Immunization Protocol

COVID-19 Vaccine (COMIRNATY®, MNEXSPIKE™, NUVAXOVID®, SPIKEVAX™)	
Last Reviewed	16 September 2025
Last Revised	16 September 2025
This order expires	16 September 2026

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1. What's new

Oregon, Washington, California, and Hawaii recently formed the West Coast Health Alliance (WCHA) to align immunization recommendations informed by trusted national medical organizations, including the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, and the American Academy of Family Physicians. This immunization protocol incorporates consensus WCHA recommendations for the use of 2025-2026 COVID-19 vaccine.

For the 2025-2026 season, the FDA approved two new vaccines for the prevention of COVID-19: MNEXSPIKE[3], an mRNA vaccine manufactured by Moderna; and NUVAXOVID[4], an adjuvanted, recombinant vaccine manufactured by Novavax. Both vaccines are approved for patients ≥65 years of age and patients 12-64 years of age with one or more underlying health conditions. COMIRNATY is no longer approved for children less than 5 years of age.

2. Oregon immunization protocol

A. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine. If ALERT IIS is unavailable, use available documentation and patient statement.

B. Screen client for contraindications and precautions.

C. Provide a Vaccine Information Statement (VIS) or Vaccine Information Fact Sheet for Recipients and Caregivers, and answer any questions. Adolescents aged 15–17 years may consent for their own vaccinations and do not need a parent to consent or to be present.

D. Record all required data elements in the client's permanent health record.

E. Verify needle length for IM injection.

F. To avoid injury related to vaccine administration, ensure staff who administer vaccines recognize the anatomic landmarks for identifying the vastus lateralis or deltoid muscle and use proper IM administration technique.

G. Administer a dose of COVID-19 vaccine according to WCHA recommendations and the vaccine package insert. See section 3 for vaccine volume and spacing based on age and vaccine formulation.

H. Ensure epinephrine hydrochloride solution (1 mg/mL), oxygen and other appropriate agents and equipment are available for immediate use in case of anaphylactic or acute hypersensitivity reaction. Refer to Guidelines for Managing Adverse Events Following Immunization.

I. Ask patient to remain seated in the clinic for 15 minutes after vaccination to monitor for syncope or other adverse events.

Health Officer Signature Date

Health Officer Signature Date

3. Vaccine schedule for COVID-19 Vaccines[1-4]

COMIRNATY – by Pfizer

Dose and Route: COMIRNATY, 0.3 mL, 10 µg, IM			
Children 5–11 years of age			
Dose	**Minimum acceptable age**	**Maximum acceptable age**	**Minimum acceptable spacing**
1*	5 years	11 years (<12 years)	If previously vaccinated, at least 8 weeks after the last dose of a COVID-19 vaccine

*Unvaccinated immunocompromised children ≤11 years of age should receive 4 doses, which includes a 3-dose initial series of COMIRNATY. For previously vaccinated immunocompromised children, the vaccine dosing schedule depends on previous vaccination status. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.[5]

Dose and Route: COMIRNATY, 0.3 mL, 30 µg, IM		
Children ≥12 years of age and adults		
Dose	**Minimum acceptable age**	**Minimum acceptable spacing**
1*	12 years	If previously vaccinated, at least 8 weeks after the last dose of a COVID-19 vaccine

*Unvaccinated immunocompromised persons should receive 4 doses, which includes a 3-dose initial series of COMIRNATY. For previously vaccinated immunocompromised children, the vaccine dosing schedule depends on previous vaccination status. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.[5,6]

SPIKEVAX – by Moderna

Dose and Route: SPIKEVAX vaccine 0.25 mL, 25 µg, IM			
Unvaccinated children 6 months through 23 months of age			
Dose	**Minimum acceptable age**	**Maximum acceptable age**	**Minimum acceptable spacing**
1	6 months	through 23 months (<24 months)	
2*			4 weeks

*Unvaccinated immunocompromised children ≤11 years of age should receive 4 doses, which includes a 3-dose initial series of SPIKEVAX. For previously vaccinated immunocompromised children, the vaccine dosing schedule depends on previous vaccination status. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.[5]

