

# **COVID-19 Vaccine FAQ**

The manufacture and distribution of COVID-19 vaccine is a fluid situation that changes from day to day. Molina Healthcare of Illinois communicates with Centers for Medicare & Medicaid Services (CMS) and other agencies regularly. The information herein is accurate as of March 9, 2021. Please use the links in this document to visit CMS, Illinois Department of Public Health, Centers for Disease Control and Prevention (CDC), and other websites for more detailed information.

# 1. When did the COVID-19 vaccines become available?

Two pharmaceutical companies released vaccines against the SARS-CoV2 virus in December 2020. Pfizer was the first to receive Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) and commenced distribution of its vaccine across the country. Moderna followed a similar progression with its vaccine and began distribution shortly afterward. Vaccinations began within the medical community and among first-responders in December 2020. The Johnson & Johnson vaccine was approved in late February 2021 and distribution began in March.

#### 2. How many doses have been given so far?

The current population of the United States is 331 million and so far, 18% (or almost 60 million Americans) have received one dose of the vaccine. More than 31 million are fully vaccinated as of March 9. The new Johnson & Johnson vaccine only requires one dose, which will help more people become fully vaccinated sooner.

# 3. Are any other COVID-19 vaccines still in development?

Yes, several manufacturers have vaccines currently in development. Some have published results from Phase 1 through 3 clinical trials. Other vaccines being tested do not yet have approval for emergency use by the FDA.

# 4. Who will get the vaccine next?

The manufacturers are partnering with the government regarding distribution and allocation of COVID-19 vaccine doses as they become available. The CDC has required each state to draft comprehensive distribution plans and has released a playbook to help states develop their vaccination plans. The <u>Illinois</u> <u>Department of Public Health</u> released an updated <u>COVID-19 Vaccination Plan</u> on February 27. The CDC lists its recommended allocation on its website: <u>cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html</u>.

#### 5. How much does the vaccine cost?

Vaccine doses purchased by the U.S. government will be given to the American people at no cost. However, vaccine providers will be able to charge administration fees for giving or administering the shot. Vaccine providers can get this fee reimbursed by the patient's public or private insurance company or, for uninsured patients, by the <u>Health Resources and Services Administration's Provider Relief Fund</u>.

One of the conditions within the <u>CDC COVID-19 Vaccination Program Provider Agreement</u> requires the "administration of COVID-19 vaccine regardless of the vaccine recipient's ability to pay."

#### 6. Will the current vaccines work for the new strains of coronavirus (called variants)?

The available information shows that the vaccines do work well against the current new strains in the U.S. The first two FDA-authorized vaccines are both mRNA vaccines that produce a broad immune response to target several parts of the viral surface spike protein. In order for the new variants of SARS-CoV-2 to evade the immune response induced by the Pfizer or Moderna vaccines, the virus would need to accumulate multiple mutations in the spike protein. This has not happened to date. The later Johnson & Johnson vaccine was tested in multiple countries against both the old and new strains of the coronavirus.

#### 7. How many vaccine doses are needed for maximum efficacy?

The first available vaccines (Pfizer and Moderna) are two-dose vaccines. Both doses are necessary. Upon administering the initial dose, vaccination providers must complete a <u>COVID-19 vaccination record card</u> for the patient containing accurate vaccine information (i.e. vaccine manufacturer, lot number, date of first dose administration, and second dose due date). The Johnson & Johnson vaccine is a single dose.

# 8. How will a patient know when to receive the second Pfizer or Moderna dose?

From you, the vaccine provider. Second-dose reminders for vaccine recipients are critical to ensure compliance with vaccine dosing intervals and achieve optimal vaccine effectiveness. As the COVID-19 vaccination provider, you should schedule a patient's second-dose appointment when they get their first dose. Encourage vaccine recipients to keep the <u>vaccination record card</u> (mentioned above) in case the CDC Immunization Information Systems (IIS) or other system is not available when they return for their second dose. The card provides room for a written reminder for the second-dose appointment.

# 9. Does the second dose need to be of the same manufacturer?

Yes. The different COVID-19 vaccine products are not interchangeable; the recipient's second dose should be from the same manufacturer as their first dose.

# 10. What is the procedure for recording the vaccinations?

As the vaccine provider, you must record certain data elements, including manufacturer, for each dose administered within 24 hours of administration. COVID-19 vaccination providers may view the data requirements on the <u>vaccination provider support page of CDC's IIS website</u>.

Providers are also required 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 the <u>COVID-19 pages of the FDA's website</u>.

#### 11. What are the side effects of receiving the vaccine?

Reported side effects may be similar to what people have experienced after receiving a flu shot. Vaccine recipients have commonly reported body aches, headache, fatigue, and soreness at the injection site after receiving the first dose Pfizer or Moderna's vaccine. Side effects are possible after the first and/or the second dose. The same is true after receiving the single Johnson & Johnson dose. In virtually all cases, these symptoms disappear after one to three days.

