

COVID-19 Vaccine Provider Guide

INFORMATION FOR HANDLING AND ADMINISTERING COVID-19 VACCINE

Updated 3/22/2024

The COVID-19 vaccine response can change periodically. Please make sure you have the most current version of this document, which can be found at [COVID-19 Vaccine Providers \(www.health.state.mn.us/diseases/coronavirus/vaccine/provider.html\)](http://www.health.state.mn.us/diseases/coronavirus/vaccine/provider.html).

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Background

In March 2020, the World Health Organization (WHO) declared COVID-19 a global pandemic. Immunization with a safe and effective COVID-19 vaccine is critical to reduce COVID-19-related illnesses, hospitalizations, and deaths.

Initial vaccines were authorized by emergency use authorizations (EUA) from the Food and Drug Administration (FDA) when enough preliminary data on their effectiveness and safety was collected. In a global health pandemic, an EUA allows the FDA to review information from a vaccine manufacturer to determine if a vaccine can be released early. They weigh the benefits of early release against the known and unknown risks of a vaccine. Information about effectiveness and safety continues to be collected. If at any time vaccine data shows more risk than benefit, an EUA is re-evaluated.

COVID-19 vaccine is no longer being supplied by the federal government. Private vaccine must be purchased to administer to persons with insurance. Public vaccine is provided through the Minnesota Vaccines for Children (MnVFC) program and Un- and Under-insured Adult Vaccine (UUAV) program for eligible persons.

Use of this guide

Anyone who handles and/or administers COVID-19 vaccine should read this guide. Bookmark this guide for easy reference and check back often for updates.

Training requirements

The vaccine coordinator and back-up coordinator at any site administering COVID-19 vaccines should read this COVID-19 vaccine provider guide and watch the CDC’s [CDC: COVID-19 Vaccine Training Module \(www2.cdc.gov/vaccines/ed/covid19/\)](https://www2.cdc.gov/vaccines/ed/covid19/) for the most up to date information about COVID-19 vaccines. Other people storing, handling, and administering COVID-19 vaccines are also highly encouraged to read this guide and complete the training to strengthen their competency in using these vaccines.

COVID-19 vaccine ordering and distribution

COVID-19 2023-2024 vaccine should be ordered through your routine vaccine ordering process. Providers enrolled in MnVFC or UUAV will order COVID-19 2023-2024 vaccine in MIIC.

COVID-19 vaccine products and recommendations

Several COVID-19 vaccines are currently available. Having multiple products makes COVID-19 vaccine more accessible, but it also increases the risk of medication errors and can lead to vaccine waste. Sites are encouraged to only store and administer one COVID-19 mRNA vaccine product. Double check the product specific EUA provider fact sheet or package insert for age indication, route, dosage, and storage and handling requirements. The currently FDA-approved or FDA-authorized COVID-19 vaccines are summarized below. None of the current

COVID-19 VACCINE PROVIDER GUIDE

vaccines are live-virus vaccines or contain any preservatives. Any COVID-19 vaccine can be used when indicated. Refer to [FDA: COVID-19 Vaccines \(www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines\)](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines) for links to the package inserts and EUA fact sheets for providers for the currently approved or authorized vaccines.

Pfizer-BioNTech-COVID-19 2023-2024 vaccines

<i>Description</i>	<i>Yellow cap</i>	<i>Blue cap</i>	<i>Gray cap</i>
Age indication	6 months-4 years	5-11 years	12 years and older
Dose and route	0.3 mL (3 mcg) IM	0.3 mL (10 mcg) IM	0.3 mL (30 mcg) IM
Amount of diluent* needed per vial	1.1 mL	NO DILUTION	NO DILUTION
Doses per vial	3-dose multi-dose vial	single dose vial	single dose vial

