# 2025-26 COVID-19 Vaccine Administration Protocol/Standing Order for Pharmacists

### VACCINE PROTOCOL FOR PERSONS 12 THROUGH 64 YEARS OF AGE

This protocol/standing order is effective September 22, and shall remain in effect until September 21, 2026, or when rescinded by the Minnesota Department of Health's (MDH) State Epidemiologist and Medical Director or her designee, whichever occurs first. MDH retains the right to modify, rescind, or supplement this protocol/standing order as needed.

## Condition for protocol/standing order

To reduce incidence of morbidity and mortality of COVID-19 disease, this protocol/standing order offers a mechanism to facilitate accessibility of COVID-19 vaccines by authorizing qualified health care professionals, as defined below, to administer 2025-26 COVID-19 vaccines to eligible individuals who meet the criteria established below by MDH.

This protocol/standing order is intended to supplement the authority that currently exists under Minnesota state and federal law for qualified health professionals to administer COVID-19 vaccines.

## Authority

This non-patient specific protocol/standing order is issued by the MDH's State Epidemiologist and Medical Director in her official capacity and authorizes qualified health professionals, practicing in the State of Minnesota and in accordance with their respective scopes of practice, to assess eligibility and administer the most updated versions of the FDA-approved 2025-26 COVID-19 vaccine appropriate for age and health status as described below.

As defined in this protocol/standing order, qualified health care professionals are pharmacists who hold an active Minnesota license and are legally permitted to administer immunizations. Pharmacists may delegate the administration of vaccines to qualified pharmacy personnel (including nurses supporting pharmacists in administration of vaccines in pharmacy settings) in accordance with the laws and rules governing their scope of practice.

## Policy

Participating pharmacists will implement this protocol/standing order for COVID-19 vaccination using the 2025-26 COVID-19 vaccine products for people 12 through 64 years of age consistent with the criteria and eligibility described below.

The indications in this protocol/standing order are based on recommendations from the American Academy of Pediatrics (AAP), the American College of Obstetricians and Gynecologists (ACOG), and the American Academy of Family Physicians (AAFP).

## Condition-specific criteria and prescribed actions

## Indications

| Criteria | Prescribed action |
|---|---|
| Person is currently healthy and aged 12 through 64 years, and is one or more of the following:<br>▪ At high risk for severe COVID-19 due to an underlying medical condition*.<br>  ▪ Includes moderate to severe immune compromise (see below).<br>▪ A resident of long-term care facility or congregate setting.<br>▪ Has never been vaccinated for COVID-19.<br>▪ A person whose household contacts are at high risk for severe COVID-19.<br>▪ Pregnant (any trimester) or lactating.<br>▪ A person who desires (or whose parent or guardian desires) protection from COVID-19. | Proceed to vaccinate. |
| Person with moderate to severe immunocompromise**. | Proceed to vaccinate using schedule for people with immunocompromising conditions. Counsel the individual and/or parent/guardian about:<br>1) The potential for reduced immune responses.<br>2) The need to continue to follow current guidance for COVID-19 prevention (visit COVID-19: Protect Yourself and Others (www.health.state.mn.us/diseases/coronavirus/prevention.html) for prevention strategies).<br>Refer to primary care provider and/or specialist if additional doses may be indicated. |
| Person is aged between 3 and 12 years. | Do not vaccinate under this protocol. Refer to the *2025-26 COVID-19 Vaccine Administration Protocol/Standing Order for Pharmacists* for persons 3-11 years of age. |
| Person is under 3 years of age. | Do not vaccinate. Refer to primary care provider for vaccination. |

*Visit AAP: 2025-2026 COVID-19 Vaccine Recommendations: FAQ (www.aap.org/en/patient-care/covid-19/covid-19-vaccine-frequently-asked-questions/) and CDC: Underlying Conditions and the Higher Risk for Severe COVID-19 (www.cdc.gov/covid/hcp/clinical-care/underlying-conditions.html) for lists of high-risk underlying conditions or treatments. **Note these lists are not exhaustive**. Patients (or their parents or guardians) may self-attest to their underlying condition.

**Visit CDC: COVID-19 Vaccination Guidance for People Who Are Immunocompromised (www.cdc.gov/covid/hcp/vaccine-considerations/immunocompromised.html) for a description of moderate and severe immunocompromising conditions and treatments. **Note this list is not exhaustive**. Additional guidance for immunocompromised patients is expected from the Infectious Diseases Society of America (IDSA) and the American College of Physicians (ACP). Patients (or their parents or guardians) may self-attest to their underlying immunocompromising condition or treatment.

