Immunization Pharmacy Protocol

COVID-19 Vaccine (Pfizer-BioNTech, Moderna, Novavax)	
Last Reviewed	27 April 2023
Last Revised	27 April 2023
This order expires	31 December 2024

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1. What's new

Erratum: Corrected table in appendix A to include 5 year olds who received monovalent Pfizer only.

In the table on page 7 listing catch-up for previously vaccinated people ≥12 years and older, the incorrect dose was listed. The correct dose of Moderna vaccine should be 0.5-mL.

On April 18th, the FDA authorized changes to simplify use of COVID-19 vaccines in the United States for most individuals. This includes:

- Withdrawal of Emergency Use Authorization (EUA) for monovalent mRNA vaccines.
- Authorizing current bivalent vaccines to be used for all doses administered to individuals ≥6 months of age.
- Persons ≥6 years of age are up-to-date if they have received a single dose of bivalent COVID-19 vaccine, regardless of any previous COVID-19 vaccination history.
- Authorizing an additional bivalent vaccine dose for adults ≥65 years of age ≥4 months after their previous bivalent dose. This dose is optional but may be administered at the recipient's request.
- Authorizing an additional bivalent vaccine dose for certain immunocompromised persons 1 or 2 months after their previous bivalent dose, depending on age. Additional doses may be administered at their provider's discretion.
- Persons who are unable or choose not to receive a bivalent mRNA vaccine, are up-to-date if they have received the recommended number of Novavax doses.
- As of May 6th, all doses of Janssen vaccine will have expired.

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 Fact Sheet for Recipients and Caregivers, and answer any questions.

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, make sure staff who administer vaccines recognize the anatomic landmarks for identifying the vastus lateralis or deltoid muscle and use proper IM administration technique.

G. For Pfizer vaccine only: thaw, if needed. The orange and maroon cap formulations require reconstitution; the gray cap formulation is ready to administer.[1]

H. For Moderna vaccine only: thaw vaccine prior to administration.[2]

I. Administer a dose of Pfizer or Moderna bivalent COVID-19 vaccine according to ACIP recommendations and the vaccine package insert. See section 3 for vaccine volume and spacing based on age and vaccine formulation.

J. Novavax monovalent vaccine may be used as a first booster in an adult patient only if an FDA-authorized mRNA bivalent booster is not accessible or clinically appropriate, or the patient elects to receive the Novavax COVID-19 vaccine because they would otherwise not receive a booster dose of a COVID-19 vaccine.[4]

K. COVID-19 vaccines appear to be more reactogenic than most.[4] Inform patient that symptoms of immune system activation are normal (see Table) and should improve without intervention in 12–24 hours.

L. Anaphylaxis has been reported after COVID-19 vaccination. Vaccinator must be prepared to respond to a severe allergic reaction. See Section 6 for a list of excipients.

M. Ask patient to remain seated in the clinic for 15 minutes after vaccination to decrease the risk of injury should they faint. Patients with a history of severe allergic reactions should be asked to remain for 30 minutes.[4]

N. Report all administered COVID-19 doses to ALERT IIS within 72 hours of administration.

I have read, understand, and agree to participate by the terms of this protocol.

Immunizing Pharmacist Date

3. Vaccine schedule for COVID-19 Vaccines

A. Any immunocompetent person 6 through 64 years of age who has received at least 1 dose of bivalent COVID-19 vaccine is currently up-to-date.[1,2]

B. Any immunocompetent unvaccinated person over 6 years of age may be brought up-to-date with a single dose of bivalent COVID-19 vaccine.[1,2]

C. Recipients ≥ 65 years of age may choose to receive an additional dose of bivalent COVID-19 vaccine at least 4 months after their most recent dose. This dose is not required to be considered up-to-date.[1,2]

Preferred vaccines

PFIZER[1]