Pfizer-BioNTech-COVID-19 2023-2024 vaccines storage conditions

<i>Storage Conditions</i>	<i>Yellow cap</i>	<i>Blue cap</i>	<i>Gray cap</i>
ULT Freezer (-90°C to -60°C/-130°F to -76°F)	Until the expiration date	Until the expiration date	Until the expiration date
Freezer (-25°C to -15°C/-13°F to 5°F)	DO NOT STORE	DO NOT STORE	DO NOT STORE
Refrigerator (2°C to 8°C/35°F to 46°F)	10 weeks or until expiration date	10 weeks or until expiration date	10 weeks or until expiration date
Room Temperature (8°C to 25°C/46°F to 77°F)	12 hours (including thaw time)	12 hours (including thaw time)	12 hours (including thaw time)
After First Puncture (2°C to 25°C/36°F to 77°F)	Discard after 12 hours	Discard after 12 hours	Discard after 12 hours

Moderna COVID-19 2023-2024 vaccines

<i>Description</i>	<i>Blue cap/green label</i>	<i>Blue cap/blue label</i>
Age indication	6 months through 11 years	12 years and older
Dose and route	0.25mL (25mcg)	0.5ml (50mcg)
Amount of diluent* needed per vial	NO DILUTION	NO DILUTION
Doses per vial	Single dose vial	Single dose vial

*Diluent sterile 0.9% Sodium Chloride Injection USP. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.

Moderna COVID-19 2023-2024 vaccines storage conditions

<i>Storage Conditions</i>	<i>Blue cap/green label</i>	<i>Blue cap/blue label</i>
Freezer (-25°C to -15°C/-13°F to 5°F)	Until expiration date	Until expiration date
Refrigerator (2°C to 8°C/35°F to 46°F)	30 days or until expiration date	30 days or until expiration date
Room Temperature (8°C to 25°C/46°F to 77°F)	Up to 24 hours (unpunctured vials)	Up to 24 hours (unpunctured vials)
After First Puncture (2°C to 25°C/36°F to 77°F)	Discard after 8 hours	Discard after 12 hours
Comments	Do not refreeze	Do not refreeze

Novavax COVID-19 2023-2024 vaccines

<i>Description</i>	<i>Blue cap/blue label</i>
Age indication	12 years and older
Dose and route	0.5ml (50mcg)
Amount of diluent* needed per vial	NO DILUTION
Doses per vial	5-dose multi-dose vial

Novavax COVID-19 2023-2024 vaccine storage conditions

<i>Storage Conditions</i>	<i>Blue cap/blue label</i>
Freezer (-25°C to -15°C/-13°F to 5°F)	Do not store
Refrigerator (2°C to 8°C/35°F to 46°F)	Until expiration date
Room Temperature (8°C to 25°C/46°F to 77°F)	12 hours
After First Puncture (2°C to 25°C/36°F to 77°F)	Discard after 12 hours
Comments	Do not refreeze

COVID-19 vaccination guidance for people NOT moderately or severely immunocompromised

CDC recommends that people ages 6 months and older receive at least one 2023-2024 COVID-19 vaccine. The number of doses varies by age, vaccine, previous COVID-19 vaccines received, and the presence of moderate or severe immune compromise. Refer to [CDC Interim Clinical Considerations for Use of COVID-19 Vaccines: Guidance for people who are not moderately or severely immunocompromised \(www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html\)](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html) for detailed schedules.

People who are unvaccinated and get Novavax 2023-2024 vaccine need 2 doses given 3-8 weeks apart.

Children 6 months through 4 years should get the same brand of vaccine for their primary series when possible. But if that vaccine is unavailable or it is unknown what previous doses were given, it is acceptable to use the brand you have. Don't miss opportunities to vaccinate kids.

COVID-19 vaccination guidance for people moderately or severely immunocompromised

People who are immunocompromised should have three doses with at least one of the doses being the new 2023-2024 COVID-19 vaccine. They may also receive additional 2023-2024 COVID-19 vaccine doses based on their clinical situation at least two months following the last 2023-2024 COVID-19 vaccine dose. Refer to: [CDC: Interim Clinical Considerations for Use of COVID-19 Vaccines: Guidance for people who are moderately or severely immunocompromised \(www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised\)](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised) for more specific information on this population.