## Contraindications

| Criteria: Allergies | Prescribed action |
|---|---|
| Person had a severe allergic reaction (e.g., anaphylaxis) to a previous dose of the same COVID-19 vaccine type or any of its components. | Do not vaccinate with the same COVID-19 vaccine type. May administer the alternate COVID-19 vaccine type. The mRNA COVID-19 vaccines (Moderna and Pfizer-BioNTech) are one |

| Criteria: Allergies | Prescribed action |
|---|---|
| | type of COVID-19 vaccine, and the protein subunit vaccine (Novavax) is another type of COVID-19 vaccine. |

## Precautions

| Criteria | Prescribed action |
|---|---|
| Person has a moderate to severe acute illness with or without fever (defined as temperature 100.4°F/38°C or higher). | Defer vaccination and refer to their primary care provider for assessment. |
| Person was diagnosed with non-severe allergy (e.g., urticaria beyond the injection site) to a component of a COVID-19 vaccine; or non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of a COVID-19 vaccine. | Defer vaccination and refer to their primary care provider to receive an assessment of their current health condition and assessment of individual benefits and risks. |
| History of severe allergic reaction (e.g., anaphylaxis) to any other vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous).<br>*This precaution includes allergies related to vaccines or injectable therapies. It does not include other kinds of allergies, e.g., food, pets, environmental allergies, latex allergies, or oral medications (including the oral equivalents of injectable medications).* | Defer vaccination and refer to their primary care provider to receive an assessment of their current health condition and assessment of individual benefits and risks. |
| Person has a history of Multisystem Inflammatory Syndrome in Children (MIS-C) or Adults (MIS-A). | Defer vaccination and refer to their primary care provider to receive an assessment of their current health condition and assessment of individual benefits and risks. |
| Person has a history of myocarditis or pericarditis within three weeks after a previous dose of any COVID-19 vaccine. | Defer vaccination and refer to their primary care provider to receive an assessment of their current health condition and assessment of individual benefits and risks. |
| Person had a delayed allergic reaction at the injection site (e.g., erythema, induration, pruritis at the injection site). | Proceed to vaccinate. Give vaccine in the opposite arm from where the previous dose was given if known. |

# Prescription

## Give any of the following products using the same vaccine product to complete the initial series and according to the schedule below:

- 2025-26 Pfizer-BioNTech Comirnaty COVID-19 vaccine, gray label; 30 mcg, **0.3 mL**, intramuscular (IM)
- 2025-26 Moderna Spikevax COVID-19 vaccine, blue label; 50 mcg, **0.5 mL**, intramuscular (IM)
- 2025-26 Moderna mNEXSPIKE COVID-19 vaccine, teal label; 10 mcg, **0.2 mL**; intramuscular (IM)
- 2025-26 Novavax Nuvaxovid COVID-19 vaccine, dark cyan label; 5 mcg, **0.5 mL**, intramuscular (IM)

## Age 12-64 years

- **Unvaccinated**
  - 12-18 years:
    - One dose of Moderna Spikevax, Pfizer-BioNTech Comirnaty, or Novavax Nuvaxovid regardless of previous vaccination status at least 8 weeks after the most recent dose.
    - One dose of Moderna mNEXSPIKE regardless of previous vaccination status at least 12 weeks after the last dose was received.
  - 19-64 years:

    - One dose 2025–26 Moderna or Pfizer-BioNTech.
    - Two doses 2025–26 Novavax at 0, 3–8 weeks.
- **If previously vaccinated before 2025-26 vaccine**
    - 12-18 years:
        - One dose of Moderna Spikevax, Pfizer-BioNTech Comirnaty, or Novavax Nuvaxovid regardless of previous vaccination status at least 8 weeks after the most recent dose.
        - One dose of Moderna mNEXSPIKE regardless of previous vaccination status at least 12 weeks after the last dose was received.
    - 19-64 years:
        - One or more doses Moderna or Pfizer-BioNTech:
            - Give one dose 2025-26 Moderna or Novavax or Pfizer vaccine at least 2 months following any previous COVID-19 vaccine dose.
        - One dose Novavax:
            - Give one dose 2025-26 Novavax 3-8 weeks after most recent dose. If more than 8 weeks after most recent dose, administer one dose 2025-26 Moderna, Novavax or Pfizer-BioNTech.
        - Two or more doses Novavax:
            - Give one dose 2025-26 Moderna or Novavax or Pfizer-BioNTech at least 8 weeks after the most recent dose.
        - One or more doses Janssen:
            - Give one dose 2025-26 Moderna or Novavax or Pfizer-BioNTech.

