

## Protocol for Coronavirus 19 Vaccines (Moderna, Novavax, Pfizer-BioNTech)

### 1) What's New

- A) Individuals 6 months and older should receive the 2024-2025 COVID-19 vaccine (Moderna, Novavax, or Pfizer-BioNTech).
- B) The PREP Act, 12th Amendment allows pharmacists to administer COVID-19 vaccines to persons aged 3 through 18 years old through 12/31/2029. Otherwise, pharmacists are only permitted to administer COVID-19 vaccines to persons  $\geq 7$  years per [ORS 689.645\(1\)\(A\)](#).
- C) Updated ACIP guidance recommending second, third, and additional doses of the 2024-2025 COVID 19 vaccine based on age, underlying conditions, vaccination history, and vaccine choice (see Sections 3 and 4 for additional information).

### 2) Immunization Protocol

- A) Administer one or more doses of the updated 2024–2025 Moderna, Novavax, or Pfizer-BioNTech COVID-19 vaccine based on level of immunocompetency, age, and previous vaccination status. See Section 3 for vaccine volume and dosing schedule.
- B) 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.

### 3) Vaccine Schedule <sup>1-8</sup>

#### A. Vaccine Schedule for Immunocompetent Individuals

**Table 1A: Immunocompetent Individuals Ages 6 Months through 4 Years\***

*Note - The [PREP Act, 12<sup>th</sup> Amendment](#) allows pharmacists to administer COVID-19 vaccines to persons aged 3 through 18 years old through 12/31/2029. Otherwise, pharmacists are only permitted to vaccinate persons  $\geq 7$  years per [ORS 689.645](#).*

COVID-19 Vaccination History Prior to Updated (2024-2025 Formula) Vaccine†	Updated (2024-2025 Formula) Vaccine	Number of Updated (2024-2025 Formula) Vaccine Doses Indicated	Dosage (mL/mcg)	Interval Between Doses
Unvaccinated	Moderna	2	0.25 mL/ 25 mcg	Dose 1 and Dose 2: 4-8 weeks‡
	Pfizer-BioNTech	3	0.3 mL/ 3 mcg	Dose 1 and Dose 2: 3-8 weeks‡  Dose 2 and Dose 3: At least 8 weeks

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1 dose any Moderna	Moderna	1	0.25 mL/ 25 mcg	4-8 weeks after last dose†
2 or more doses any Moderna	Moderna	1	0.25 mL/ 25 mcg	At least 8 weeks after last dose
1 dose any Pfizer- BioNTech	Pfizer-BioNTech	2	0.3 mL/ 3 mcg	Dose 1: 3-8 weeks after last dose†  Dose 1 and Dose 2: At least 8 weeks
2 doses any Pfizer- BioNTech	Pfizer-BioNTech	1	0.3 mL/ 3 mcg	At least 8 weeks after last dose
3 or more doses any Pfizer-BioNTech	Pfizer-BioNTech	1	0.3 mL/ 3 mcg	At least 8 weeks after last dose

†COVID-19 vaccination history refers to previous receipt of doses of Original monovalent mRNA or bivalent mRNA vaccine or a combination of the two.

\*Per FDA authorization, all COVID-19 vaccine doses in this age group should be homologous. In the following circumstances, an age-appropriate COVID-19 vaccine from a different manufacturer may be administered:

- Same vaccine not available at the vaccination site at the time of the clinic visit
- Previous dose unknown
- Person would otherwise not receive a recommended vaccine dose
- Person starts but unable to complete a vaccination series with the same COVID-19 vaccine due to a contraindication

**Table 1B: Immunocompetent Individuals Ages 5 through 11 years<sup>§</sup>**

*Note - The [PREP Act, 12<sup>th</sup> Amendment](#) allows pharmacists to administer COVID-19 vaccines to persons aged 3 through 18 years old through 12/31/2029. Otherwise, pharmacists are only permitted to vaccinate persons ≥ 7 years per ORS 689.645.*

COVID-19 Vaccination History Prior to Updated (2024-2025 Formula) Vaccine†	Updated (2024-2025 Formula) Vaccine	Number of Updated (2024-2025 Formula) Vaccine Doses Indicated	Dosage (mL/mcg)	Interval Between Doses
Unvaccinated	Moderna	1	0.25 mL/ 25 mcg	-
	OR			
	Pfizer-BioNTech	1	0.3 mL/ 10 mcg	-

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1 or more doses any mRNA	Moderna	1	0.25 mL/ 25 mcg	At least 8 weeks after last dose
	OR			
	Pfizer-BioNTech	1	0.3 mL/ 10 mcg	At least 8 weeks after last dose

†COVID-19 vaccination history refers to previous receipt of doses of Original monovalent mRNA or bivalent mRNA vaccine or a combination of the two.