COVID-19 vaccination guidance for people 65 years and older NOT moderately or severely immunocompromised

All people ages 65 years and older should receive 1 additional dose of any 2023–2024 COVID-19 vaccine at least 4 months following the previous dose of 2023–2024 COVID-19 vaccine. For initial vaccination with Novavax COVID-19 Vaccine, the 2-dose series should be completed before administration of the additional dose. Refer to [CDC Interim Clinical Considerations for Use of COVID-19 Vaccines: Guidance for people who are not moderately or severely immunocompromised \(www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html\)](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html) for more specific information.

COVID-19 vaccination guidance for people 65 years and older that are moderately or severely immunocompromised

All people ages 65 years and older who are moderately or severely immunocompromised should receive 1 additional dose of any 2023–2024 COVID-19 vaccine at least 2 months after the last dose of 2023–2024 COVID vaccine indicated. Further additional doses may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last 2023–2024 COVID-19 vaccine dose. [CDC: Interim Clinical Considerations for Use of COVID-19 Vaccines: Guidance for people who are moderately or severely immunocompromised \(www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised\)](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised) for more specific information on this population.

COVID-19 vaccine storage and handling

COVID-19 vaccine products are temperature-sensitive, must be stored, and handled correctly to ensure efficacy and maximize shelf life. Proper storage and handling practices are critical to minimize vaccine loss and limit risk of administering COVID-19 vaccine with reduced effectiveness.

Storage and handling requirements for COVID-19 vaccine products vary. Follow specific shipping, storage, and handling requirements for each vaccine product in their respective package insert or EUA fact sheet for health care providers at [FDA: COVID-19 Vaccines \(www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines\)](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines).

Vaccine must be stored in dedicated refrigeration/freezer units. Find more information on CDC's storage and handling recommendations at [Vaccine Storage and Handling Toolkit \(www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html\)](https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html). Storing vaccine in the freezer of a combination household unit is not recommended. If your facility provides frozen vaccine, you must have a separate freezer.

Providers new to vaccine storage and handling, should view CDC's, You Call the Shots module. Learn more at [CDC: CE Instructions for WB4417: Immunization: You Call the Shots-Module Ten-Storage and Handling—2021 \(www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp\)](https://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp).

Expiration date and beyond-use date (BUD)

In certain conditions vaccines must be used before the actual expiration date. This is referred to as the beyond-use date (BUD). The BUD is determined based on the storage conditions and the time a vial is first punctured for COVID-19 vaccines. The person that performs the step in the administration process that changes the BUD (e.g., punctures the vial, reconstitutes it, moves it from the freezer to refrigerator, etc.) must document the new BUD on a label. BUD tracker labels are available on CDC's website.

Check expiration dates and beyond-use dates closely. **Discard the vaccine based on the earliest date, whether that is the manufacturer's labeled expiration date or the BUD.**

Example: Pfizer vaccine can be stored for 10 weeks in the refrigerator. If it was placed in the refrigerator on December 20, its BUD is February 28. However, if the vaccine vial's expiration date is February 8, then it needs to be discarded at the end of the day on February 8.

Keep in mind that COVID-19 vaccine products do not contain any preservative and therefore can't be used after a certain number of hours after the vial is first punctured. **Carefully read and follow the EUA fact sheet for health care providers and/or manufacturers' package inserts or websites for each vaccine product regarding expiration and beyond-use dates.**

Managing out-of-range temperatures (excursions)

As with all vaccines, if COVID-19 vaccines are exposed to out-of-range temperatures, take immediate action. **Mark the vaccine "do not use" until its usability is determined. If vaccine thaws, do not re-freeze.**

Contact MDH's Immunization Program Monday through Friday between 8:00 a.m. and 4:30 p.m. at 651-201-5414 to determine your next steps. Make sure to have specific information about temperatures, duration of excursion, etc. available. Refer to [Storage and Handling Mishap Checklist \(www.health.state.mn.us/people/immunize/hcp/mnvfc/vaxchklist.pdf\)](https://www.health.state.mn.us/people/immunize/hcp/mnvfc/vaxchklist.pdf) for steps to take and a form to document actions taken.