Children 6 months through 23 months of age previously vaccinated with Moderna vaccine		
Received	**Needs Now**	**Minimum Spacing**
1 dose	1 dose SPIKEVAX	4 weeks after last dose*
2 or more doses	1 dose SPIKEVAX	8 weeks after last dose*

*For previously vaccinated immunocompromised children, the vaccine dosing schedule depends on previous vaccination status. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.[5]

Children 6 months through 23 months of age previously vaccinated with Pfizer vaccine		
Received	**Needs Now**	**Minimum Spacing**
1 dose Pfizer	2 dose SPIKEVAX	First dose: 4 weeks after last dose of Pfizer* Second dose: 8 weeks after last dose*
2 or more doses Pfizer	1 dose SPIKEVAX	8 weeks after last dose*

*For previously vaccinated immunocompromised children, the vaccine dosing schedule depends on previous vaccination status. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.[5]

Dose and Route: SPIKEVAX vaccine 0.25 mL, 25 µg, IM			
Children 2–11 years of age			
Dose	**Minimum acceptable age**	**Maximum acceptable age**	**Minimum acceptable spacing**
1*	2 years	11 years (<12 years)	If previously vaccinated, 8 weeks after the last dose of a COVID-19 vaccine

*Unvaccinated immunocompromised children ≤11 years of age should receive 4 doses, which includes a 3-dose initial series of SPIKEVAX. For previously vaccinated immunocompromised children, the vaccine dosing schedule depends on previous vaccination status. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.[5]

Dose and Route: SPIKEVAX vaccine, 0.5 mL, 50 µg, IM		
Children ≥12 years of age and adults		
Dose	**Minimum acceptable age**	**Minimum acceptable spacing**
1*	12 years	If previously vaccinated, at least 8 weeks after the last dose of a COVID-19 vaccine

*Unvaccinated immunocompromised persons should receive 4 doses, which includes a 3-dose initial series of SPIKEVAX. For previously vaccinated immunocompromised children, the vaccine dosing schedule depends on previous vaccination status. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.[5,6]

MNEXSPIKE – by Moderna

Dose and Route: MNEXSPIKE vaccine, 0.2 mL, 10 µg, IM		
Children ≥12 years of age and adults		
Dose	**Minimum acceptable age**	**Minimum acceptable spacing**
1*	12 years	At least 3 months after the last dose of COVID-19 vaccine

*Unvaccinated immunocompromised persons should receive 4 doses, which includes a 3-dose initial series of MNEXSPIKE. For previously vaccinated immunocompromised children, the vaccine dosing schedule depends on previous vaccination status. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.[5,6]

NUVAXOVID – by Novavax

Dose and Route: NUVAXOVID®, adjuvanted vaccine, 0.5 mL, 5 µg, IM (prefilled syringes)		
Children ≥12 and adults		
Dose	**Minimum acceptable age**	**Minimum acceptable spacing***
1	12 years	If previously vaccinated, at least 8 weeks after the last dose of a COVID-19 vaccine

*Unvaccinated immunocompromised persons should receive 3 doses, which includes a 2-dose initial series of NUVAXOVID. For previously vaccinated immunocompromised children, the vaccine dosing schedule depends on previous vaccination status. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.[5,6]

4. Licensed COVID-19 vaccines

Product Name	Vaccine Components	Presentation	Acceptable age range
Preferred vaccines			
COMIRNATY[1]	mRNA	0.3-mL, single-dose vial	5–11 years
		0.3-mL, prefilled syringe	≥12 years
SPIKEVAX[2]	mRNA	0.25-mL, prefilled syringe	6 months – 11 years
		0.5-mL, prefilled syringe	≥12 years
MNEXSPIKE[3]	mRNA	0.2-mL, prefilled syringe	≥12 years
NUVAXOVID[4]	Adjuvanted	0.5-mL, prefilled syringe	≥12 years