§ For children who transition from age 4 years to age 5 years during the initial vaccination series:

- **Moderna series:** Children are recommended to complete the 2-dose series with the updated 2024–2025 Formula Moderna COVID-19 Vaccine, 0.25 mL/25 mcg ( ), as per the FDA EUA; there is no dosage change.
- **Pfizer-BioNTech series:** Children who received 1 or 2 doses of Pfizer-BioNTech vaccine for ages 6 months through 4 years, 0.3 mL/3 mcg are recommended to receive 1 dose of the updated 2024–2025 Formula Pfizer-BioNTech COVID-19 Vaccine, 0.3 mL/10 mcg on or after turning age 5 years. If the 10 mcg dose is the second dose, administer 3–8 weeks after the first dose; if it is the third dose, administer at least 8 weeks after the second dose. Alternatively, these children may complete the 3-dose series with the updated 2024–2025 Formula Pfizer-BioNTech COVID-19 Vaccine for ages 6 months through 4 years, 0.3 mL/3 mcg (as per the FDA EUA).

**Table 1C: Immunocompetent Individuals Ages 12 years and older**

COVID-19 Vaccination History Prior to Updated (2024-2025 Formula) Vaccine†§	Updated (2024-2025 Formula) Vaccine	Number of Updated (2024-2025 Formula) Vaccine Doses Indicated	Dosage (mL/mcg)	Interval Between Doses
Unvaccinated	Moderna	1§	0.5 mL/ 50 mcg	-
	OR			
	Novavax	2§	0.5 mL/ 5 mcg rS protein and 50 mcg Matrix-M adjuvant	Dose 1 and Dose 2: 3-8 weeks‡
	OR			
1 or more doses any mRNA; 1 or more doses Novavax or Janssen, including in combination with any Original monovalent or bivalent COVID-19 vaccine doses	Pfizer-BioNTech	1	0.3 mL/ 30 mcg	-
	Moderna	1	0.5 mL/ 50 mcg	At least 8 weeks after last dose
	OR			
	Novavax	1	0.5 mL/ 5 mcg rS protein and 50 mcg Matrix-M adjuvant	At least 8 weeks after last dose
OR				

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	Pfizer-BioNTech	1	0.3 mL/ 30 mcg	At least 8 weeks after last dose
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†COVID-19 vaccination history refers to previous receipt of doses of Original monovalent mRNA or bivalent mRNA vaccine or a combination of the two; for people ages 12 years and older, original monovalent Novavax COVID-19 Vaccine doses, alone or in combination with any mRNA vaccine doses; and for people ages 18 years and older, Janssen COVID-19 Vaccine doses, alone or in combination with any mRNA or Original monovalent Novavax vaccine doses.

‡ An [8-week interval](#) between the first and second COVID-19 vaccine doses (Moderna, Novavax, and Pfizer-BioNTech) might be optimal for some people as it might reduce the small risk of myocarditis and pericarditis associated with these vaccines.

¶The updated 2024-2025 formula Moderna and Pfizer-BioNTech COVID-19 vaccines are also available in a prefilled, single-dose syringe for individuals 12 years and older.

§ People ages 65 years and older are **recommended** to receive 2 doses of any 2024–2025 COVID-19 vaccine (i.e., Moderna, Novavax, or Pfizer-BioNTech) separated by 6 months (minimum interval 2 months) regardless of vaccination history, with one exception: Unvaccinated people who initiate vaccination with 2024–2025 Novavax COVID-19 Vaccine are recommended to receive 2 doses of Novavax followed by a third dose of any 2024-2025 COVID-19 vaccine 6 months (minimum interval 2 months) later<sup>7</sup>.

### B. Vaccine Schedule for Individuals with Moderately or Severely Immunocompromising Conditions

**Table 2A: Age 6 months through 4 years with Moderately or Severely Immunocompromising Conditions\***

\*See Section 4B for list of immunocompromising conditions.

