

Northwell Health IPA COVID-19 Vaccine Guide



COVID-19 Vaccine: Information for Providers

Providers Should Prepare to Order the COVID-19 Vaccine

Step One: Register for the Immunization Information System

Healthcare providers are strongly recommended to register in <u>NYSIIS for providers in NYS, outside of</u> <u>NYC</u>, and with <u>CIR for providers located in NYC</u>. This is because all COVID-19 Vaccination Program providers will need a NYSIIS account (for providers outside of NYC) or CIR account (for providers located in NYC). Your organization may currently have a NYSIIS or CIR account, but it is important to ensure that the appropriate staff have access.

Step Two: Enroll in the COVID-19 Vaccination Program

- In addition to registering with NYSIIS or CIR, providers must enroll in the COVID-19 Vaccination Program. NYSDOH and NYC DOHMH are implementing a phased approach to provider enrollment and will notify healthcare facilities, providers and professional groups as each new group is opened for enrollment.
- Providers in NYS, outside of NYC, will enroll in the NYS COVID-19 Vaccination Program through the Health Commerce System application "COVID-19 Vaccine Program Provider Enrollment" and should review the <u>NYSDOH COVID-19 Vaccination Program Enrollment Letter</u> for guidance. Providers in NYC will enroll in the NYC COVID-19 Vaccination Program through the CIR.
- Networks with facilities or providers in both NYS and NYC should enroll their facilities or providers outside of NYC in the NYS COVID-19 Vaccination Program through the Health Commerce System and enroll their facilities or providers in NYC in the NYC Covid-19 Vaccination Program through the CIR.

Step Three: Ordering, Receiving and Administering Vaccine

- When COVID-19 vaccine is available, providers will order COVID-19 vaccine through NYSIIS (for providers in NYS, outside of NYC) and CIR (for providers in NYC). Orders will be reviewed and approved by NYS DOH and shipped directly from the vaccine manufacturer or CDC distributor.
- When vaccine is available, providers will monitor vaccine inventory; enter doses administered and/or perform data exchange (uploading and downloading data) between the provider's electronic health system and NYSIIS/CIR; enter vaccine returns and wastage; and generate reports for internal review (e.g. doses administered) in NYSIIS/CIR.

Providers in NYS, outside of NYC, <u>must be enrolled</u> in the NYS COVID-19 vaccination program to be eligible to receive the vaccine and necessary supplies. <u>The deadline to enroll in this program is</u> <u>December 18, 2020</u>.

Additional information for NYC Providers can be found <u>here</u>, and for NYS providers outside of NYC, <u>here</u>.

Please refer to NYS COVID-19 Vaccine Information for Providers for updated information.



Frequently Asked Questions

With the possibility of one or more COVID-19 vaccines becoming available before the end of the year, below are some frequently asked questions regarding the vaccine:

Benefits, dosage, and prevention

Q: What are the benefits of the COVID-19 vaccine?

Because there is currently no cure for COVID-19, prevention is our best strategy. The development of COVID-19 vaccines is an important step in helping minimize the effects of this potentially deadly virus. Vaccines work by training your immune system to recognize and fight off the viruses and bacteria they target. By triggering an immune system response to a virus through a vaccine, your body is better equipped to destroy these disease-causing microbes in the future should you be exposed and the microbe gains entry into your body.

Q: How does the COVID-19 vaccine work?

COVID-19 mRNA vaccines give instructions for our cells to make a harmless piece of what is called the "spike protein." The spike protein is found on the surface of the virus that causes COVID-19. COVID-19 mRNA vaccines are given in the upper arm muscle. Once the instructions (mRNA) are inside the muscle cells, the cells use them to make the protein piece. Our immune systems recognize that the protein doesn't belong there and begin building an immune response and making antibodies, like what happens in natural infection against COVID-19.

At the end of the process, our bodies have learned how to protect against future infection. The benefit of mRNA vaccines, like all vaccines, is those vaccinated gain this protection without ever having to risk the serious consequences of getting sick with COVID-19.