Dose and Route: Pfizer bivalent pediatric mRNA vaccine 0.2 mL, 3 µg, IM (maroon cap and maroon border)			
Unvaccinated children			
Dose	**Minimum acceptable age**	**Maximum acceptable age**	**Minimum acceptable spacing**
1	3 years	through 4 years* (<5 years)	
2			3 weeks
3			8 weeks

*Notwithstanding the age limitations for use of the vaccine, individuals turning from 4 to 5 years of age during the vaccination series should receive all doses with Pfizer-BioNTech COVID-19 Vaccine, Bivalent supplied in vials with maroon caps and labels with maroon borders.[1]

Children <5 years previously vaccinated with Pfizer vaccine		
Received	**Needs Now**	**Minimum Spacing**
1 monovalent dose	2 doses bivalent Pfizer	3 weeks after monovalent. 8 weeks between bivalent doses.
2 or 3 monovalent doses	1 dose bivalent Pfizer	8 weeks after last monovalent dose
2 monovalent doses and 1 bivalent dose	Up-to-date	

Dose and Route: Pfizer bivalent pediatric mRNA vaccine 0.2 mL, 10 µg, IM (orange cap and orange border)			
Unvaccinated children 5-11 years of age			
Dose	**Minimum acceptable age**	**Maximum acceptable age**	**Minimum acceptable spacing**

1	5 years	11 years	
Additional dose*			8 weeks

*Immunocompromised children may be administered a single additional dose at least 2 months following the initial dose of a bivalent COVID-19 vaccine; additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.

Children 5 - 11 years of age previously vaccinated with 1 or more doses of a monovalent COVID-19 vaccine	
Received	**Needs Now**
Any number of monovalent doses, no bivalent	1 dose bivalent Pfizer 8 weeks after last dose*
Any number of monovalent doses and 1 bivalent	Up-to-date*

*Immunocompromised children may be administered a single additional dose at least 2 months following the initial dose of a bivalent COVID-19 vaccine; additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.

Dose and Route: Pfizer bivalent mRNA vaccine 0.3 mL, 30 µg, IM (gray cap, gray border)

Children ≥ 12 and adults

Dose	Minimum acceptable age	Minimum acceptable spacing
1	12 years	
Additional dose*		8 weeks
Optional Dose+	65 years	4 months

*Immunocompromised persons may be administered a single additional dose at least 2 months following the initial dose of a bivalent COVID-19 vaccine; additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.

+Optional dose, at recipient's request

MODERNA[2]

Dose and Route: Moderna bivalent mRNA vaccine 0.25 mL, 25 µg, IM (dark blue cap, gray border)

Unvaccinated children

Dose	Minimum acceptable age	Maximum acceptable age	Minimum acceptable spacing
1	6 months	through 5 years (<6 years)	
2			28 days

Additional dose*			4 weeks

*Immunocompromised children may be administered a single additional dose at least 1 month following the initial dose of a bivalent COVID-19 vaccine; additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.

Children <6 years previously vaccinated with Moderna vaccine		
Received	**Needs Now**	**Minimum Spacing**
1 monovalent dose	1 dose bivalent Moderna (0.25 mL, dark blue cap, gray border)	1 dose bivalent Moderna 4 weeks after last dose*
2 monovalent doses	1 dose bivalent Moderna (0.2 mL, **dark pink cap, yellow border**)	1 dose bivalent Moderna 8 weeks after last dose*
2 monovalent doses and 1 bivalent dose	Up-to-date	

*Immunocompromised children may be administered a single additional dose at least 1 month following the initial dose of a bivalent COVID-19 vaccine; additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.

Dose and Route: Moderna bivalent mRNA vaccine 0.25 mL, 25 µg, IM (dark blue cap, gray border)

Unvaccinated children

Dose	Minimum acceptable age	Maximum acceptable age	Minimum acceptable spacing
1	6 years	11 years (<12 years)	
Additional dose*			8 weeks

* Immunocompromised children may be administered a single additional dose at least 2 months following the initial dose of a bivalent COVID-19 vaccine; additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.