*Note - The [PREP Act, 12<sup>th</sup> Amendment](#) allows pharmacists to administer COVID-19 vaccines to persons aged 3 through 18 years old through 12/31/2029. Otherwise, pharmacists are only permitted to vaccinate persons ≥ 7 years per ORS 689.645.*

COVID-19 Vaccination History Prior to Updated (2024-2025 Formula) Vaccine†	Updated (2024-2025 Formula) Vaccine	Number of Updated (2024- 2025 Formula) Vaccine Doses Indicated‡	Dosage (mL/mcg)	Interval Between Doses
Unvaccinated	Moderna	3	0.25 mL/ 25 mcg	Dose 1 and Dose 2: 4 weeks  Dose 2 and Dose 3: At least 4 weeks
	OR			
	Pfizer-BioNTech	3	0.3 mL/ 3 mcg	Dose 1 and Dose 2: 3 weeks  Dose 2 and Dose 3: At least 8 weeks

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1 dose any Moderna	Moderna	2	0.25 mL/ 25 mcg	Dose 1: 4 weeks after last dose  Dose 1 and Dose 2: At least 4 weeks
2 doses any Moderna	Moderna	1	0.25 mL/ 25 mcg	At least 4 weeks after last dose
3 or more doses any Moderna	Moderna	1	0.25 mL/ 25 mcg	At least 8 weeks after last dose
1 dose any Pfizer-BioNTech	Pfizer-BioNTech	2	0.3 mL/ 3 mcg	Dose 1: 3 weeks after last dose Dose 1 and Dose 2: At least 8 weeks
2 doses any Pfizer-BioNTech	Pfizer-BioNTech	1	0.3 mL/ 3 mcg	At least 8 weeks after last dose
3 or more doses any Pfizer BioNTech	Pfizer-BioNTech	1	0.3 mL/ 3 mcg	At least 8 weeks after last dose

†COVID-19 vaccination history refers to previous receipt of doses of Original monovalent mRNA or bivalent mRNA vaccine or a combination of the two.

¥ Recommendations for children ages 6 months through 4 years who are moderately or severely immunocompromised: <sup>7,8</sup>

- **Unvaccinated:** A multidose initial series with an age-appropriate 2024-2025 COVID-19 vaccine followed by 1 dose 6 months (minimum interval 2 months) after completion of the initial series; may receive additional doses via shared clinical decision-making, administered at least 2 months after the last updated 2024–2025 mRNA vaccine dose.
- **Previously completed the multidose initial series:** 2 age-appropriate doses of 2024–2025 COVID-19 vaccine 6 months (minimum interval 2 months) apart. May receive additional doses via shared clinical decision-making, administered at least 2 months after the last updated 2024–2025 mRNA vaccine dose.
- **Additional doses (i.e., 3 or more doses)** of 2024-2025 COVID-19 vaccine may be administered via shared clinical decision-making, at least 2 months after the last updated 2024-2024 COVID-19 vaccine dose.

**Pfizer-BioNTech series:** Children are recommended to receive an updated 2024–2025 Pfizer-BioNTech COVID-19 Vaccine, 0.3 mL/10 mcg for all doses received on or after turning age 5 years. Alternatively, they may complete the 3-dose series with updated 2024–2025 Pfizer-BioNTech COVID-19 Vaccine for ages 6 months through 4 years, 0.3 mL/3 mcg

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**Table 2B: Ages 5 through 11 years with Moderately or Severely Immunocompromising Conditions \***

\*See Section 4B for list of immunocompromising conditions.

*Note - The [PREP Act, 12<sup>th</sup> Amendment](#) allows pharmacists to administer COVID-19 vaccines to persons aged 3 through 18 years old through 12/31/2029. Otherwise, pharmacists are only permitted to vaccinate persons ≥ 7 years per ORS 689.645.*

COVID-19 Vaccination History Prior to Updated (2024-2025 Formula) Vaccine†	Updated (2024-2025 Formula) Vaccine	Number of Updated (2024-2025 Formula) Vaccine Doses Indicated±	Dosage (mL/mcg)	Interval Between Doses
Unvaccinated	Moderna	3	0.25 mL/ 25mcg	Dose 1 and Dose 2: 4 weeks  Dose 2 and Dose 3: At least 4 weeks
	OR			
	Pfizer-BioNTech	3	0.3 mL/ 10 mcg	Dose 1 and Dose 2: 3 weeks  Dose 2 and Dose 3: At least 4 weeks
1 dose any Moderna	Moderna	2	0.25 mL/ 25 mcg	Dose 1: 4 weeks after last dose  Dose 1 and Dose 2: At least 4 weeks
2 doses any Moderna	Moderna	1	0.25 mL/ 25 mcg	At least 4 weeks after last dose
1 dose any Pfizer-BioNTech	Pfizer-BioNTech	2	0.3 mL/ 10 mcg	Dose 1: 3 weeks after last dose  Dose 1 and Dose 2: At least 4 weeks
2 doses any Pfizer-BioNTech	Pfizer-BioNTech	1	0.3 mL/ 10 mcg	At least 4 weeks after last dose

