#### 1. What's New

- A. Individuals ≥ 65 years and older should receive an additional dose of the 2023-2024 COVID-19 vaccine (Moderna, Novavax, or Pfizer-BioNTech) at least four months after the receipt of a previous 2023-2024 COVID-19 dose.
- B. There is a new formulation of COVID-19 Vaccine (Comirnaty by Pfizer-BioNTech) that is supplied in a pre-filled single dose glass syringe. The glass syringe is stored in the refrigerator and cannot be frozen.
- C. ACIP no longer categorizes Pfizer and Moderna as preferred Coronavirus 19 (COVID-19) vaccines for the 2023-2024 season. Individuals ages 12 years and older may receive either the 2023-2024 mRNA (Moderna or Pfizer-BioNTech) or the 2023-2024 adjuvanted (Novavax) vaccine, as appropriate.

#### 2. Immunization Protocol

- A. Administer one or more doses of the updated 2023–2024 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 based on age and vaccine formulation. 1-6
- 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>1-6</sup>

### A. <u>Vaccine Schedule for Immunocompetent Individuals</u>

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

Note - The PREP Act,  $11^{th}$  Amendment allows pharmacists to administer COVID-19 vaccines to persons aged 3 through 18 years old through 12/31/2024. Otherwise, pharmacists are only permitted to vaccinate persons  $\geq$  7 years per ORS 689.645.

COVID-19 Vaccination History Prior to Updated (2023-2024 Formula) Vaccine†	Updated (2023-2024 Formula) Vaccine	Number of Updated (2023- 2024 Formula) Vaccine Doses Indicated	Dosage (mL/mcg)	Vaccine Vial Cap and Label Colors	Interval Between Doses
	Moderna	2	0.25 mL/ 25 mcg	Dark blue cap; Green label	Dose 1 and Dose 2: 4-8 weeks‡
		(	OR		
Unvaccinated	Pfizer-BioNTech	3	0.3 mL/ 3 mcg	Yellow cap; Yellow label	Dose 1 and Dose 2: 3-8 weeks‡  Dose 2 and Dose 3: At least 8 weeks
1 dose any Moderna	Moderna	1	0.25 mL/ 25 mcg	Dark blue cap; Green label	4-8 weeks after last dose‡

2 or more doses any Moderna	Moderna	1	0.25 mL/ 25 mcg	Dark blue cap; Green label	At least 8 weeks after last dose
1 dose any Pfizer- BioNTech	Pfizer-BioNTech	2	0.3 mL/ 3 mcg	Yellow cap; Yellow label	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	Yellow cap; Yellow label	At least 8 weeks after last dose
3 or more doses any Pfizer-BioNTech	Pfizer-BioNTech	1	0.3 mL/ 3 mcg	Yellow cap; Yellow label	At least 8 weeks after last dose

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

- 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§

Note - The <u>PREP Act, 11<sup>th</sup> Amendment</u> allows pharmacists to administer COVID-19 vaccines to persons aged 3 through 18 years old through 12/31/2024. Otherwise, pharmacists are only permitted to vaccinate persons  $\geq$  7 years per ORS 689.645.

COVID-19 Vaccination History Prior to Updated (2023-2024 Formula) Vaccine†	Updated (2023-2024 Formula) Vaccine	Number of Updated (2023- 2024 Formula) Vaccine Doses Indicated	Dosage (mL/mcg)	Vaccine Vial Cap and Label Colors	Interval Between Doses
Unvaccinated	Moderna	1	0.25 mL/ 25 mcg	Dark blue cap; Green label	-
Univaccinated	OR				
	Pfizer-BioNTech	1	0.3 mL/ 10 mcg	Blue cap; Blue label	-
1 or more doses any	Moderna	1	0.25 mL/ 25 mcg	Dark blue cap; Green label	At least 8 weeks after last dose
· ·	OR				
mRNA	Pfizer-BioNTech	1	0.3 mL/ 10 mcg	Blue cap; Blue label	At least 8 weeks after last dose

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

<sup>\*</sup>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:

§ 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 2023–2024 Formula Moderna COVID-19 Vaccine, 0.25 mL/25 mcg (dark blue cap; green label), 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—4 years, 0.3 mL/3 mcg (yellow cap; yellow label) are recommended to receive 1 dose of the updated 2023—2024 Formula Pfizer-BioNTech COVID-19 Vaccine, 0.3 mL/10 mcg (blue cap; blue label) 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 2023—2024 Formula Pfizer-BioNTech COVID-19 Vaccine for ages 6 months—4 years, 0.3 mL/3 mcg (yellow cap; yellow label), as per the FDA EUA.