Contact information for vaccine manufacturers:

- **Moderna:**
Phone: 1-866-MOD-ERNA or 1-866-663-3762
Email: excursions@modernatx.com
- **Pfizer:**
Pfizer U.S. Medical Information
Phone: 1-800-438-1985
- **Novavax:**
Phone: 1-844-668-2829
Email: Fill out our contact form (www.novavax.com/contact-us/email-us)

Some vaccine manufacturers have online temperature excursion tools you may use:

- [Moderna: Storage & temperature excursion for Moderna COVID-19 vaccine \(https://tools.modernamedinfo.com/en-US/excursion/introduction-landing-page\)](https://tools.modernamedinfo.com/en-US/excursion/introduction-landing-page).

Contact MDH even if you have contacted the vaccine manufacturer or used their online temperature excursion tool and the issue was resolved.

Clinical considerations for authorized vaccines

ACIP has issued interim recommendations for the use of COVID-19 vaccines for the prevention of COVID-19. These recommendations are published in [CDC: Use of COVID-19 Vaccines in the United States \(www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html\)](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html). A summary of recent changes and the date they were last updated is at the top of the webpage.

Resources for screening patients before COVID-19 vaccination

- [Template: COVID-19 Vaccine Screening and Agreement on COVID-19 Vaccine Providers \(www.health.state.mn.us/diseases/coronavirus/vaccine/provider.html\)](http://www.health.state.mn.us/diseases/coronavirus/vaccine/provider.html).
- [CDC: Prevaccination Checklist for COVID-19 Vaccines \(www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf\)](https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf).

Verify patient COVID-19 immunization data

Prior to administering a dose of COVID-19 vaccine, please review the patient’s immunization history. The primary source of COVID-19 vaccine administration data should be the Minnesota Immunization Information Connection (MIIC). If the data for a patient is not in MIIC, other acceptable sources include:

1. Their CDC vaccination card.
2. An official document from a health care provider or another state’s Immunization Information System (IIS) with day, month, year, and product administered as well as the patient’s name and date of birth.
3. Electronic documentation from a health care provider or another state’s Immunization Information System (IIS) such as the MyChart app or another consumer access application (app) that includes day, month, year, and product administered as well as the patient’s name and date of birth.
4. A patient’s U.S. Department of State’s Vaccination Documentation form DS-3025 that includes a patient’s verified past immunizations.

Verbal presentations of data are not acceptable. Please enter immunization data from these acceptable sources here

For more information, review MIIC user guidance for looking up a client at [Client Search and Printing Immunization Records \(www.health.state.mn.us/people/immunize/miic/train/clientsearch.html\)](http://www.health.state.mn.us/people/immunize/miic/train/clientsearch.html) and entering immunization data at [Adding Immunizations Not Using Inventory \(www.health.state.mn.us/people/immunize/miic/train/addnoinv.html\)](http://www.health.state.mn.us/people/immunize/miic/train/addnoinv.html).

COVID-19 vaccine administration

Based on their scope of practice, all people who administer vaccines should receive comprehensive, competency-based staff training and education, including the “rights of vaccine administration,” patient care before, during, and after vaccine administration, vaccine preparation, and skill validation.

Vaccine administration resources for all people who vaccinate, including staff who are new to vaccination and staff who need a refresher:

- [CDC: Immunization Education and Training \(www.cdc.gov/vaccines/ed/index.html\)](http://www.cdc.gov/vaccines/ed/index.html)
- [CDC: COVID-19 Vaccination Training Programs and Reference Materials \(www.cdc.gov/vaccines/covid-19/downloads/COVID-19-Clinical-Training-and-Resources-for-HCPs.pdf\)](http://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-Clinical-Training-and-Resources-for-HCPs.pdf)
- [CDC: You Call the Shots \(www.cdc.gov/vaccines/ed/youcalltheshots.html\)](http://www.cdc.gov/vaccines/ed/youcalltheshots.html)
Watch the “Vaccine Administration” e-Learn.
- [CDC: Epidemiology and Prevention of Vaccine-Preventable Diseases \(www.cdc.gov/vaccines/pubs/pinkbook/index.html\)](http://www.cdc.gov/vaccines/pubs/pinkbook/index.html)
Known as the “Pink Book”.
- [How to Administer IM \(Intramuscular\) Injections \(www.health.state.mn.us/people/immunize/hcp/admim.pdf\)](http://www.health.state.mn.us/people/immunize/hcp/admim.pdf)
- [Intramuscular \(IM\) Injection: Sites \(https://youtu.be/PqSuCPnPeYE\)](https://youtu.be/PqSuCPnPeYE)
- [Preparing COVID-19 Vaccines for Administration \(www.health.state.mn.us/diseases/coronavirus/vaccine/adminprep.pdf\)](http://www.health.state.mn.us/diseases/coronavirus/vaccine/adminprep.pdf)
- [Preparing to Vaccinate Young Children: COVID-19 \(www.health.state.mn.us/diseases/coronavirus/vaccine/pedstips.html\)](http://www.health.state.mn.us/diseases/coronavirus/vaccine/pedstips.html)
- [COVID-19 Vaccine Trainings for Health Professionals \(www.health.state.mn.us/diseases/coronavirus/vaccine/training.html#supp\)](http://www.health.state.mn.us/diseases/coronavirus/vaccine/training.html#supp)
Immunization Basic Principles supplemental on-demand training for vaccine providers.
- [COVID-19 PPE and Source Control Grids \(www.health.state.mn.us/diseases/coronavirus/hcp/ppegrid.pdf\)](http://www.health.state.mn.us/diseases/coronavirus/hcp/ppegrid.pdf)
- [One & Only Campaign \(www.cdc.gov/injectionsafety/one-and-only.html\)](http://www.cdc.gov/injectionsafety/one-and-only.html)

Vaccine information sheets (VISs) and emergency use authorization (EUA) fact sheets

Vaccine information sheets (VIS)

Vaccines licensed through the FDA and added to the vaccine injury table are required to have a vaccine information sheet (VIS). Federal law requires that patients receive a VIS prior to administration of a licensed vaccine. For recipients who are 12 or older receiving Pfizer or Moderna vaccine, a provider may use the COVID-19

VIS found at [CDC: Vaccine Information Statement \(www.cdc.gov/vaccines/hcp/vis/current-vis.html\)](https://www.cdc.gov/vaccines/hcp/vis/current-vis.html). As more COVID-19 vaccines are licensed new VIS will be developed.

EUA fact sheets

EUA fact sheets for vaccination providers are product-specific information sheets that replace the usual package insert. The fact sheet for vaccine recipients is similar to a licensed product's VIS.

The EUA fact sheet for vaccine recipients explains the vaccine risks and benefits, specific vaccine product information and its use, and information from clinical trials that support the FDA's emergency use authorization.

- You are legally required to give an EUA fact sheet to each recipient/parent/legal representative prior to vaccination. Be prepared to answer questions about the vaccine.

EUA fact sheets for providers and recipients are available on FDA, CDC, MDH, and vaccine manufacturer websites. Translated fact sheets in multiple languages are on the FDA website.

- [FDA: Fact Sheet for Recipients and Caregivers about Pfizer COVID-19 Vaccine \(2023-2024\) in Individuals 6 months Through 11 Years of Age \(www.fda.gov/media/167209/download?attachment\)](https://www.fda.gov/media/167209/download?attachment).
- [FDA: Fact Sheet for Recipients and Caregivers About Moderna COVID-19 Vaccine \(2023-2024\) in Individuals 6 Months Through 11 Years of Age \(www.fda.gov/media/167209/download?attachment\)](https://www.fda.gov/media/167209/download?attachment).
- [FDA: Novavax COVID-19 Vaccine, Adjuvanted \(2023-2024 Formula\) Fact Sheet for Recipients and Caregivers \(www.fda.gov/media/159898/download?attachment\)](https://www.fda.gov/media/159898/download?attachment).

COVID-19 vaccine reminders

Most people aged 5 years and older now only need one dose of the 2023-2024 COVID-19 vaccine. For those under 5 years old or who are immunocompromised and need more than one dose for a primary series, it is important that people receive all doses, and that doses are the same vaccine product. Try to keep doses within the recommended interval. If the interval is missed, the dose should be given as soon as possible, and the series does not need to be restarted. Providers should refer to: [CDC Interim Clinical Considerations for Use of COVID-19 Vaccines: Overview of COVID-19 vaccination \(www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html# covid-vaccines\)](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html# covid-vaccines) to understand the schedule for situations that require more than one dose.