Children 6 through 11 years previously vaccinated with any monovalent COVID-19 vaccine		
Received	**Needs Now**	**Minimum Spacing**
1 or more monovalent doses	1 dose bivalent Moderna (0.25 mL, dark blue cap, gray border)	1 dose bivalent Moderna 8 weeks after last dose*
Any bivalent dose	Up-to-date*	

* Immunocompromised children may be administered a single additional dose at least 2 months following the initial dose of a bivalent COVID-19 vaccine; additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.

Dose and Route: Moderna bivalent mRNA vaccine 0.5 mL, 50 µg, IM (dark blue cap, gray border)		
Unvaccinated children ≥ 12 and adults		
Dose	**Minimum acceptable age**	**Minimum acceptable spacing**
1	12 years	
Additional dose*		8 weeks
+	65 years	4 months

* Immunocompromised persons may be administered a single additional dose at least 2 months following the initial dose of a bivalent COVID-19 vaccine; additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.

+Optional dose, at recipient's request

Immunocompetent children ≥12 and adults previously vaccinated with any monovalent vaccine		
Received	**Needs Now**	**Minimum Spacing**
1 or more monovalent doses	1 dose bivalent Moderna (0.5 mL, dark blue cap, gray border)	8 weeks
Any bivalent dose	Up-to-date	

NOVAVAX[3]

Dose and Route: Novavax, adjuvanted vaccine 0.5 mL, 5 µg, IM		
Dose	**Minimum acceptable age**	**Minimum acceptable spacing**
1	12 years	
2		21 days
Booster*	18 years	6 months

*For use only in individuals 18 years of age and older for whom an FDA-authorized mRNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate, or in individuals 18 years of age and older who elect to receive a Novavax COVID-19 vaccine because they would otherwise not receive a booster dose of a COVID-19 vaccine. This dose is not authorized to follow any prior booster dose.[4]

4. Licensed COVID-19 vaccines

Product Name	Vaccine Components	Presentation	Acceptable age range	
Preferred vaccines				
Pfizer Bivalent[1]	mRNA	2.2-mL, 10-dose vial	3 years – 4 years	
		2.2-mL, 10-dose vial	5–11 years	
		0.3-mL, Single-dose vials	≥12 years	
		2.25-mL, 6-dose vial	≥12 years	
Moderna Bivalent[2]	mRNA	0.4-mL, 2 dose vial	3 years – 5 years	
		2.5-mL 10- dose vial	≥3 years	
NVX-CoV2373[3] (Novavax)	Protein subunit	2.5-mL, 5-dose vial	≥12 years ≥18 years (booster)	

5. Recommendations for use[1, 2, 4]

A. A bivalent mRNA COVID-19 vaccine series should be offered to all persons aged 3 years through 5 years of age. A bivalent mRNA COVID-19 vaccine should be offered to all children and adults ≥6 years and older. For adults and children ≥12 years of age, a protein subunit (Novavax) vaccine may be used.

B. Covid-19 vaccines are not interchangeable. When multiple doses are indicated (i.e. 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. Doses for adults and immunocompromised persons ≥6 years of age may be any authorized product.

C. Novavax vaccine is currently approved as a two-dose primary series and as a first booster dose in certain circumstances, regardless of immunocompetency status. Persons who complete the Novavax series may receive a bivalent mRNA booster dose at least 2 months after their final dose of Novavax. Alternatively, Novavax may be administered as a first booster dose 6 months after completion of a primary series for individuals 18 and older for whom an

FDA-authorized mRNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate, or who elect to receive the Novavax COVID-19 vaccine because they would otherwise not receive a booster dose of a COVID-19 vaccine. A Novavax booster dose is not authorized to follow any prior booster dose.[3]

D. Children 3 years through 5 years who received the two-dose primary series of Moderna and are moderately to severely immunocompromised should be offered an additional dose of Moderna bivalent COVID-19 vaccine ≥28 days after their previous dose. Additional doses of vaccine may be administered at the discretion of the healthcare provider, based on the individual's clinical circumstances.