5. Recommendations for use

A. All persons in the following groups should receive an age-appropriate 2025-2026 COVID-19 vaccine.[6]

Children	• All aged 6-23 months • 2-18 years of age with risk factors for severe COVID-19* • All with close contact with others with risk factors
Pregnancy	• All planning, pregnant, postpartum, and lactating
Adults	• All aged ≥65 years • 19-64 years of age with risk factors for severe COVID-19* • All with close contact with others with risk factors

*Risk factors for severe adverse outcomes include cardiovascular disease, chronic lung disease, chronic metabolic disease, gastrointestinal and liver disease, immunosuppressive conditions, neurologic disorders, obesity, renal disease, rheumatologic and autoimmune disorders. For children, factors such as feeding tube dependence and prematurity also apply.[6,7]

B. All persons 6 months and older not included in the groups above who desire or whose parents/guardians desire their protection from COVID-19 should be offered an age-appropriate 2025-2026 COVID-19 vaccine.[6]

C. COVID-19 vaccines are not interchangeable. When multiple doses are indicated (e.g., in unvaccinated children), the same vaccine brand should be used. In exceptional situations in which an mRNA vaccine series was begun, but the particular product administered for previous doses is not available, the other mRNA COVID-19 vaccine may be administered to complete the primary vaccine series.[8]

D. Unvaccinated persons with immune compromise require a 2- or 3-dose primary series, depending on the vaccine product. All primary series doses should be the same vaccine brand.[8]

E. For all persons with immune compromise, additional doses of vaccine may be administered at the discretion of the healthcare provider, based on the individual's clinical circumstances.[9]

F. Persons with immune compromise may self-attest to their moderately or severely immunocompromised status and receive COVID-19 doses. Vaccinators should not deny COVID-19 vaccination to a person due to lack of documentation.[9]

G. Conditions causing moderate to severe immunodeficiency include:[9]

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR*-T-cell or hematopoietic cell transplant (HCT) within 2 years of transplantation or taking immunosuppression therapy
- Moderate or severe primary immunodeficiency (e.g., DiGeorge, Wiskott-Aldrich syndromes)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm^3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day)
- Alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, TNF blockers, and other biologic agents that are

immunosuppressive or immunomodulatory.

*Chimeric antigen receptor. Added to a patient's T lymphocytes so that they recognize and attack cancer cells.

6. Contraindications

Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.

Vaccine	Vaccine Excipient Summary
COMIRNATY[1] 5-11 years Single dose vial	Lipids (0.14 mg ((4- hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.02 mg 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide, 0.03 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.06 mg cholesterol), 31 mg sucrose, 0.06 mg tromethamine hydrochloride.
COMIRNATY[1] 12 years and older Prefilled syringe	Lipids (0.43 mg ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate),0.05 mg 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.19 mg cholesterol), 0.06 mg tromethamine, 0.4 mg tromethamine hydrochloride, and 31 mg sucrose.
SPIKEVAX[2] 6 months-11 years	Total lipid content of 0.5 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.13 mg tromethamine, 0.62 mg tromethamine hydrochloride, 0.011 mg acetic acid, 0.049 mg sodium acetate trihydrate, and 21.8 mg sucrose.
SPIKEVAX[2] 12 years and older	Total lipid content of 1.01 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.25 mg tromethamine, 1.2 mg tromethamine hydrochloride, 0.021 mg acetic acid, 0.10 mg sodium acetate trihydrate, and 43.5 mg sucrose.
MNEXSPIKE[3]	Total lipid content of 0.2 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3- phosphocholine [DSPC]), 0.09 mg tromethamine, 0.51 mg tromethamine hydrochloride, and 17 mg sucrose.
NUVAXOVID[4]	Cholesterol (30.5 µg), phosphatidylcholinem (23 µg), potassium dihydrogen phosphate (3.85 µg), potassium chloride (2.25 µg), disodium hydrogen phosphate dihydrate (14.7 µg), disodium hydrogen phosphate heptahydrate (2.465 mg), sodium dihydrogen phosphate monohydrate (0.445 mg), sodium chloride (8.766 mg) and polysorbate 80 (0.050 mg) and water for injection. The pH is adjusted

