial, regardless of whether primary or booster doses, no wastage needs to be reported even if there is vaccine remaining in the vial.

#### **Vaccine Provider Responsibilities:**

- COVID-19 vaccine must be given according to eligibility and criteria established by the ACIP recommendations as well as EUAs and associated fact sheets or emergency use instruction, as applicable, for immunocompromising conditions that would benefit from an additional dose of Pfizer-BioNTech or Moderna COVID-19 vaccines.
- As the ordering quantities and the storage conditions have become more practical, providers are encouraged to place direct orders in NYSIIS and avoid redistribution whenever possible, even if all doses cannot be used. Vaccine may be redistributed to another facility, provider, practice, or local health department that is enrolled in the COVID-19 vaccination program, with proper notice to the NYSDOH. Prior to redistributing vaccine, facilities must submit a completed [redistribution form](#) to [COVIDVaccineRedistribution@health.ny.gov](mailto:COVIDVaccineRedistribution@health.ny.gov) and can proceed with the redistribution once submitted. Direct orders are the preferred and safest way to receive vaccine.
  - A provider may transport vaccine to another location for the purpose of holding a limited duration vaccination clinic without notifying the NYSDOH. If the provider is administering the doses and reporting doses administered against their own inventory in NYSIIS, all unused vaccine must be transported back to the original location at the conclusion of the clinic that day. The provider must retain possession and control of the vaccine for the duration of the transport and administration.
- When managing vaccine inventory, vaccines should always follow a first-in, first-out process in which vials that have the earliest expiration or beyond use date are used first.
- All vaccine providers should minimize the amount of vaccine that goes unused, consistent with CDC guidance, which states that while enrolled providers must continue to follow best practices to use every dose possible, it should not be at the expense of missing an opportunity to vaccinate every eligible person when they are ready to get vaccinated. (See Responsible Wastage section for further guidance.)
- Providers should not prefill more syringes than they can use within 30 minutes. Excess prefilling can lead to waste if a clinic must end early or an excessive number of recipients fail medical screening or do not show up for their appointment.
- All facilities or practices are required to track vaccine uptake among their staff and must furnish uptake data to the NYSDOH via HERDS survey upon request, or as directed by your agency or organization.

### **Each provider that receives vaccine:**

- Must ensure all individuals receiving the COVID-19 vaccine complete the [New York State COVID-19 Vaccine Form](#) for the first dose, and attest that they are eligible to be vaccinated. All practices, providers, and entities must confirm adherence to this requirement at the time of vaccine administration.
- Must make best efforts to use all vaccine doses before expiration or reaching beyond use dates based on temperature storage requirements by assessing the COVID-19 vaccination status of each patient and offering the vaccine to all eligible individuals.
- Providers should continue to report all doses administered to NYSIIS and CIR, including third vaccine doses and booster doses as appropriate based on ACIP recommendations. It is critical that providers follow the appropriate intervals and product combinations in order for these doses to be considered valid. Providers should fully utilize both NYSIIS and CIR to confirm patients' previous dose dates and vaccine type. Full contact information for the individual receiving the vaccination, including phone number, email and zip code, should be entered as well.
- With respect to pharmacies, pharmacists are authorized to vaccinate individuals 5 years of age and older for COVID-19, pursuant to [current COVID-19 PREP Act declarations](#).

In addition, to ensure all New Yorkers can find vaccination locations close to them, **vaccine providers are strongly encouraged to have their facility/facilities opt-in to the CDC's online VaccineFinder tool ([Vaccines.gov](#))**. To do so, providers should set the display field in the [COVID-19 Locating Health Portal](#) to "display" if the facility is currently providing vaccinations to the general public. This will allow patients in the local area to see in real-time whether the facility has doses of each brand available, enabling vaccination access for a broader population.

- NYSDOH reports inventory to the CDC every Monday through Friday for each organization. Therefore, organizations do not need to report inventory to VaccineFinder (despite having access).
- Additional information on the VaccineFinder tool can be found [here](#).

### **Message for COVID-19 Vaccine Clinical Trial Sites:**

As a reminder, all COVID-19 vaccines administered in the State of New York must be entered in to NYSIIS or CIR. This includes any doses administered as part of an experimental arm of a clinical trial as well as doses offered and administered to participants in the control group (originally received placebo) after the clinical trial ended or at other time points per trial protocol. Staff at the participating site of the clinical trial must provide participants with a vaccination card and enter participant's immunization history into NYSIIS/CIR as applicable. Please note that only vaccines that have been issued an Emergency Use Authorization (EUA) or that have been approved by the United States Food and Drug Administration (FDA) can be entered.

**The Second COVID-19 Vaccine Dose:** (Note: The following ONLY applies to the primary series, NOT for booster/additional third doses, as discussed above.)



Pfizer-BioNTech and Moderna vaccines require two doses, whereas Janssen (Johnson & Johnson) vaccine requires only a single dose. The second dose must be administered 21 days (Pfizer-BioNTech vaccine) or 28 days (Moderna vaccine) after the first dose. To facilitate this, all providers **must** schedule the second dose appointment for recipients **at the time the first dose is administered**.

Individuals must receive two doses of the same vaccine (e.g., you must receive two doses of the Pfizer-BioNTech vaccine or two doses of the Moderna vaccine). They are **not** interchangeable. Please see [Guidance for Administration of the Second Dose of COVID-19 Vaccine](#) for additional information regarding administration of the second dose.

If an individual requests a second dose after missing the 42-day window, they should still be administered a second dose. There is no need to restart the series, pursuant to CDC guidance. Providers who have insufficient vaccine to administer a second dose that was delayed beyond the 42-day window should work with their local health department.