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3 or more doses any mRNA vaccine	Moderna	1	0.25 mL/ 25 mcg	At least 8 weeks after last dose
	OR			
	Pfizer-BioNTech	1	0.3 mL/ 10 mcg	At least 8 weeks after last dose

†COVID-19 vaccination history refers to previous receipt of doses of Original monovalent mRNA or bivalent mRNA vaccine or a combination of the two.

± Recommendations for children ages 5 through 11 years who are moderately or severely immunocompromised :<sup>7,8</sup>

- **Unvaccinated:** A multidose initial series with an age-appropriate 2024-2025 COVID-19 vaccine followed by 1 dose 6 months (minimum interval 2 months) after completion of the initial series; may receive additional doses via shared clinical decision-making, administered at least 2 months after the last updated 2024–2025 mRNA vaccine dose.
- **Previously completed the multidose initial series:** 2 age-appropriate doses of 2024–2025 COVID-19 vaccine 6 months (minimum interval 2 months) apart. May receive additional doses via shared clinical decision-making, administered at least 2 months after the last updated 2024–2025 mRNA vaccine dose.
- **Additional doses (i.e., 3 or more doses)** of 2024-2025 COVID-19 vaccine may be administered via shared clinical decision-making, at least 2 months after the last updated 2024-2024 COVID-19 vaccine dose.

\* For children who transition from age 4 years to age 5 years during the initial vaccination series:

- **Moderna series:** Children are recommended to receive an updated 2024–2025 Moderna COVID-19 Vaccine, 0.25 mL/25 mcg for all doses.
- **Pfizer-BioNTech series:** Children are recommended to receive an updated 2024–2025 Pfizer-BioNTech COVID-19 Vaccine, 0.3 mL/10 mcg for all doses received on or after turning age 5 years. Alternatively, they may complete the 3-dose series with updated 2024–2025 Pfizer-BioNTech COVID-19 Vaccine for ages 6 months–4 years, 0.3 mL/3 mcg (yellow cap; yellow label).

**Table 2C: Ages 12 years and older with Moderately or Severely Immunocompromising Conditions \***

\* See Section 4B for list of immunocompromising conditions.

COVID-19 Vaccination History Prior to Updated (2024-2025 Formula) Vaccine†	Updated (2024-2025 Formula) Vaccine	Number of Updated (2024-2025 Formula) Vaccine Doses Indicated‡§	Dosage (mL/mcg)	Interval Between Doses
Unvaccinated	Moderna	3	0.5 mL/ 50 mcg	Dose 1 and Dose 2: 4 weeks  Dose 2 and Dose 3: At least 4 weeks
	OR			
	Novavax	2	0.5 mL/ 5 mcg rS protein and 50 mcg	Dose 1 and Dose 2: 3 weeks

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			Matrix-M adjuvant	
	OR			
	Pfizer-BioNTech	3	0.3 mL/ 30 mcg	Dose 1 and Dose 2: 3 weeks  Dose 2 and Dose 3: At least 4 weeks
1 dose any Moderna	Moderna	2	0.5 mL/ 50 mcg	Dose 1: 4 weeks after last dose  Dose 1 and Dose 2: At least 4 weeks
2 doses any Moderna	Moderna	1	0.5 mL/ 50 mcg	At least 4 weeks after last dose
1 dose any Pfizer-BioNTech	Pfizer-BioNTech	2	0.3 mL/ 30 mcg	Dose 1: 3 weeks after last dose  Dose 1 and Dose 2: At least 4 weeks
2 doses any Pfizer-BioNTech	Pfizer-BioNTech	1	0.3 mL/ 30 mcg	At least 4 weeks after last dose
3 or more doses any mRNA vaccine	Moderna	1	0.5 mL/ 50 mcg	At least 8 weeks after last dose
	OR			
	Novavax	1	0.5 mL/ 5 mcg rS protein and 50 mcg Matrix-M adjuvant	At least 8 weeks after last dose
	OR			
	Pfizer-BioNTech	1	0.3 mL/ 30 mcg	At least 8 weeks after last dose