E. People over 5 years of age who previously received Pfizer vaccine and are moderate to severely immunocompromised should be offered an additional dose of Pfizer bivalent COVID-19 vaccine 2 months after their previous dose. Additional doses of vaccine may be administered at the discretion of the healthcare provider, based on the individual's clinical circumstances.

F. People over 6 years of age who previously received Moderna vaccine and are moderate to severely immunocompromised should be offered an additional dose of Moderna bivalent COVID-19 vaccine 2 months after their previous dose.

   Immunocompromised children under 6 years of age should be offered an additional dose 1 month after their previous dose.

   Additional doses of vaccine may be administered at the discretion of the healthcare provider, based on the individual's clinical circumstances.

G. Persons with immune compromise may self-attest to the need for additional doses. No other documentation is necessary.

H. Conditions causing moderate to severe immunodeficiency include:

   - 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[1-4]

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

Vaccine	Vaccine Excipient Summary
Pfizer bivalent[1] [maroon cap, maroon border]	Lipids (0.04 mg ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.005 mg 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.01 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.02 mg cholesterol), 3.2 mg sucrose, 0.006 mg tromethamine, and 0.04 mg tromethamine hydrochloride. The diluent (sterile 0.9% Sodium Chloride Injection, USP) contributes1.52 mg sodium chloride per dose.
Pfizer bivalent[1] [orange cap, orange border]	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), 10.3 mg sucrose, 0.02 mg tromethamine, and 0.13 mg tromethamine hydrochloride. The diluent (sterile 0.9% Sodium Chloride Injection, USP) contributes 0.9 mg sodium chloride per dose.
Pfizer bivalent[1] [gray cap, gray border]	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.
Moderna bivalent[2] [dark pink cap with yellow border]	Total lipid content of 0.20 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, 0.0042 mg acetic acid, 0.02 mg sodium acetate trihydrate, and 17.4 mg sucrose
Moderna bivalent[2] [dark blue cap, gray border]	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
NVX-CoV2373 (Novavax)[3]	Cholesterol, phosphatidylcholine, 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). The Matrix-M adjuvant is composed of Fraction-A (42.5 µg) and Fraction-C (7.5 µg) of saponin extracts from the soapbark tree, *Quillaja saponaria* Molina. The pH is adjusted with sodium hydroxide or hydrochloric acid.

7. Warnings and precautions[4]

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 the Novavax 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. See Appendix A for additional information.

C. Moderate or severe acute illness.

8. Other considerations[4]

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. Patients who received monoclonal antibodies or convalescent plasma during COVID-19 treatment may be vaccinated as soon as their symptoms have resolved.

C. Patients with a known community or outpatient setting COVID-19 exposure should wait until the end of their quarantine period before seeking vaccination to avoid potentially exposing healthcare personnel.

D. Patients who have been exposed to COVID-19 living in congregate settings, including long-term care, homeless shelters, or correctional institutions, where exposure or transmission can occur repeatedly over a long period of time may be vaccinated without completing a quarantine period.

E. COVID-19 vaccine may be administered concomitantly with other vaccines. There is no need to separate COVID-19 vaccine from other vaccinations by 2 weeks.

F. CDC recommends that vaccine for 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.

G. COVID-19 vaccination is recommended for all people of childbearing age, including people who are pregnant, breastfeeding, trying to get pregnant now, or might become pregnant in the future.

H. Persons who are trying to become pregnant do not need to avoid pregnancy after receiving COVID-19 vaccine. There is no recommendation for routine pregnancy testing before receipt of a COVID-19 vaccine.