In extremely rare cases, an allergic or anaphylactoid reaction occurs, so it is recommended that vaccine recipients remain on premises for 15 minutes post-injection. People who have had severe reactions to other vaccines or to the components of these new vaccines should not take the vaccine. The Johnson & Johnson vaccine may be less likely to cause a reaction, but more information is needed to be certain.

# 12. What can I tell vaccine recipients regarding when they will be protected from COVID-19?

Experts are still tracking and evaluating the protection that COVID-19 vaccines provide under real-life conditions. From the early information available, it appears that recipients of the Pfizer and Moderna vaccines will be protected within 14 days after their second dose of vaccine. Recipients of the Johnson & Johnson vaccine are protected after 28 days.

It is important to note that no vaccine gives 100% immunity, and that precautions such as social distancing and mask wearing should still be followed, even after vaccination. It is also important to note that those receiving full doses of the vaccines appear to be very well protected against hospitalization and death from the virus.

# 13. How can I join the pool of providers administering the vaccine?

Visit the CMS website to enroll for administering the COVID-19 vaccine: <u>cms.gov/medicare/covid-19/enrollment-administering-covid-19-vaccine-shots</u>.

# 14. How can I secure a vaccine supply?

Information regarding vaccine supply will be available through state and local health agencies and the <u>CDC</u> <u>VaccineFinder</u>. The Centers for Medicare & Medicaid Services (CMS) offers resources for providers here: <u>cms.gov/COVIDvax</u>.

# 15. How do I store the vaccine?

As part of the <u>COVID-19 Vaccination Provider Agreement</u>, providers are required to store and handle COVID-19 vaccines under proper conditions, including maintaining cold-chain conditions and chain of

custody at all times in accordance with an Emergency Use Authorization (EUA) or vaccine package insert, manufacturer guidance, and CDC guidance in the <u>Vaccine Storage and Handling Tool Kit</u>.

Monitor storage unit temperatures at all times, using equipment and practices that comply with guidance in the tool kit. Comply with immunization program guidance for handling temperature excursions. Monitor and comply with COVID-19 vaccine expiration dates. Preserve all records related to COVID-19 vaccine management for a minimum of three years or longer, as required by your jurisdiction.

#### 16. How do I know if I have the proper equipment to store it?

Each provider should have the capacity to consistently store the vaccines at the following temperatures: Store COVID-19 vaccine (Pfizer) between -112°F and -76°F. <u>Pfizer temperature chart document</u>. Store COVID-19 vaccine (Moderna) between -13°F and +5°F. <u>Moderna temperature chart document</u>. Store COVID-19 vaccine (Johnson & Johnson) between 36°F and 46°F. <u>Temperature chart document</u>.

Check the CDC website or the manufacturer's website for up-to-date information on storage as new information becomes available.

#### 17. Should I vaccinate a patient who has already had COVID-19 and recovered?

The current recommendation is that all people who have had COVID-19 should receive the vaccine because immunity from the infection may not be long lasting.

#### 18. How do I report an adverse event in a patient after getting the COVID-19 vaccine?

The CDC and FDA require providers to use the <u>Vaccine Adverse Event Reporting System (VAERS)</u>. This national system collects data to look for adverse events that are unexpected, appear to happen more often than expected, or have unusual patterns of occurrence. Providers are also required 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 FDA's website.

#### References:

- https://www.cdc.gov/coronavirus/2019-ncov/vaccines/8-things.html
- <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html</u>
- https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html
- <u>https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/temp-log-freezer-storage-celsius.pdf</u>
- https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/temp-log-ultra-cold-storage-celsius.pdf
- https://www.cdc.gov/vaccines/covid-19/reporting/vaccinefinder.html
- https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html
- https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html
- https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html
- <u>https://www.cms.gov/COVIDvax</u>
- <u>https://www.cms.gov/covidvax-provider</u>
- https://www.cms.gov/medicare/covid-19/enrollment-administering-covid-19-vaccine-shots
- https://www.defense.gov/observe/photo-gallery/igphoto/2002536141/

- <u>https://www.dph.illinois.gov/covid19/vaccination-plan</u>
- https://www.dph.illinois.gov/sites/default/files/COVID19/IL%20COVID-19%20Vaccination%20Plan%20V4.20210110.pdf
- <u>https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-frequently-asked-questions</u>
- https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines
- https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html
- https://www.hrsa.gov/CovidUninsuredClaim
- <u>https://www.idsociety.org/covid-19-real-time-learning-network/vaccines/vaccines/</u>
- https://www.jnj.com/johnson-johnson-covid-19-vaccine-authorized-by-u-s-fda-for-emergency-usefirst-single-shot-vaccine-in-fight-againstglobal-pandemic
- <u>https://www.nch.org/news/covid-19-q-a/</u>
- <u>https://www.pfizer.com/science/coronavirus/vaccine</u>
- <u>https://vaers.hhs.gov/reportevent.html</u>

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