Q: How soon will vaccines become available?

There will be a limited supply of COVID-19 vaccines in December 2020, but supply will continually increase in the weeks and months that follow.

The goal is for everyone to be able to easily get a COVID-19 vaccination as soon as large quantities are available. The plan is to have several thousand vaccination providers available, including doctors' offices, retail pharmacies, hospitals, and federally qualified health centers.

Q: When will I have the chance to receive the vaccine?

To protect health care personnel and the most vulnerable, the CDC has advised that health care workers and residents of long-term care facilities be offered the COVID-19 vaccine in the initial phase of the nation's vaccination program.

Q: Will I need more than one dose of the COVID-19 vaccine?

Yes, receiving two doses of the BioNTech/Pfizer mRNA COVID-19 vaccine is the only way to create an effective antibody response and protect you from COVID-19. The first shot starts building protection. A second shot a few weeks later is needed to get the most protection the vaccine has to offer. Highest immunity through the vaccine is achieved one week after receiving both doses. The duration of immunity is currently unknown.



Q: If I wear a mask and social distance, do I need a vaccine?

The combination of getting vaccinated and following guidelines such as mask wearing and social distancing offer the best protection from COVID-19.

Q: Will I benefit from the vaccine if I have already recovered from COVID-19?

Due to the severe health risks associated with COVID-19 and the fact that re-infection with COVID-19 is possible, people may be advised to get a COVID-19 vaccine even if they have been sick with COVID-19 before. At this time, experts do not know how long someone is protected from getting sick again after recovering from COVID-19. The immunity someone gains from having an infection, called natural immunity, varies from person to person. Some early evidence suggests natural immunity may not last very long.

Q: How long will my immunity last after vaccination?

It is unknown at this time how long immunity will last; ongoing studies will help determine if repeat vaccination is needed and if it is, how often we may need a booster

Vaccine development, storage and distribution

Q: How was the COVID-19 vaccine developed so quickly?

The work of scientists began nearly a year ago in January 2020 on a COVID-19 vaccine. Vaccine funding have come together to move vaccine candidates through the pre-clinical/clinical assessments and trials both quickly and thoughtfully. This has enabled researchers to advance into phase 3 clinical trials (testing the vaccine on large groups of people to evaluate safety and effectiveness) in six months instead of the typical two years. The vaccine was mass produced before the clinical studies were complete to save time.

To learn more about the rigorous scientific and regulatory processes in place to facilitate development and ensure safety, effectiveness and quality of the COVID-19 vaccines, please refer to the Food and Drug Administration's (FDA) website.

Q: Are any of the COVID-19 vaccines that are in development better than the others?

The safety and efficacy can vary by vaccine. That said, all vaccines undergo the same stringent review processes, regardless of manufacturer. FDA approval or EUA means the agency has determined, based on rigorous review and evidence that the vaccine is safe and effective for intended use.

Q: What is Emergency Use Authorization (EUA)?

A: The FDA can issue an EUA during a public health emergency, like a pandemic, to allow the use of unapproved medical products to diagnose, treat or prevent serious or life-threatening diseases. If there's evidence that strongly suggests that patients have benefited from a treatment or test, the FDA can issue an EUA to make it available. Safety and efficacy must be demonstrated, and certain criteria must be met, including that there are no adequate, approved and available alternatives. The EUA was issued, because longer term follow up is needed for formal FDA approval, which will likely occur after six months of observation.

Q: How should the COVID-19 vaccine be stored?

In order to address the critical time constraints in distributing this material, New York State will work with local jurisdictions to identify and operationalize appropriate regionally based storage locations,



each that comply with CDC and manufacturer recommendations for storage including at temperatures as low as minus 80 degrees Celsius.

Q: How will COVID-19 vaccines be distributed?

The federal government will oversee a centralized system to order, distribute, and track COVID-19 vaccines. All vaccines will be ordered through CDC. Vaccine providers will receive vaccines from CDC's centralized distributor or directly from a vaccine manufacturer.