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1 or more doses Novavax or Janssen, including in combination with any Original monovalent or bivalent COVID-19 vaccine doses	Moderna	1	0.5 mL/ 50 mcg	At least 8 weeks after last dose
	OR			
	Novavax	1	0.5 mL/ 5 mcg rS protein and 50 mcg Matrix-M adjuvant	At least 8 weeks after last dose
	OR			
	Pfizer-BioNTech	1	0.3 mL/ 30 mcg	At least 8 weeks after last dose

†COVID-19 vaccination history refers to previous receipt of doses of original monovalent mRNA or bivalent mRNA vaccine or a combination of the two; for people ages 12 years and older, original monovalent Novavax COVID-19 Vaccine doses, alone or in combination with any mRNA vaccine doses; and for people ages 18 years and older, Janssen COVID-19 Vaccine doses, alone or in combination with any mRNA or original monovalent Novavax vaccine doses.

‡Apart from the administration of additional doses, the FDA EUA for the updated 2024–2025 Novavax COVID-19 vaccine does not provide for a specific vaccination schedule for people who are moderately or severely immunocompromised.

§ Recommendations for people 12 years of age and older who are moderately or severely immunocompromised: <sup>7,8</sup>

- **Unvaccinated:** A multidose initial series with an age-appropriate COVID-19 vaccine and 1 dose 6 months (minimum interval 2 months) after completion of the initial series; may receive additional doses via shared clinical decision-making, administered at least 2 months after the last updated 2024–2025 mRNA vaccine dose.
- **Previously completed the multidose initial series:** 2 age-appropriate doses of 2024–2025 COVID-19 vaccine 6 months (minimum interval 2 months) apart. May receive additional doses via shared clinical decision-making, administered at least 2 months after the last updated 2024–2025 mRNA vaccine dose
- **Additional Doses** of 2024–2025 COVID-19 vaccine may be administered via shared clinical decision-making, at least 2 months after the last updated 2024–2024 COVID-19 vaccine dose.

¶ The updated 2024–2025 Moderna and Pfizer-BioNTech COVID-19 vaccines are also available in a prefilled, single-dose syringe for people ages 12 years and older.

\*For children who transition from age 11 years to age 12 years during the initial vaccination series:

- **Moderna series:** Children are recommended to receive an updated 2024–2025 Moderna COVID-19 Vaccine, 0.5 mL/50 mcg for all doses received on or after turning age 12 years. Alternatively, they may complete the 3-dose series with an updated 2024–2025 Moderna COVID-19 Vaccine for children ages 5 through 11 years, 0.25 mL/25 mcg.
- **Pfizer-BioNTech series:** Children are recommended to receive an updated 2024–2025 Formula Pfizer-BioNTech COVID-19 Vaccine, 0.3 mL/30 mcg for all doses received on or after turning age 12 years. Alternatively, they may complete the 3-dose series with an updated 2024–2025 Pfizer-BioNTech COVID-19 Vaccine for children ages 5–11 years, 0.3 mL/10 mcg).

#### 4) Additional Considerations for Use <sup>7-9</sup>

##### A) Shared clinical decision-making:

- i) Unlike routine, catch-up, and risk-based recommendations, shared clinical decision-making vaccinations are not recommended for everyone in a particular age group or everyone in an identifiable risk group. Rather, shared clinical decision-making

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recommendations are individually based and informed by a decision process between the health care provider and the patient or parent/guardian.

- ii) For shared clinical decision-making recommendations, there is no default—the decision about whether or not to vaccinate may be informed by the best available evidence of who may benefit from vaccination; the individual’s characteristics, values, and preferences; the health care provider’s clinical discretion; and the characteristics of the vaccine being considered.
- iii) Generally, ACIP makes shared clinical decision-making recommendations when individuals may benefit from vaccination, but broad vaccination of people in that group is unlikely to have population-level impacts.
- iv) See link in Reference #9 for guidance document.