Vaccination reminders are critical to ensure compliance with vaccine dosing intervals and to achieve optimal vaccine effectiveness. Use these tips for COVID-19 vaccine reminders:

- Make sure each person getting vaccinated knows if they need additional doses and schedule an appointment for the next dose.
- If the patient has a smartphone, ask them to enter the date when the next vaccine is due into their electronic calendar.

Using Minnesota Immunization Information Connection (MIIC) for vaccine reminders:

- Record all vaccinations in MIIC within 7 days after vaccine administration.
- Pull lists of people overdue/recommended for COVID-19 vaccine using the MIIC client follow-up functionality in MIIC. Information on client follow-up is available at [Client Follow-Up \(www.health.state.mn.us/people/immunize/miic/train/followup.html\)](https://www.health.state.mn.us/people/immunize/miic/train/followup.html).
- Partner with MDH to text your clients who are overdue or recommended for vaccines, including COVID routine doses, Zoster, or routine child/adolescent immunizations. This program is free to the participating

provider and is easy to set up. For more information, email the MIIC Texting Program at health.miiicexting@state.mn.us. For more information on this project visit [Reminder/Recall Using Text Messages \(www.health.state.mn.us/diseases/coronavirus/vaccine/remindrecall.pdf\)](http://www.health.state.mn.us/diseases/coronavirus/vaccine/remindrecall.pdf).

- Look at your electronic health record or vaccine management tool to identify if there is a next dose reminder function already built in (e.g., patient portal).
- Use other methods, such as text messaging, phone calls, email, and mail.

Post-vaccination care

Vaccine efficacy

All COVID-19 vaccines currently approved or authorized in the United States (Pfizer-BioNTech, Moderna and Novavax) are effective at preventing severe disease, hospitalizations, and death from COVID-19.

Post-vaccination instructions

Preparing people for what to expect after vaccination and when to follow up with a health care provider is a best practice and expectation. Patient instructions should include information specific to the product they are receiving. This information should include:

- Common side effects (listed in the VIS and EUA fact sheet).
- When to contact their health care provider (such as signs of an allergic reaction or medical concerns that may or may not be related to vaccination).
- For vaccine(s) requiring more than one dose, the importance of receiving all recommended dose(s) of vaccine to build an adequate immune response.
- What it means to be up to date with your COVID-19 Vaccines refer to: [CDC: Stay Up to Date with Your COVID-19 Vaccines \(www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html\)](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html).

Treatment of post-vaccination symptoms

After receiving a COVID-19 vaccine dose, over the counter fever, or pain medication (e.g., acetaminophen, non-steroidal anti-inflammatory drugs) may be used for local or systemic symptoms, if medically appropriate. Refer to the applicable EUA fact sheet for recipients to view side effects listed for each vaccine product.

It is not recommended to routinely take over-the-counter fever or pain medication prior to vaccination to prevent symptoms following vaccination.

Allergic reaction (anaphylaxis)

Anaphylactic reactions in people receiving the COVID-19 vaccine outside of clinical trials have been reported. While rare, these events highlight the importance of a quick and competent response. Antihistamines should not be taken before vaccination to prevent allergic reactions, as they do not prevent anaphylaxis and might mask cutaneous (skin) symptoms. Refer to [CDC Interim Clinical Considerations for Use of COVID-19 Vaccines: Contraindications and precautions \(www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html\)](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html) for more information regarding adverse reactions.

Appropriate medical treatment used to manage immediate allergic reactions (e.g., epinephrine) must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine.

An allergic reaction to a vaccine can be a life-threatening event. Know the early signs of anaphylaxis: throat closing sensation, swelling of throat, face or lips, hives or itching, stridor (high-pitched whistling sound), wheezing, coughing, dizziness, fainting, fast heart rate, low blood pressure, nausea, vomiting, diarrhea, and/or abdominal pain. CDC has a helpful poster on [Recognizing and Responding to Anaphylaxis \(www.cdc.gov/vaccines/covid-19/downloads/recognizing-responding-to-anaphylaxis-508.pdf\)](https://www.cdc.gov/vaccines/covid-19/downloads/recognizing-responding-to-anaphylaxis-508.pdf).

