VACCINE INFORMATION STATEMENT

COVID-19 Vaccine:

What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

COVID-19 vaccine can prevent **COVID-19 disease**. Vaccination can help reduce the severity of COVID-19 disease if you get sick.

COVID-19 is caused by a coronavirus called SARS-CoV-2 that spreads easily from person to person. COVID-19 can be mild to moderate, lasting only a few days, or it can be severe, requiring hospitalization, intensive care, or a ventilator to help with breathing. COVID-19 can also result in death.

COVID-19 symptoms may appear 2 to 14 days after exposure to the virus. A person can have mild, moderate, or severe symptoms.

- Symptoms can include fever; chills; cough; shortness of breath or difficulty breathing; fatigue (tiredness); muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea; vomiting; and diarrhea.
- More serious symptoms can include trouble breathing; persistent pain or pressure in the chest; new confusion; inability to wake or stay awake; and pale, gray, or bluecolored skin, lips, or nail beds (depending on skin tone).

Older adults and people of any age with certain underlying medical conditions (like heart or lung disease or diabetes) are more likely to get very sick with COVID-19.

After COVID-19 illness, some people get Long COVID, a chronic condition with symptoms lasting 3 months or longer. Symptoms of Long COVID may get better, get worse, or stay the same.

People who are up to date with COVID-19 vaccination have a lower risk of severe illness, hospitalization, and death from COVID-19 than people who are not up to date. COVID-19 vaccination is the best way to prevent Long COVID.

Getting a COVID-19 vaccine helps the body learn how to defend itself from the disease and reduces the risk for severe illness and complications. Additionally, COVID-19 vaccines can offer added protection to people who have already had COVID-19, including protection against being hospitalized if they become infected with COVID-19 again.

2. COVID-19 vaccine

Updated 2024–2025 COVID-19 vaccine is recommended for everyone 6 months of age and older. This includes women who are pregnant, breastfeeding, trying to get pregnant now, or who might become pregnant in the future.

2024–2025 COVID-19 vaccines for infants and children 6 months through 11 years of age are available under Emergency Use Authorization from the U. S. Food and Drug Administration (FDA). Please refer to the Fact Sheets for Recipients and Caregivers for more information.

For people 12 years of age and older, 2024–2025 COVID-19 vaccines, manufactured by ModernaTX, Inc. or Pfizer, Inc., are approved by FDA.

Novavax COVID-19 Vaccine Adjuvanted (2024–2025 Formula) vaccine is available under Emergency Use Authorization from FDA for people 12 years and older. Please refer to the Fact Sheet for Recipients and Caregivers for more information.

- Everyone 6 months of age and older is recommended to receive an age-appropriate FDA-approved or authorized updated 2024–2025 COVID-19 vaccine.
- Certain people, such as those who have medical conditions or are taking medications that affect the immune system, may need additional doses of COVID-19 vaccine. Your health care provider can advise you.

To allow medical care provider(s) accurate immunization status information, an immunization assessment, and a recommended schedule for future immunizations, information will be sent to the Michigan Care Improvement Registry. Individuals have the right to request that their medical care provider not forward immunization information to the Registry.



3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an allergic reaction after a previous dose of COVID-19 vaccine or has any severe, life-threatening allergies
- Has had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside of the heart)
- Has had multisystem inflammatory syndrome (called MIS-C in children and MIS-A in adults)

In some cases, your health care provider may decide to postpone COVID-19 vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill, including with COVID-19, should usually wait until they recover.

COVID-19 vaccine may be given at the same time as other vaccines.

4. Risks of a vaccine reaction

- Pain, swelling, and redness where the shot is given, fever, tiredness (fatigue), headache, chills, muscle pain, joint pain, nausea, vomiting, and swollen lymph nodes can happen after COVID-19 vaccination.
- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have been seen rarely after COVID-19 vaccination. These risks have been observed most frequently in adolescent and young adult males. The chance of this occurring is low.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

V-Safe is a safety monitoring system that lets you share with CDC how you, or your dependent, feel after getting COVID-19 vaccine. You can find information and enroll in V-Safe at <u>vsafe.cdc.gov</u>.

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

Seek medical attention right away if the vaccinated person experiences chest pain, shortness of breath, or feelings of having a fast-beating, fluttering, or pounding heart after COVID-19 vaccination. These could be symptoms of myocarditis or pericarditis.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at www.vaers.hhs.gov or call 1-800-822-7967. VAERS is only for reporting reactions, and VAERS staff do not give medical advice.

6. Countermeasures Injury Compensation Program

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit the program's website at www.hrsa.gov/cicp, or call 1-855-266-2427.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for COVID-19 Fact Sheets, package inserts, and additional information at www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines.
- Contact the Centers for Disease Control and Prevention (CDC):
- Call 1-800-232-4636 (1-800-CDC-INFO) or
- Visit CDC's COVID-19 vaccines website at www.cdc.gov/covid/vaccines/index.html.



MDHHS Addendums:

To allow medical care provider(s) accurate immunization status information, an immunization assessment, and a recommended schedule for future immunizations, information will be sent to the Michigan Care Improvement Registry. Individuals have the right to request that their medical care provider not forward immunization information to the Registry.

The mRNA vaccines (those by Pfizer and Moderna) did not use a fetal cell line to produce or manufacturer the vaccine. However, a fetal cell line was used in a very early phase to confirm efficacy prior to production and manufacturing.

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