Table 1C: Immunocompetent Individuals Ages 12 years and older

COVID-19 Vaccination History Prior to Updated (2023-2024 Formula) Vaccine†	Updated (2023-2024 Formula) Vaccine	Number of Updated (2023- 2024 Formula) Vaccine Doses Indicated	Dosage (mL/mcg)	Vaccine Vial Cap and Label Colors¶	Interval Between Doses		
	Moderna	1	0.5 mL/ 50 mcg	Dark blue cap; Blue label	-		
			OR				
Unvaccinated	Novavax	2	0.5 mL/ 5 mcg rS protein and 50 mcg Matrix-M adjuvant	Blue cap; Blue label	Dose 1 and Dose 2: 3-8 weeks‡		
	OR						
	Pfizer-BioNTech	1	0.3 mL/ 30 mcg	Gray cap; gray label	-		
	Moderna	1	0.50 mL/ 50 mcg	Dark blue cap; Blue label	At least 8 weeks after last dose		
1 or more doses any		(	OR				
mRNA; 1 or more doses Novavax or Janssen, including in combination with any Original monovalent or	Novavax	1	0.5 mL/ 5 mcg rS protein and 50 mcg Matrix-M adjuvant	Blue cap; Blue label	At least 8 weeks after last dose		
bivalent COVID-19			OR				
vaccine doses	Pfizer-BioNTech	1	0.3 mL/ 30 mcg	Gray cap; Gray label	At least 8 weeks after last dose		

People ages 65 years and older should receive 1 additional dose of any updated (2023-2024 Formula) COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech) at least 4 months following the last recommended dose of updated 2023-2024 COVID-19 vaccine. For initial vaccination with updated 2023-2024 Formula Novavax COVID-19 vaccine, the 2-dose series should be completed before administration of the additional dose. If Moderna is used, administer 0.5 mL/50 mcg; if Novavax is used, administer 0.5 mL/5 mcg rS protein and 50 mcg Matrix-M adjuvant; if Pfizer-BioNTech is used, administer 0.3 mL/30 mcg.

†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 <u>8-week interval</u> between the first and second COVID-19 vaccine (Moderna, Novavax, and Pfizer-BioNTech) doses might be optimal for some people as it might reduce the small risk of myocarditis and pericarditis associated with these vaccines.

¶The updated 2023-2024 formula Moderna and Pfizer-BioNTech COVID-19 vaccines are also available in a prefilled, single-dose syringe for individuals 12 years and older.

#### 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<sup>\*</sup>

See section 5a for list of immunocompromising conditions.

Note - The <u>PREP Act, 11<sup>th</sup> Amendment</u> allows pharmacists to administer COVID-19 vaccines to persons aged 3 through 18 years old through 12/31/2024. Otherwise, pharmacists are only permitted to vaccinate persons  $\geq$  7 years per ORS 689.645.

COVID-19 Vaccination History Prior to Updated (2023-2024 Formula) Vaccine†	Updated (2023-2024 Formula) Vaccine	Number of Updated (2023- 2024 Formula) Vaccine Doses Indicated¥	Dosage (mL/mcg)	Vaccine Vial Cap and Label Colors	Interval Between Doses
	Moderna	3	0.25 mL/ 25 mcg	Dark blue cap; Green label	Dose 1 and Dose 2: 4 weeks  Dose 2 and Dose 3: At least 4 weeks
Unvaccinated			OR		
	Pfizer-BioNTech	3	0.3 mL/ 3 mcg	Yellow cap; Yellow label	Dose 1 and Dose 2: 3 weeks  Dose 2 and Dose 3: At least 8 weeks
1 dose any Moderna	Moderna	2	0.25 mL/ 25 mcg	Dark blue cap; Green label	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	Dark blue cap; Green label	At least 4 weeks after last dose
3 or more doses any Moderna	Moderna	1	0.25 mL/ 25 mcg	Dark blue cap; Green label	At least 8 weeks after last dose

1 dose any Pfizer- BioNTech	Pfizer-BioNTech	2	0.3 mL/ 3 mcg	Yellow cap; Yellow label	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	Yellow cap; Yellow label	At least 8 weeks after last dose
3 or more doses any Pfizer BioNTech	Pfizer-BioNTech	1	0.3 mL/ 3 mcg	Yellow cap; Yellow label	At least 8 weeks after last dose

