MI COVID-19 VACCINE FREQUENTLY ASKED QUESTIONS

Facing COVID-19 Together

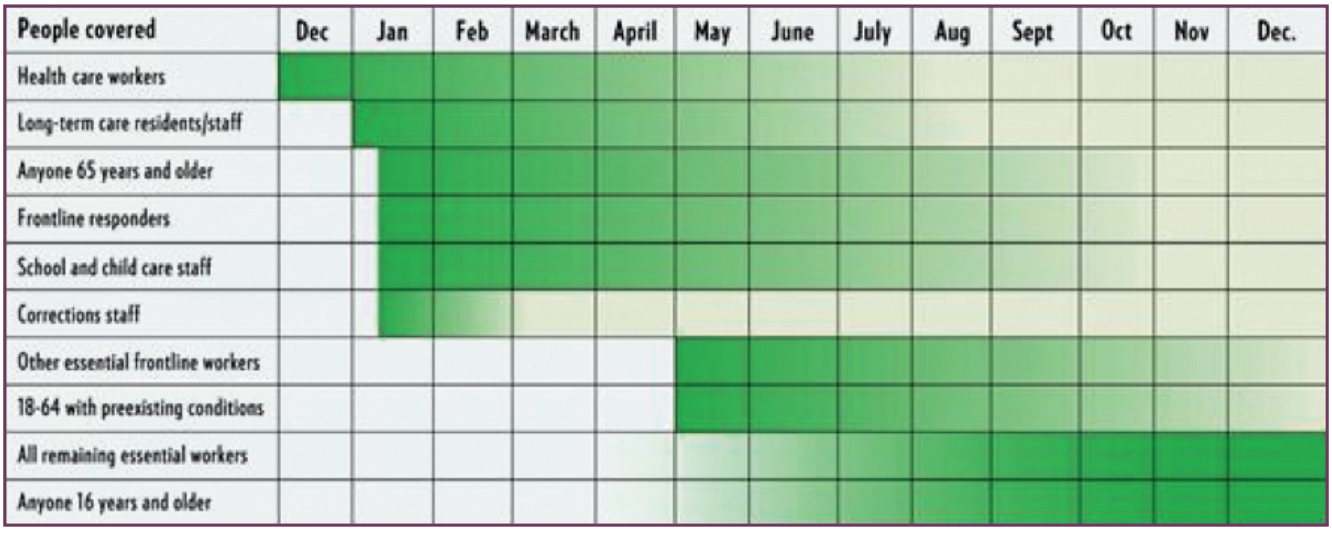
ATTENTION: Michigan residents 65 years and older are now eligible to receive the COVID-19 vaccine. For more information about the vaccine and vaccine locations, please visit **www.michigan.gov/COVIDVaccine**

Who will get the vaccine first?

Michigan Department of Health and Human Services (MDHHS) has prioritized the vaccine distribution in the following order:

1. Health care workers, long-term care workers and residents, and essential workers not in healthcare
2. People 65 and older
3. Adults 18-64 with high-risk medical conditions
4. Anyone 16 or older who was not covered in the previous groups

How will Michigan distribute COVID-19 vaccines?



* As of January 6, 2021
Credit: Michigan Department of Health and Human Services

Core vaccine administration period

Vaccines continue to be available for anyone not yet vaccinated

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Where can I get the vaccine?

Visit **www.Michigan.gov/COVIDVaccine** for information on where to make an appointment at available healthcare providers and local health agencies.

Does it require more than one dose to be effective?

- Yes, two doses are needed, a few weeks apart, from the same manufacturer.
- To make sure the vaccine is effective, it's recommended that you see the same provider for both doses.
- Request a completed COVID-19 vaccination record card and keep it safe.

Are there side effects?

Like with a flu shot, some people have reported mild fatigue, headache, body aches, chills and pain at the injection site for a day or two.

Can I get COVID-19 from the vaccine?

No. The live COVID-19 virus is not present in any vaccine currently in development and there is no risk from becoming infected as a direct result of receiving the vaccine. Side effects for 1-2 days after receiving the vaccine, including body aches, low-grade fever, or fatigue are generally mild and are merely a sign that your body is building an immune response.