I. Persons with underlying medical conditions who have no contraindications may receive COVID-19 vaccine.

9. Side effects and adverse reactions

Adverse Event (Pfizer[1] and Moderna[2])	Frequency
Injection site events (pain at the injection site, redness, swelling)	Up to 93%

Systemic events (fatigue, headache, muscle ache, joint pain)	Up to 77%
Fever	Up to 16%
Lymphadenopathy*	Up to 20%
Serious adverse events	Up to 1% (similar to placebo group)
Adverse Event (Novavax[3])	**Frequency**
Injection site events (pain at the injection site, redness, swelling)	Up to 82%
Systemic events (fatigue, muscle pain, headache, nausea)	Up to 62%
Fever	Up to 6%

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

10. Storage and handling

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

Vaccine	Temp	Storage Issues	Notes
Pfizer[1]	-90° to -60° C	Vaccine may be stored until the expiration date.	.
	2° to 8° C	**Adolescent/adult bivalent formulation (gray cap)**: store in the refrigerator for up to 10 weeks	
		Pediatric bivalent formulations (orange and maroon caps): before mixing, the vaccine may be stored in the refrigerator for up to 10 weeks.	
	Ambient temperatures	**Adolescent/adult bivalent formulation (gray cap)**: vaccine may be held at room temperature for up to 12 hours.	Any unused vaccine should be discarded.

		Pediatric bivalent formulations (orange and maroon caps): once mixed, vaccine may be held at room temperature for up to 12 hours.	
Moderna[2]	-50° to -15° C	Vaccine is viable until the expiration date.	Once vial stopper has been punctured, all doses must be used within: Pink cap: 8 hours Dark blue cap: 12 hours Do not refreeze once thawed. Protect vaccine from light.
	2° to 8° C	Vaccine is viable under refrigeration for up to 30 days.	
	Ambient temperatures	Unpunctured vials of vaccine viable for up to 24 hours at room temperature.	
Novavax[3]	2° to 8° C	No expiration date is printed on vial or carton. Lookup the expiration date of the batch/Lot number at www.novavaxcovidvaccine.com: enter "United States" as the "country/region."	Once vial stopper has been punctured, store vial at 2° to 25° C for use within 6 hours. Discard the vial 6 hours after first puncture. Do not freeze. Protect vaccine from light.

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

Adverse events that must be reported under the Emergency Use Authorization

A. Vaccine administration errors, whether or not associated with an adverse event
B. Serious adverse events, irrespective of attribution to vaccination
C. Multisystem Inflammatory Syndrome
D. Cases of COVID-19 resulting in hospitalization or death

12. References

1. Pfizer-BioNTech COVID-19 Vaccine, bivalent. Emergency use authorization (EUA) fact sheet, 18 Apr 2023. Available at: https://www.fda.gov/media/167211/download. Accessed 20 Apr 2023.
2. Moderna COVID-19 vaccine, bivalent. Emergency use authorization (EUA) fact sheet and prescribing information, 18 Apr 2023. Available at https://www.fda.gov/media/167208/download. Accessed 20 Apr 2023.
3. Novavax, Inc. Full emergency use authorization (EUA) prescribing information, 28 Mar 2023. Available at www.fda.gov/media/159897/download. Accessed 2023.
4. Janssen Biotech, Inc. Full emergency use authorization (EUA) prescribing information, March 13, 2023. Available at www.fda.gov/media/146304/download. Accessed 17 Mar 2023.
5. Interim clinical considerations for use of COVID-19 vaccines in the United States, March 16, 2023. Available at www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html. Accessed 17 Mar 2023.
6. Pfizer-BioNTech COVID-19 vaccine, bivalent, booster dose for 5 through 11 years of age and older, emergency use authorization (EUA) fact sheet. December 8, 2022. Available at www.fda.gov/media/162250/download. Accessed 17 Mar 2023.
7. Moderna COVID-19 vaccine, bivalent, booster dose for 6 months through 5 years of age, emergency use authorization (EUA) fact sheet, December 8, 2022. Available at www.fda.gov/media/163785/download. Accessed 17 Mar 2023.

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: immunization protocols

Electronic copy of this pharmacy protocol is available at: pharmacy protocols

13. Appendix A

COVID-19 vaccination schedule for people who are not moderately or severely immunocompromised by COVID-19 vaccination history, April 2023.