	with sodium hydroxide or hydrochloric acid. Each 0.5 mL dose of NUVAXOVID may also contain residual amounts of baculovirus and Sf9 851 cell proteins (≤ 0.96 µg), baculovirus and cellular DNA (≤ 0.00016 µg), lentil lectin 852 (< 0.025 µg), methyl-α-D-mannopyranoside (2 µg), simethicone (< 0.92 µg), pluronic F-68 853 (< 2.19 µg), Triton X-100 (< 0.025 µg), Tergitol (NP9) (< 0.05 µg), and DL-α-tocopherol 854 (≤ 0.05 µg)

7. Warnings and precautions

A. History of severe allergic reaction (e.g. anaphylaxis) to any other vaccine or injectable therapy (e.g. intravenous, intramuscular or subcutaneous).

B. Persons who have a contraindication to additional doses of mRNA COVID-19 vaccines are considered to have a precaution to Nuvaxovid vaccine. A single dose may be given in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Consider referral to an allergist-immunologist.

   This additional dose could be considered after a minimum interval of 28 days after the mRNA COVID-19 vaccine dose.

C. Moderate or severe acute illness.

8. Other considerations[8,9]

A. Patients with known COVID-19 infection should wait until their symptoms have resolved and criteria have been met to discontinue isolation. Persons who have a history of COVID-19 disease should be vaccinated if otherwise indicated. If desired, persons with acute COVID-19 may wait up to 90 days to receive vaccination, as reinfection within 90 days is uncommon. Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection solely for the purposes of vaccine decision-making is not recommended.

B. COVID-19 vaccine may be administered concomitantly with other vaccines.

C. An 8-week interval between the first and second mRNA (Pfizer, Moderna) COVID-19 vaccine doses might be optimal for some non-immunocompromised people, as it might reduce the risk of myocarditis and pericarditis associated with these COVID-19 vaccines, particularly in males ages 12-39 years.

D. CDC recommends that vaccination of children aged 5–17 years of age with history of Multisystem Inflammatory Syndrome of Children (MIS-C) be delayed for 90 days after their diagnosis of MIS-C. Providers should inform patients that the risk of reinfection, and therefore the potential benefit from vaccination, may increase with time following initial infection.

E. Persons with underlying medical conditions who have no contraindications may

receive COVID-19 vaccine.

9. Side effects and adverse reactions[1-4]

Adverse Event (Pfizer and Moderna)	Frequency
Injection site events (pain at the injection site, redness, swelling)	Up to 98%
Systemic events (fatigue, headache, muscle ache, joint pain)	Up to 77%
Fever	Up to 27%
Lymphadenopathy*	Up to 6%
Serious adverse events	Up to 1% (similar to placebo group)
Adverse Event (Novavax)	**Frequency**
Injection site events (pain at the injection site, redness, swelling)	Up to 72%
Systemic events (fatigue, muscle pain, headache, nausea)	Up to 63%
Fever	Up to 17%

*Lymph node swelling in the underarm is more common after the booster dose than after the initial series.

10. Storage and handling[1-5]

For COVID-19 vaccines only, clinics with vaccine storage and handling concerns should contact the manufacturer directly.

Vaccine	Temp	Storage Issues	Notes
COMIRNATY	-90° to -60° C	**Vials:** may be stored until the expiration date.	.
	2° to 8° C	**Prefilled glass syringes**: Store only in the refrigerator. Use through the expiration date on the carton.	**DO NOT FREEZE.**
		Single-dose vials: store in the refrigerator for up to 10 weeks.	Do not refreeze vials once thawed.
	Ambient temperatures	**Prefilled glass syringes**: Time out of refrigeration must not exceed 12 hours.	Any unused vaccine should be discarded.
SPIKEVAX	-50° to -15° C	Frozen: Vaccine is viable until the expiration date.	Do not refreeze once thawed.

