Emergency Use Instructions (EUI) Fact Sheet for Recipients and Caregivers: Moderna COVID-19 Vaccine for Primary, Additional and/or Booster Doses

This Fact Sheet describes Emergency Use Instructions (EUI) that have been issued by the Centers for Disease Control and Prevention (CDC) to provide information about the primary, additional, and booster doses of the COVID-19 vaccine by Moderna that go beyond its FDA-approved labeling. These uses under EUI include, but are not limited to, longer interval between primary doses of the COVID-19 vaccine by Moderna, use in certain individuals who received primary vaccination with certain COVID-19 vaccines not authorized or approved by the Food and Drug Administration(FDA) for such use and in immunocompromised individuals who received one primary dose of the Janssen COVID-19 Vaccine. See below for more information on the uses of the COVID-19 vaccine by Moderna under EUI.

mRNA vaccines are preferred for persons with moderate or severe immune compromise. If you are 18 years and older and you are receiving vaccination for uses provided under EUI, you have a choice of receiving the COVID-19 vaccine by either Moderna or Pfizer-BioNTech (see the Pfizer-BioNTech EUI Fact Sheet for Recipients and Caregivers). Persons 12–17 years of age should only receive the COVID-19 vaccine by Pfizer-BioNTech.

What are Emergency Use Instructions (EUI)?
EUI are issued by CDC to provide information about emergency use of FDA-approved (licensed) medical products thatmay not be included in or differ in some way from the information provided in the FDA-approved labeling (package insert). EUI consist of fact sheets for healthcare providers and recipients.

Why is CDC issuing EUI for the COVID-19 vaccine by Moderna?
The COVID-19 vaccine by Moderna is an FDA-approved COVID-19 vaccine (brand name Spikevax, mRNA) to prevent COVID-19 in persons ages 18 years and older. CDC is issuing EUI to provide information about this vaccine for the below uses that extend beyond its FDA-approved labeling (see "Who can receive primary, additional, and/or boosterdose(s) of the COVID-19 vaccine by Moderna under the EUI?"). The COVID-19 vaccine by Pfizer-BioNTech can also beused under EUI for similar uses as an alternative mRNA COVID-19 vaccine (see the Pfizer-BioNTech EUI Fact Sheet for Recipients), and the same or similar recommendations in this EUI also apply to the use of the COVID-19 vaccine by Pfizer-BioNTech under EUI.

What is COVID-19?
Coronavirus disease 2019 (COVID-19) is an infectious disease caused by a coronavirus called SARS-CoV-2. It is predominantly a respiratory illness that can also affect other organs. People with SARS-CoV-2 infection have reported a wide range of symptoms, from no symptoms to severe illness leading to death. Symptoms may appear 2 to 14 daysafter exposure to the virus. Symptoms may include: fever or chills, cough, shortness of breath, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, and diarrhea.

Who can receive primary, additional, and/or booster dose(s) of the COVID-19 vaccine by Moderna under the EUI?
People who can receive the COVID-19 vaccine by Moderna under EUI are described below.

- People ages 18 years and older, especially those at higher risk of myocarditis associated with mRNA COVID-19 vaccines, may receive the second primary dose of the COVID-19 vaccine by Moderna 4–8 weeks after the first primary dose. The second dose should not be received earlier than 4 weeks after the first dose.
- People ages 18 years and older who recently had SARS-CoV-2 infection may receive a second primary dose after a deferral period of 3 months from symptom onset or positive test (if infection was asymptomatic)

- People ages 18 years and older who received an incomplete primary dose series (only the first dose of a 2- dose primary series) with certain non-FDA authorized or approved COVID-19 vaccines at least 28 days ago should receive a primary dose of the COVID-19 vaccine by Moderna to complete the series.
- People ages 18 years and older who are not immunocompromised and completed their primary vaccination with mRNA COVID-19 vaccine or primary vaccination that included certain non-FDA authorized or approved COVID-19 vaccines should receive a booster dose of the COVID-19 vaccine by Moderna at least 5 months aftercompletion of primary vaccination.
- People ages 18–49 years who received a primary dose and booster dose of the Janssen COVID-19 Vaccine should receive a second booster dose of the COVID-19 vaccine by Moderna at least 4 months after the previous booster dose. A second booster dose for people ages 50 years and older is authorized under EUA.
- For people who are moderately or severely immunocompromised:
    - People ages 18 years and older who are moderately or severely immunocompromised and completed their primary vaccination with mRNA COVID-19 vaccine or primary vaccination that included certain non-FDA authorized or approved COVID-19 vaccines should receive a booster dose of the COVID-19 vaccine by Moderna at least 3 months after completion of primary vaccination.
    - People ages 18 years and older who are moderately or severely immunocompromised and received their primary vaccination with certain non-FDA authorized or approved COVID-19 vaccines at least 28days ago should receive an additional (third) primary dose of the COVID-19 vaccine by Moderna.
    - People ages 18 years and older with a moderately or severely immunocompromising condition who received a primary dose of the Janssen COVID-19 Vaccine should receive an additional dose with theCOVID-19 vaccine by Moderna at least 28 days after receiving the Janssen COVID-19 Vaccine primarydose. People who already received a booster dose with an authorized COVID-19 vaccine after receiving the Janssen COVID-19 Vaccine primary dose should receive an additional dose with the COVID-19 vaccine by Moderna at least 2 months after the booster dose.
    - People ages 18 years and older with a moderately or severely immunocompromising condition who received dose(s) of COVID-19 vaccine prior to or during certain therapies (indicated below) should berevaccinated with the COVID-19 vaccine by Moderna, regardless of which vaccine was received initially.
        - Received COVID-19 vaccine dose(s) during treatment with B-cell-depleting therapies over alimited period: the suggested interval to start revaccination is about 6 months after completion of the B-cell-depleting therapy
        - Received COVID-19 vaccine dose(s) prior to or during treatment with hematopoietic cell transplant (HCT) or chimeric antigen receptor (CAR)-T-cell therapy: revaccination at least 3 months after treatment

The COVID-19 vaccine by Pfizer-BioNTech can also be used under EUI for similar uses in persons ages 12 years andolder as an alternative mRNA COVID-19 vaccine (see the Pfizer-BioNTech EUI Fact Sheet for Recipients).