Observation periods following vaccination

Syncope (fainting) might occur in association with any injectable vaccine, especially in adolescents. In accordance with [CDC: General Best Practice Guidelines for Immunization \(GBPG\) \(www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html\)](https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html), vaccination providers, particularly when vaccinating adolescents, should consider observing vaccine recipients for 15 minutes after vaccination.

Additionally, providers should consider observing people with the following medical histories for 30 minutes after COVID-19 vaccination to monitor for allergic reactions:

- Allergy-related contraindication to a different type of COVID-19 vaccine.
- Non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine.
- Anaphylaxis after non-COVID-19 vaccines or injectable therapies.

Refer to [CDC Interim Clinical Considerations for Use of COVID-19 Vaccines: Contraindications and precautions \(www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html\)](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html)

Emergency preparation

Administer vaccines in settings where staff are trained to recognize and respond to reactions. Immediate systemic reactions can include fainting (syncope) and severe allergic reaction (anaphylaxis). Learn more about how to prepare for anaphylactic reactions at [CDC: Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination \(www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html\)](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

Report vaccine adverse events and administration errors

As with licensed vaccines, vaccines under an Emergency Use Authorization have the same requirements to report to the Vaccine Adverse Event Report System (VAERS) any situations, including serious adverse events, that occurred after vaccination. This is regardless of determination of cause. As part of the CDC COVID-19 Vaccination Program Provider Agreement, vaccination providers are required to report the following to VAERS:

- Vaccine administration errors, even if they did not involve an adverse effect.
- Serious adverse events:
 - Death.
 - A life-threatening adverse event.
 - An event requiring hospitalization or prolonged hospitalization.
 - Prolonged impact on a person's ability to perform daily activities.
 - A congenital anomaly/birth defect.

- A significant medical event that may cause harm to a person and may require medical or surgical intervention to prevent one of the outcomes listed above.
- Cases of Multisystem Inflammatory Syndrome (MIS) in children and adults.
- Cases of myocarditis or pericarditis.
- Cases of COVID-19 (including vaccine breakthrough cases) that result in hospitalization or death.

Learn more about VAERS at [CDC: Vaccine Adverse Event Reporting System \(VAERS\): How VAERS works \(www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html\)](https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html). To submit an event, go to [VAERS: Report an Adverse Event \(vaers.hhs.gov/reportevent.html\)](https://vaers.hhs.gov/reportevent.html). There is a checklist on this page to help gather information needed when submitting a report ([VAERS 2.0 Checklist \[vaers.hhs.gov/docs/VAERS_2.0_Checklist.pdf\]](https://vaers.hhs.gov/docs/VAERS_2.0_Checklist.pdf)).

HIPAA permits reporting of vaccine adverse events and medical documentation to VAERS for public health purposes under 45 CFR, section 164.512(b), as authorized by 42 USC 300aa-25.

Resources to assist clinicians in possible COVID-19 vaccine-related adverse events

Urgent consults: Health care providers can contact the CDC Emergency Operations Center at 770-488-7100 if they need an urgent COVID-19 vaccine safety consultation. In case of a health emergency, providers should call 911.

Complex health situations following COVID-19 vaccination: For complex vaccine safety questions, health care providers or health departments in the United States can request a consultation from the [CDC: Clinical Immunization Safety Assessment \(CISA\) Project \(www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html\)](https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html) COVIDvax clinicians. For non-urgent concerns, providers may [Contact CDC-INFO \(www.cdc.gov/DCS/ContactUs/Form\)](https://www.cdc.gov/DCS/ContactUs/Form).

COVID-19 vaccine reporting requirements

The [Minnesota Immunization Information Connection \(MIIC\) \(www.health.state.mn.us/miic\)](https://www.health.state.mn.us/miic) is a statewide immunization information system that stores electronic immunization records for Minnesota health service providers and for the public. MIIC combines immunizations a person has received into a single record, even if the shots were given by different health care providers in the state.