	2° to 8° C	After thawing, vaccine may be stored refrigerated for up to 60 days or up to the expiration date printed on the carton, whichever comes first.	Protect vaccine from light.
	Ambient temperatures	Prefilled syringes are viable for up to 12 hours at room temperature.	
NUVAXOVID	2° to 8° C	Store prefilled syringes in the refrigerator through the expiration date.	Do not freeze. Protect vaccine from light.
MNEXSPIKE	-40°C to -15°C	Frozen: Vaccine is viable until the expiration date.	Do not refreeze once thawed. Protect vaccine from light.
	2°C to 8°C	After thawing, may be stored refrigerated for up to 90 days or up to the expiration date printed on the carton, whichever comes first.	
	Ambient temperatures	Prefilled syringes are viable for up to 24 hours at room temperature.	

11. Adverse events reporting

Report adverse events online to the Vaccine Adverse Events Reporting System (VAERS) at https://vaers.hhs.gov/reportevent.html.

VAERS Reporting Table: https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

Reporting of the following adverse events is strongly encouraged
• Any adverse event that occurs after administration, whether or not it is clear the vaccine caused the adverse event • Vaccine administration errors, whether or not associated with an adverse event

12. References

1. Pfizer Comirnaty, package insert, July 2025. Available at: https://www.fda.gov/vaccines-blood-biologics/comirnaty. Accessed 15 September

2025.

2. Moderna Spikevax, package insert, July 2025. Available at: https://www.fda.gov/vaccines-blood-biologics/spikevax. Accessed 15 September 2025.
3. Moderna Mnexspike, package insert, June 2025. Available at: https://www.fda.gov/vaccines-blood-biologics/mnexspike. Accessed 15 September 2025.
4. Novavax Nuvaxovid, package insert, June 2025. Available at: https://www.fda.gov/vaccines-blood-biologics/vaccines/nuvaxovid. Accessed 15 September 2025.
5. The American Academy of Pediatrics' Recommended Child and Adolescent Immunization Schedule, September 9, 2025. Available at: https://downloads.aap.org/AAP/PDF/AAP-Immunization-Schedule.pdf?_gl=1*e1uv44*_ga*NzU0MDQ3Nzc5LjE3MjMwNTIwNzQ.*_ga_FD9D3XZVQQ*czE3NTgwNDg2NDUkbzEyJGcxJHQxNzU4MDQ5NjE4JGo0NiRsMCRoMA. Accessed 15 September 2025.
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7. Centers for Disease Control and Prevention. People with Certain Medical Conditions and COVID-19 Risk Factors, June 11, 2025. Available at: https://www.cdc.gov/covid/risk-factors/index.html#:~:text=Like%20adults%2C%20children%20and%20teens,information%20on%20vaccinating%20your%20child. Accessed 28 July 2025.
8. Panagiotakopoulos L, Moulia D, Godfrey M, et al. Use of COVID-19 Vaccines for Persons Aged ≥6 Months: Recommendations of the Advisory Committee on Immunization Practices – United States, 2024-2025. MMWR 2024;73:819-824. Available at: https://www.cdc.gov/mmwr/volumes/73/wr/mm7337e2.htm. Accessed 28 July 2025.
9. Roper L, Godfrey M, Link-Gelles R, et al. Use of Additional Doses of 2024–2025 COVID-19 Vaccine for Adults Aged ≥65 Years and Persons Aged ≥6 Months with Moderate or Severe Immunocompromise: Recommendations of the Advisory Committee on Immunization Practices — United States, 2024. MMWR 2024;73:1118-1123. Available at: https://www.cdc.gov/mmwr/volumes/73/wr/mm7349a2.htm. Accessed 28 July 2025.

To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 971-673-0300 and 711 for TTY. For other questions, consult with the vaccine recipient's primary health care provider or a consulting physician.

Electronic copy of this immunization protocol is available at: www.oregon.gov/oha/ph/preventionwellness/vaccinesimmunization/immunizationproviderresources/pages/stdgordr.aspx.