Talk to your healthcare provider about if and when you should receive a primary, additional and/or a booster dose. See CDC's Interim Clinical Considerations for additional information on moderately and severely immunocompromised persons recommended for an additional primary dose and populations eligiblefor a booster dose

Who should NOT get the COVID-19 vaccine by Moderna?
You should not get the vaccine if you:

- had a severe allergic reaction after a previous dose of the COVID-19 vaccine by Moderna
- had a severe allergic reaction to any ingredient of the COVID-19 vaccine by Moderna

What should I mention to the vaccination provider before getting the COVID-19 vaccine by Moderna? Tell your vaccination provider the name, number of doses, and date(s) of COVID-19 vaccine(s) you received previously. Also,mention all of your medical conditions, including if you:

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- have ever fainted in association with an injection

How is the COVID-19 vaccine by Moderna given?
COVID-19 vaccine by Moderna is given as an injection into the muscle.

Has the COVID-19 vaccine by Moderna been used before?
Yes. Millions of people have received this vaccine in the United States since it became available starting December 18, 2020. Also, in clinical trials, approximately 15,400 people 18 ages years and older received at least 1 dose of the vaccine. There have been some studies in people who received the COVID-19 vaccine by Moderna after completing a primary vaccination with a non-FDA authorized or approved COVID-19 vaccine or Janssen COVID-19 Vaccine.

What are the risks of the COVID-19 vaccine by Moderna?
Limited data are available on use of the COVID-19 vaccine by Moderna as an additional primary dose or a booster dose in people who completed their primary vaccination with a non-FDA authorized or approved COVID-19 vaccine, or as an additional or second booster dose for individuals who received Janssen COVID-19 Vaccine for primary vaccination.
Side effects of the COVID-19 vaccine by Moderna include injection site pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness; fatigue; headache; muscle pain; joint pain; chills; nausea and
vomiting; fever; and rash. Common side effects reported were mostly mild, but some people had side effects that affected their ability to do daily activities.

Cases of myocarditis and pericarditis have rarely been reported in some people. Cases have occurred predominantly in adolescents and young adult males within the first week after the second dose of vaccine. There is evidence from multiple sources that suggest a higher risk for myocarditis following Moderna compared to Pfizer-BioNTech vaccination; however, it is not possible to directly compare the risk in people ages 12–17 years because Pfizer- BioNTech is the only COVID-19 vaccine authorized in this age group.

Additional information on the common and serious side effects of the COVID-19 vaccine by Moderna can be found in the package insert for Spikevax and in the EUA Fact Sheet for Recipients and Caregivers.

What are the benefits of the COVID-19 vaccine by Moderna?
The COVID-19 vaccine by Moderna has been shown in clinical studies to be effective in preventing COVID-19. Receiving the second primary dose of the COVID-19 vaccine by Moderna 4–8 weeks after the first dose may reduce the risk of myocarditis and result in greater immune response and better protection against COVID-19. Primary, additional, and/ or booster doses of the COVID-19 vaccine by Moderna as described under EUI may help to increase immune response in people, which could improve protection against COVID-19. Similarly, for individuals who received the Janssen Vaccine for primary vaccination, an additional primary or second booster dose of the COVID-19 vaccine by Moderna could improve protection against COVID-19. The COVID-19 vaccine by Moderna may not protect everyone.

What are the Risks and Benefits of the COVID-19 vaccine by Moderna?
The FDA approved the COVID-19 vaccine by Moderna to prevent COVID-19 based on safety and efficacy data available from clinical trials. Additionally, the FDA issued an Emergency Use Authorization of the COVID-19 vaccine by Modernaas an additional primary or a booster dose, determining, among other things, that the known and potential benefits ofvaccination outweigh the known and potential risks of the vaccine. Based on available information, the use of the COVID-19 vaccine by Moderna as described in this Fact Sheet could help improve or restore protection that may not have been sufficient or may have decreased over time after the primary vaccination.

What alternative choices are available for primary, additional, and/or booster doses other than the COVID-19vaccine by Moderna?
Currently, the Moderna COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine are the only FDA-approved COVID-19 vaccines for which EUI provide information about primary, additional, and/or booster doses following the COVID-19 vaccine that you received. If vaccinated outside of the United States or through a clinical trial and the
COVID-19 vaccine you initially received for primary vaccination is not authorized or approved in the United States, then the vaccine you initially received may not be available to you.

It is your choice to receive or not receive the COVID-19 vaccine by Moderna as a primary, additional, and/ or booster dose. Should you decide not to receive it, it will not change your standard medical care.

Will I get a vaccination card?
When you are administered a primary, additional, or a booster dose of the COVID-19 vaccine by Moderna, you will get a vaccination card to document when you received the shot. You should keep your vaccination card.

What is the 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 www.hrsa.gov/cicp/or call 1-855-266-2427.

How can I learn more?

- Ask the vaccination provider.
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html.
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
- Contact your local or state public health department.

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 manufacture the vaccine. However, a fetal cell line was used in a very early phase to confirm efficacy prior to production and manufacturing.