Ages 3 years - 4 years

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
unvaccinated	Moderna *-or-* Pfizer	2	0.25 mL/25 ug	dark blue cap; gray label border	dose 1 and dose 2: 4-8 weeks
		3	0.2 mL/3 ug	maroon	dose 1 and dose 2: 3-8 weeks dose 2 and dose 3: at least 8 weeks
1 dose monovalent Moderna	Moderna	1	0.25 mL/25 ug	dark blue cap; gray label border	4-8 weeks after monovalent dose
2 doses monovalent Moderna	Moderna	1	0.2 mL/10 ug	dark pink cap; yellow label border	at least 8 weeks after last monovalent dose
2 doses monovalent Moderna and 1 dose bivalent Moderna	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA
1 dose monovalent Pfizer	Pfizer	2	0.2 mL/3 ug	maroon	dose 1: 3-8 weeks after monovalent dose dose 1 and dose 2: at least 8 weeks
2 doses monovalent Pfizer	Pfizer	1	0.2 mL/3 ug	maroon	at least 8 weeks after last monovalent dose
3 doses monovalent Pfizer	Pfizer	1	0.2 mL/3 ug	maroon	at least 8 weeks after last monovalent dose
2 doses monovalent Pfizer and 1 dose bivalent Pfizer	NA; previously received 1 bivalent dose	NA	NA	NA	NA

Age 5 years

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses

unvaccinated	Moderna *-or-* Pfizer	2	0.25 mL/25 ug	dark blue cap; gray label border	dose 1 and dose 2: 4-8 weeks
		1	0.2 mL/10 ug	orange	
1 dose monovalent Moderna	Moderna *-or-* Pfizer	1	0.25 mL/25 ug	dark blue cap; gray label border	4-8 weeks after monovalent dose
		1	0.2 mL/10 ug	orange	at least 8 weeks after last monovalent dose
2 doses monovalent Moderna	Moderna *-or-* Pfizer	1	0.2 mL/10 ug	dark pink cap; yellow label border	at least 8 weeks after last monovalent dose
		1	0.2 mL/10 ug	orange	at least 8 weeks after last monovalent dose
2 doses monovalent Moderna and 1 dose bivalent mRNA	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA
1 or more doses monovalent Pfizer	Pfizer	1	0.2 mL/10 ug	orange	at least 8 weeks after last monovalent dose
ever received bivalent Pfizer	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA

Ages 6-11 years

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
unvaccinated	Moderna *-or-* Pfizer	1	0.25 mL/25 ug	dark blue cap; gray label border	
		1	0.2 mL/10 ug	orange	
1 or more doses monovalent mRNA (no bivalent)	Moderna *-or-* Pfizer	1	0.25 mL/25 ug	dark blue cap; gray label border	8 weeks after last monovalent dose
		1	0.2 mL/10 ug	orange	at least 8 weeks after last monovalent dose
2 or more doses monovalent mRNA and 1 dose bivalent mRNA	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA

ever received 1 dose bivalent mRNA (regardless of monovalent vaccine history	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA

Ages 12 years and older

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
unvaccinated	Moderna *-or-* Pfizer	1	0.5 mL/50 ug	dark blue cap; gray label border	
		1	0.3 mL/30 ug	gray	
1 or more doses monovalent mRNA (no doses bivalent mRNA)	Moderna *-or-* Pfizer	1	0.5 mL/50 ug	dark blue cap; gray label border	8 weeks after last monovalent dose
		1	0.3 mL/30 ug	gray	at least 8 weeks after last monovalent dose
ever received 1 dose bivalent mRNA (regardless of monovalent vaccine history	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA
People ages 65 years and older have the option to receive 1 additional bivalent mRNA vaccine dose at least 4 months after the first dose of a bivalent mRNA vaccine. If Moderna is used, administer 0.5 mL/50 ug (dark blue cap and label with a gray border); if Pfizer-BioNTech is used, administer 0.3 mL/30 ug (gray cap and label with a gray border).					

Abbreviation: NA=not authorized