Vaccine safety and concerns

Q: Can the vaccine cause COVID-19?

No. None of the COVID-19 vaccines currently in development in the US, including the BioNTech/Pfizer COVID-19 vaccine, use the live virus that causes COVID-19. There are several different types of vaccines in development. However, the goal for each of them is to teach our immune systems how to recognize and fight the virus that causes COVID-19.

Q: Is the COVID-19 vaccine safe and effective?

The FDA is responsible for protecting public health by ensuring the safety and efficacy of drugs, inclusive of vaccines. They have now given the BioNTech/Pfizer COVID-19 vaccine EUA because it met the needed safety and efficacy criteria.

Q: Are the first to receive the vaccine serving as a test for safety and effectiveness?

The safety and efficacy of the BioNTech/Pfizer vaccine established in phase 3 clinical trials was a primary factor in the FDA issuing EUA for its use. The FDA will continue to monitor the safety and efficacy of all COVID-19 vaccines that receive EUA before providing full approval for those that meet federal safety and efficacy standards.

Q: Will receiving the vaccine cause any side effects?

Some people may experience more symptoms compared to prior vaccinations. The booster shot can produce symptoms more severe than experienced with the first dose. This is all normal and not serious and will disappear with time.

The most common side effect is muscle soreness or achiness in the arm, which will resolve without treatment. Other common side effects after vaccination may include:

- Swelling or redness where the vaccine was administered
- Low-grade fever
- Chills
- Fatigue
- Headache
- Muscle and joint achiness elsewhere

Self-care for side effects includes:

- Over the counter medication such as acetaminophen or ibuprofen for fever or muscle/joint aches
- An alternating warm/cool compress at the vaccination site for soreness



- Rest
- Staying well hydrated

Q: How do I report it if I have a problem or reaction after getting a COVID-19 vaccine?

CDC and FDA encourage the public to report possible side effects (called adverse events) to the Vaccine Adverse Event Reporting System (VAERS). This national system collects these data to look for adverse events that are unexpected, appear to happen more often than expected, or have unusual patterns of occurrence. Reports to VAERS help CDC monitor the safety of vaccines. Safety is a top priority.

Healthcare providers will be required to report certain adverse events following vaccination to VAERS. Healthcare providers also have to adhere to any revised safety reporting requirements according to FDA's conditions of authorized use throughout the duration of any Emergency Use Authorization; these requirements would be posted on <u>FDA's website</u>.

Q: Can anyone get the vaccine (e.g., children, the elderly, people who are immunocompromised, women who are breastfeeding/pregnant/considering becoming pregnant, those with a significant history of allergic reactions)?

If you have questions about the COVID-19 vaccine and children, elderly, people who are immunocompromised, women who are breastfeeding/pregnant/considering becoming pregnant, and those with a significant history of allergic reactions, please learn more from the Centers for Disease Control and Prevention (CDC) on the CDC website and consult your health care provider.

Q: Is it safe to get a COVID-19 vaccine if I have an underlying medical condition?

Yes. COVID-19 vaccination is especially important for people with underlying health problems like heart disease, lung disease, diabetes, and obesity. People with these conditions are more likely to get very sick from COVID-19.

Q: Are there long-term side effects from COVID-19 vaccine?

Because all COVID-19 vaccines are new, it will take more time and more people getting vaccinated to learn about very rare or possible long-term side effects. The good news is, at least 8 weeks' worth of safety data were gathered in the clinical trials for all the authorized vaccines, and it's unusual for vaccine side effects to appear more than 8 weeks after vaccination.

Additional Resources:

Learn more about the COVID-19 vaccine on the <u>CDC website</u> and find <u>Clinical Resources for each COVID-19 Vaccine</u>.

Learn how, with oversight and regulation, the FDA ensures vaccine quality, safety and effectiveness while helping to facilitate the timely development of COVID-19 vaccines on the <u>FDA website</u>.

Learn how the CDC is making vaccine recommendations.