# For persons with immunocompromising conditions 12 through 64 years of age

## Unvaccinated*

- Give four doses (three-dose initial series Moderna at 0, 4 weeks, and at least 4 weeks after dose two, followed by one dose Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]).**

OR

- Give four doses (three-dose initial series Pfizer-BioNTech at 0, 3 weeks, and at least 4 weeks after dose two, followed by one dose Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]).**

OR

- Give three doses (two-dose initial series Novavax at 0, 3 weeks, followed by one dose Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]).**

## Incomplete initial vaccination series

**Previous vaccination with Moderna**

- One dose Moderna: Give two doses Moderna at least 4 weeks apart (administer dose one Moderna 4 weeks after most recent dose), followed by one dose Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months).**
- Two doses Moderna: Give one dose Moderna at least 4 weeks after most recent dose, followed by one dose Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months).**

**Previous vaccination with Pfizer-BioNTech**

- One dose Pfizer-BioNTech: Give two doses Pfizer-BioNTech at least 4 weeks apart (administer dose one Pfizer-BioNTech 3 weeks after most recent dose), followed by one dose Moderna or Novavax or Pfizer BioNTech 6 months later (minimum interval 2 months).**
- Two doses Pfizer-BioNTech: Give one dose Pfizer-BioNTech at least 4 weeks after most recent dose, followed by one dose Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months).**

**Previous vaccination with Novavax**

- One dose Novavax: Give one dose Novavax at least 3 weeks after most recent dose, followed by one dose Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months).**

### Completed initial three-dose vaccination series

- Three or more doses Moderna or three or more doses Pfizer BioNTech: Give two doses Moderna or Novavax or Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose one at least 8 weeks after the most recent dose.**
- Two or more doses Novavax: Give two doses Moderna or Novavax or Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose one at least 8 weeks after the most recent dose.**

*Use vaccine from the same manufacturer for all doses in the initial vaccination series. Either Moderna product (Spikevax or mNEXSPIKE) can be used unless otherwise specified.

**Additional doses of COVID-19 vaccine for moderately or severely immunocompromised: Based on shared clinical decision making and administered at least 2 months after the most recent dose.

## Medical emergency or anaphylaxis

Vaccinators should be prepared to recognize and manage vaccine reactions and medical emergencies related to the administration of vaccines, including anaphylaxis. Follow your organization's pre-established protocol for anaphylaxis or refer to these suggested resources:

- CDC: Preventing and Managing Adverse Reactions (www.cdc.gov/vaccines/hcp/imz-best-practices/preventing-managing-adverse-reactions.html)
- Immunize.org: Medical Management of Vaccine Reactions in Children and Teens in a Community Setting (www.immunize.org/wp-content/uploads/catg.d/p3082a.pdf)
- Immunize.org: Medical Management of Vaccine Reactions in Adults in a Community Setting (www.immunize.org/wp-content/uploads/catg.d/p3082.pdf)

## Provide Vaccine Information Statements (VIS)

Provide all patients with a copy of the most current federal vaccine information statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language, if one is available.

- CDC: COVID-19 Vaccine VIS (www.cdc.gov/vaccines/hcp/current-vis/covid-19.html)

## Report adverse events to VAERS

Report all adverse events following the administration of COVID-19 vaccine to the federal Vaccine Adverse Event Reporting System (VAERS).

- VAERS: Report an Adverse Event (https://vaers.hhs.gov/reportevent.html)

## Record keeping and documentation

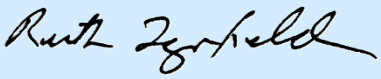
- Qualified health professionals that are using this document must keep a copy of it on site at all locations administering vaccines pursuant to this protocol/standing order.
- Document each patient's vaccine administration information in the Minnesota Immunization Information Connection (MIIC).

## Insurance and billing

This protocol/standing order does not guarantee insurance coverage of the COVID-19 vaccine. overage for the COVID-19 vaccine is dependent upon and may vary based on insurance policies and individual plans.

Name of prescriber: Dr. Ruth Lynfield MD, State Epidemiologist and Medical Director, Minnesota Department of Health

License No.: 40312 NPI No.: 1285960302

Prescriber signature: 

Date: September 22, 2025

## Ingredient list

- 2025-26 Pfizer-BioNTech COVID-19 vaccine for age 12 years and older: Package Insert and Patient Package Insert - COMIRNATY (https://www.fda.gov/media/151707/download?attachment)
- 2025-26 Moderna Spikevax COVID-19 vaccine for age 12 years and older: Package Insert - SPIKEVAX (https://www.fda.gov/media/155675/download?attachment)
- 2025-26 Moderna mNEXSPIKE COVID-19 vaccine for age 12 years and older: Package Insert - MNEXSPIKE (https://www.fda.gov/media/186738/download?attachment)
- 2025-26 Novavax Nuvaxovid COVID-19 vaccine for age 12 years and older: Package Insert and Patient Package Insert - NUVAXOVID (https://www.fda.gov/media/186544/download?attachment)