Become familiar with MIIC. If your organization already submits data to MIIC via one of the following ways, please implement these steps.

- **Electronic data exchange:** Review your messages to ensure you are sending timely messages and that those messages contain a CVX/CPT code pair or an NDC code, as well as an MVX code. Verify that your organization has a process to routinely review rejection (ACK) messages. Confirm your organization has a process for adding new vaccines in a timely manner to accommodate any new COVID-19 vaccine products that may be approved or recommended in the future.
- **Uploaded file via the user interface:** Ensure you are submitting a CVX/CPT code pair, as well as the manufacturer (MVX) code. The current spreadsheet template is available in MIIC, and the latest user guide can be found at [General Immunization Upload Using the Spreadsheet Template \(www.health.state.mn.us/people/immunize/miic/data/spreadsheet.pdf\)](https://www.health.state.mn.us/people/immunize/miic/data/spreadsheet.pdf). Please download the template from MIIC each time you use it. Consider creating an electronic interface with MIIC to reduce staff burden and help ensure timely data reporting.
- **Direct data entry in the user interface:** Ensure staff are selecting the correct vaccine group and then the correct option from the “Trade Name” drop-down menu. The COVID Pandemic vaccine group includes the original formulation(s) through the bivalent booster vaccines. The COVID Routine vaccine group includes

COVID vaccines starting with the monovalent formulation approved in Fall 2023. Strongly consider using one of the above reporting methods. Connecting to MIIC for electronic data exchange can reduce staff burden, especially during high-volume times.

Minnesota Statutes, chapter 144.3351 allows vaccine providers to share immunization data, which is defined in the statute, with MDH without patient consent. This data includes race and ethnicity. MIIC is a tool that providers can use to share this information. Find Vaccine Administration Codes from CDC at [Data Code Sets \(www.cdc.gov/vaccines/programs/iis/code-sets.html\)](https://www.cdc.gov/vaccines/programs/iis/code-sets.html). For more information on entering correct COVID-19 product information into MIIC, please review this resource: [Entering COVID-19 Product Information in MIIC \(www.health.state.mn.us/people/immunize/miic/train/entercovidproduct.pdf\)](https://www.health.state.mn.us/people/immunize/miic/train/entercovidproduct.pdf).

If you have any questions, please contact the MIIC Help Desk at health.miichelp@state.mn.us.

Billing and reimbursement

COVID-19 vaccine is no longer supplied by the pandemic federal government response.

- Insurance plans should reimburse providers for the cost of the vaccine and the administration fee. Vaccine providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine for the vaccine recipient.
- For patients who have a Minnesota Health Care Plan (MHCP), providers will be reimbursed for the administration fee. Children with a MHCP should get MnVFC vaccine and not billed for the cost of the vaccine. Adults with a MHCP should get privately purchased vaccine and bill the MHCP for the cost of the vaccine. As a reminder, COVID-19 vaccines are exempt from cost-sharing. MHCP also covers vaccine counseling that occurs during visits and for those COVID-19 vaccines they can administer. For details, refer to the [MHCP Provider Manual: Immunizations and Vaccinations \(www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=dhs16_136660\)](https://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=dhs16_136660). Contact the MHCP Provider Call Center at 651-431-2700 with any related questions.
- Adults 18 years and older without health insurance and adults whose health insurance does not cover all COVID-19 vaccine costs at an in-network provider can get free updated COVID-19 vaccines through the Bridge Access Program. This program will end by December 31, 2024. For more details, refer to [CDC: Bridge Access Program \(www.cdc.gov/vaccines/programs/bridge/index.html\)](https://www.cdc.gov/vaccines/programs/bridge/index.html).

Additional resources:

- For more information regarding COVID-19 billing, refer to the [Centers for Medicare & Medicaid Services: COVID-19 \(www.cms.gov/covidvax-provider\)](https://www.cms.gov/covidvax-provider).
- Find vaccine administration codes from CDC at [Data Code Sets \(www.cdc.gov/vaccines/programs/iis/code-sets.html\)](https://www.cdc.gov/vaccines/programs/iis/code-sets.html).

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To obtain this information in a different format contact health.communications@state.mn.us.