### B) Considerations for Immunocompetent Individuals:

- i) The **extended interval** consideration applies only to the following people who are not moderately or severely immunocompromised:
  - Ages 6 months through 4 years, depending on their vaccination history
  - Ages 12 years through 64 years and receiving a 2-dose Novavax series
- ii) The **minimum interval** between the first and second doses continues to be recommended for:
  - People who are moderately or severely immunocompromised
  - People ages 65 years and older receiving Novavax vaccine
  - Situations when the fullest possible protection needs to be achieved sooner (e.g., increased concern about an individual’s higher risk for severe disease)

### C) Considerations for Individuals with Moderately or Severely Immunocompromising Conditions:

- i) A **second dose** of 2024-2025 COVID-19 vaccine is recommended for people ages 6 months through 64 years who are moderately or severely immunocompromised
- ii) If **previously unvaccinated and receiving Novavax**, 2 doses are recommended as initial vaccination series followed by a third dose of any age-appropriate 2024-2025 COVID-19 vaccine 6 months (minimum interval 2 months) after second dose.
- iii) **Additional doses** (i.e., 3 or more doses) of 2024-2025 COVID-19 vaccine for people ages 6 months and older who are moderately or severely immunocompromised may be administered via shared clinical decision-making, at least 2 months after the last 2024-2025 COVID-19 vaccine dose.
- iv) **Conditions causing moderate to severe immunodeficiency include<sup>‡</sup>:**
  - Active treatment for solid tumor and hematologic malignancies
  - Receipt of solid-organ transplant and taking immunosuppressive therapy
  - Receipt of Chimeric antigen receptor (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)

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- Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm<sup>3</sup>, 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

‡ Individuals with immunocompromising conditions not listed above may receive subsequent vaccination doses with a prescription from a healthcare provider.

### **D) Miscellaneous Considerations <sup>7,8</sup>:**

- i) Individuals 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.
- ii) Individuals who received monoclonal antibodies or convalescent plasma during COVID-19 treatment may be vaccinated as soon as their symptoms have resolved.
- iii) Individuals 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.
- iv) Individuals 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.
- v) Ask patient to remain seated in the clinic for 15 minutes after vaccination to decrease the risk of injury should they faint. Individuals with a history of severe allergic reactions should be asked to remain for 30 minutes.
- vi) CDC recommends that vaccine for children aged 5 through 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 individuals that the risk of reinfection, and therefore the potential benefit from vaccination, may increase with time following initial infection.

### **5) Pregnancy and Lactation <sup>7,8</sup>**

- A) 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.

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- B) 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.

### **6) Warnings and Precautions <sup>7</sup>**

- 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.
- C) Moderate or severe acute illness.
- D) Development of myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine is a precaution to a subsequent dose of any COVID-19 vaccine, and subsequent doses should generally be avoided.

### **7) Contraindications**

- A) Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.<sup>1-5</sup>
- B) See current prescribing information for more details about formulation and contents.

### **8) Storage and Handling**

- A) Store medications according to [OAR 855-041-1036](#).
- B) See current prescribing information for more details about storage and handling.
- C) All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

### **9) References**

1. Pfizer-BioNTech COVID-19 Vaccine, 2024–2025 formulation. Emergency use authorization (EUA) fact sheet, 11 Sep 2023. Available at: <https://www.fda.gov/media/167211/download>.
2. Moderna COVID-19 vaccine, 2024–2025 formulation. Emergency use authorization (EUA) fact sheet and prescribing information, 11 Sep 2023. Available at: <https://www.fda.gov/media/167208/download>.
3. Pfizer-BioNTech Comirnaty, 2024-2025 formulation. Package insert, August 2024. Available at: <https://www.fda.gov/media/151707/download>.
4. Moderna Spikevax, 2024-2025 formulation. Package insert, August 2024. Available at: <https://www.fda.gov/media/155675/download>.
5. Novavax, Inc. Full emergency use authorization (EUA) prescribing information, 3 Oct 2023. Available at: <https://www.fda.gov/media/159897/download>.

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6. Centers for Disease Control and Prevention (2024, August 29). ACIP Vaccine Recommendations and Schedules. Centers for Disease Control and Prevention. Available at: <https://www.cdc.gov/acip/vaccine-recommendations/index.html>.
7. Interim clinical considerations for use of COVID-19 vaccines in the United States, October 31, 2024. Available at: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html>
8. Centers for Disease Control and Prevention. Advisory Committee on Immunization Practices (ACIP) Vaccine Recommendations. August 29, 2024. Available at: <https://www.cdc.gov/acip/vaccine-recommendations/index.html>.
9. Centers for Disease Control and Prevention. Advisory Committee on Immunization Practices (ACIP) Shared Clinical Decision-Making Recommendations. Available at: <https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html>

### **10) Appendix**

- A) COVID-19 vaccination schedule for people who are not moderately or severely immunocompromised by COVID-19 vaccination history, April 2024: <https://www.cdc.gov/vaccines/covid-19/downloads/covid-19-immunization-schedule-ages-6months-older.pdf>