Circumstances may arise where individuals need to receive their second dose at a different location than their first. Providers who have determined that the individual cannot return to the location where they received their first dose should schedule a second dose for these individuals or coordinate with the local health department to find a provider who has extra doses of the appropriate vaccine to vaccinate the individual. Vaccine availability can also be located using the [CDC's VaccineFinder](#). Individuals should not be tasked with locating second dose appointments. This obligation is on the provider who administered the first dose.

#### **Special Considerations for Individuals Receiving Their First Dose within the United States but Outside New York State:**

Individuals who received their first dose of COVID-19 vaccine outside of New York State will not have a record of this dose in NYSIIS or CIR. Providers administering a second dose should either enter the first dose in NYSIIS/CIR as part of the historical record using data listed on the individual's COVID-19 Vaccination Record Card OR advise the patient that they should ask their primary care provider to enter their first dose into NYSIIS/CIR so the state has a full record of both doses of COVID-19 vaccine.

#### **Responsible Wastage:**

The CDC released guidance on May 11, 2021, regarding wastage with the critical message to “take every opportunity to vaccinate every eligible person.” As more vaccination opportunities are created, the likelihood of leaving unused doses in a vial may increase. While enrolled providers must continue to follow best practices to use every dose possible, it should not be at the expense of missing an opportunity to vaccinate every eligible person when they are ready to get vaccinated.

To ensure providers do not miss an opportunity to vaccinate every eligible person:

- Providers must follow [clinical best practice for vaccination as well as best practices when managing inventory](#) to maximize vaccination and minimize dose wastage.
- Providers should not miss any opportunities to vaccinate every eligible person who presents at a vaccination site.
  - Consider establishing and promoting standing vaccination days or half-days to increase likelihood of larger numbers of people presenting for vaccination on the same day.

- Vaccinate family members or friends who accompany patients to medical visits even if they are not established patients at the vaccinating practice.
- Continue outreach to employers or other community partners that have a large membership or network to arrange vaccination events.
- As contingency plan, vaccine providers should attempt to contact additional persons (i.e., from a standby list or through personal contacts of persons being vaccinated) to use as many vaccine doses as possible.
- Once punctured, multidose vials must be used within:
  - 12 hours [Moderna and Pfizer Adult/Adolescent Tris (Gray Cap, age 12+, no diluent)]
  - 6 hours (Pfizer-BioNTech 12+ purple cap vials)
  - 6 hours (refrigerated) **or** up to 2 hours at room temperature (J&J/Janssen). These times are NOT cumulative (i.e., you cannot store a punctured vial for 6 hours at refrigerated temperatures and then another 2 hours at room temperature).

### **Vaccine Safety:**

Post-vaccination monitoring is an essential part of the COVID-19 vaccination program. The Centers for Disease Control and Prevention (CDC) is promoting and encouraging all those being vaccinated to participate in V-Safe, a smart-phone based application that will allow those vaccinated to enter their symptoms in the days after vaccination using text messaging. V-Safe also provides reminders for the second dose and telephone follow up for anyone who reports medically significant adverse events. V-Safe materials can be found at <http://www.cdc.gov/vsafe>, including a V-Safe information sheet. Please print out the information sheet and hand to each person vaccinated. You must report any adverse events that occur after vaccination to the Vaccine Adverse Events Reporting System (VAERS) at [info@VAERS.org](mailto:info@VAERS.org) or by calling 1-800-822-7967.

### **Equity and Access:**

Effort must be made to do outreach to persons 12 years of age and older in all communities and settings. Persons in areas that have a high social vulnerability index are particularly vulnerable to COVID-19 and should be notified about how they can receive vaccine. Every effort should be made to increase their access to vaccination opportunities.

### **Communicating the Plan:**

Please be sure to clearly communicate this critical guidance to all staff involved in the vaccination program.

This guidance is in effect from the date of issuance until it is updated, or additional guidance is issued by NYSDOH. For questions, please contact the New York State Department of Health, Bureau of Immunization at [COVID19vaccine@health.ny.gov](mailto:COVID19vaccine@health.ny.gov).

## New York State COVID-19 Vaccination Program Guidance Appendix A

All individuals 5 years of age and older are eligible to be vaccinated. **However, minors 5 through 17 are NOT authorized to receive the Janssen/Johnson & Johnson or Moderna COVID-19 vaccines. They may ONLY receive Pfizer-BioNTech at this time pursuant to the FDA EUA. Children under 5 years of age are not yet authorized to receive ANY COVID-19 vaccine.**

It is important to verify the age of individuals who appear to be a minor to confirm eligibility and ensure the administration of the proper COVID-19 vaccine.

Proof of age should be requested but is not required where the parent or guardian is available to attest to the minor's age. Documentary proof may include (but is not limited to):

- Driver's license or non-driver ID
- Birth certificate issued by a state or local government
- Consulate ID
- Current U.S passport or valid foreign passport
- Permanent resident card
- Certificate of Naturalization or Citizenship
- Life insurance policy with birthdate
- Parent/Guardian attestation

### **Minor Consent:**

#### **16 and 17-year-olds:**

For all minors, a parent or legal guardian must provide consent for vaccination. For minors 16 or 17 years of age, such consent should be provided either in person or by phone, at the time of vaccine appointment. Providers may elect whether to accept a written statement of consent from the parent or guardian, where the parent or guardian is not available by phone to provide consent to vaccinate an unaccompanied minor. The [NYS COVID-19 Immunization Screening and Consent Form](#) may be considered for this purpose.

#### **5 through 15-year-olds:**

For minors who are 5 through 15 years of age, additionally, an adult caregiver should accompany the minor. If the adult caregiver is not the parent/guardian, the adult caregiver should be designated by the parent/guardian. The parent/guardian must still provide consent to the vaccination.