If I have already had COVID-19 and recovered, do I still need to get vaccinated?

Yes, you should still get the COVID-19 vaccine, even if you have had COVID-19. There is not enough information currently available to say if or for how long after infection someone is protected from getting COVID-19 again; this is called natural immunity. Early evidence suggests natural immunity from COVID-19 may not last very long, but more studies are needed to better understand this.

What should I do if I am Pregnant?

MDHHS is advising that pregnancy is listed as one of the conditions that puts women at increased risk for severe COVID-19 related illness. Please contact your provider to schedule an appointment for the vaccine to determine if you should get vaccinated.

How much will the vaccine cost?

Vaccine doses purchased with U.S. taxpayer dollars 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 to someone. Vaccine providers can get this fee reimbursed by the patient's public or private insurance company or, for uninsured patients, by the Health Resources and Services Administration's Provider Relief Fund. One of the conditions within The CDC COVID-19 Vaccination Program Provider Agreement requires the "administration of COVID-19 vaccine regardless of the vaccine recipient's ability to pay."

How will the healthcare provider know which manufacturer is needed for a 2nd dose?

In addition to standard medical recordkeeping, the CDC requires that vaccination providers enrolled in the COVID-19 Vaccination Program report certain data elements, including manufacturer, for each dose administered within 24 hours of administration. COVID-19 vaccination providers may view the data requirements on CDC's IIS website.

You will also receive a vaccine card from your vaccine provider. Please keep the card to remind you about your manufacturer, date of first dose and when to get you second dose.

Will I still need to wear a mask, practice social distancing, wash my hands, and limit my exposure to others after I get a vaccine?

Yes. While experts learn more about the protection that COVID-19 vaccines provide, it will be important for everyone to continue using **all the tools** available to help stop this pandemic. It will take several months for vaccine supply to become widely available to all the population and it is important to continue to maintain proper preventative measures to control spread. The CDC recommends everyday preventive actions to help prevent the spread of respiratory diseases. They include:

- **Wash your hands** often with plain soap and water. The CDC recommends washing your hands often with soap and water for at least 20 seconds. It's important to wash your hands after being in a public place, blowing your nose, coughing, or sneezing. If soap and water are not available, the CDC recommends using an alcohol-based hand sanitizer that contains at least 60 percent alcohol. Learn more about safely using hand sanitizer.
- **Cover your mouth and nose** with a cloth face covering or non-surgical mask when around others. Find more information about how to select, wear, and clean your mask.
- **Avoid crowds and practice social distancing** by staying at least 6 feet apart from others.

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

CDC and FDA encourages 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. Learn about the difference between a vaccine side effect and an adverse event. 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 FDA's website.

CDC is also implementing a new smartphone-based tool called **V-safe** to check-in on people's health after they receive a COVID-19 vaccine. When you receive your vaccine, you should also receive a V-safe information sheet telling you how to enroll in V-safe. If you enroll, you will receive regular text messages directing you to surveys where you can report any problems or adverse reactions you have after receiving a COVID-19 vaccine.

What is an Emergency Use Authorization (EUA)?

An Emergency Use Authorization (EUA) is a tool to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies. In issuing an EUA, the FDA must determine, among other things, that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition.

Emergency use authorization is NOT the same as FDA approval or licensure.

What is the difference between an Emergency Use Authorization (EUA) and an FDA approval?

FDA approves New Drug Applications (NDAs) under section 505(c) of the FD&C Act. The NDA is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical that is not a biologic for sale and marketing in the U.S. In approving an NDA, FDA reviewers must determine, among other things, that the:

- Drug is safe and effective for its labeled use(s)
- Benefits of the drug outweigh the risks
- Drug's labeling (package insert) is appropriate
- Methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.

The statutory standard for an NDA approval requires substantial evidence of effectiveness, which is a higher level of evidence of effectiveness than required for an EUA.

References:

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/8-things.html

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html

https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-frequently-asked-questions

https://www.pfizer.com/science/coronavirus/vaccine

https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html

https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6950e2-H.pdf

https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html