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

- ¥Children ages 6 months through 4 years who are moderately or severely immunocompromised may receive 1 additional dose of a homologous updated 2023–2024 Formula mRNA vaccine at least 2 months after the last updated 2023–2024 mRNA vaccine dose. Further additional homologous updated 2023–2024 mRNA dose(s) may be administered by a pharmacist with a prescription issued by a healthcare provider. Any further additional doses should be administered at least 2 months after the last updated 2023–2024 mRNA vaccine dose. For Moderna, administer 0.25 mL/25 mcg (dark blue cap; green label); for Pfizer-BioNTech, administer 0.3 mL/3 mcg (dark blue cap; green label) for all doses.
- Pfizer-BioNTech series: Children are recommended to receive an updated 2023—2024 Pfizer-BioNTech COVID-19 Vaccine, 0.3 mL/10 mcg (blue cap; blue label) for all doses received on or after turning age 5 years.
   Alternatively, they may complete the 3-dose series with updated 2023—2024 Pfizer-BioNTech COVID-19 Vaccine for ages 6 months—4 years, 0.3 mL/3 mcg (yellow cap; yellow label).

Table 2B: Ages 5 through 11 years with Moderately or Severely Immunocompromising Conditions \*
See section 5a for list of immunocompromising conditions.

Note - The <u>PREP Act, 11<sup>th</sup> Amendment</u> allows pharmacists to administer COVID-19 vaccines to persons aged 3 through 18 years old through 12/31/2024. Otherwise, pharmacists are only permitted to vaccinate persons  $\geq$  7 years per ORS 689.645.

COVID-19 Vaccination History Prior to Updated (2023-2024 Formula) Vaccine†	Updated (2023-2024 Formula) Vaccine	Number of Updated (2023- 2024 Formula) Vaccine Doses Indicated±	Dosage (mL/mcg)	Vaccine Vial Cap and Label Colors	Interval Between Doses
	Moderna	3	0.25 mL/ 25mcg	Dark blue cap; Green label	Dose 1 and Dose 2: 4 weeks  Dose 2 and Dose 3: At least 4 weeks
Unvaccinated		ı	OR		
	Pfizer-BioNTech	3	0.3 mL/ 10 mcg	Blue cap; Blue label	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	Dark blue cap; Green label	Dose 1: 4 weeks after last dose  Dose 1 and Dose 2: At least 4
2 doses any Moderna	Moderna	1	0.25 mL/ 25 mcg	Dark blue cap; Green label	weeks At least 4 weeks after last dose
1 dose any Pfizer- BioNTech	Pfizer-BioNTech	2	0.3 mL/ 10 mcg	Blue cap; Blue label	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	Blue cap; Blue label	At least 4 weeks after last dose
3 or more doses any	Moderna	1	0.25 mL/ 25 mcg	Dark blue cap; Green label	At least 8 weeks after last dose
mRNA vaccine			OR		At least 8
	Pfizer-BioNTech	1	0.3 mL/ 10 mcg	Blue cap; Blue label	weeks after last dose

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

±Children ages 5–11 years who are moderately or severely immunocompromised may receive 1 additional dose of updated 2023–2024 Moderna COVID-19 Vaccine, 0.25mL/25 mcg (dark blue cap; green label) or updated 2023–2024 Pfizer-BioNTech COVID-19 Vaccine, 0.3 mL/10 mcg (blue cap; blue label) at least 2 months after the last updated 2023–2024 mRNA vaccine dose indicated in Table 2B. Further additional dose(s) may be administered by a pharmacist with a prescription issued by a healthcare provider. Any further additional doses should be administered at least 2 months after the last updated (2023–2024 Formula) mRNA vaccine dose.

- Moderna series: Children are recommended to receive an updated 2023—2024 Moderna COVID-19 Vaccine,
   0.25 mL/25 mcg (dark blue cap; green label) for all doses.
- Pfizer-BioNTech series: Children are recommended to receive an updated 2023—2024 Pfizer-BioNTech COVID-19 Vaccine, 0.3 mL/10 mcg (blue cap; blue label) for all doses received on or after turning age 5 years.
   Alternatively, they may complete the 3-dose series with updated 2023—2024 Pfizer-BioNTech COVID-19 Vaccine for ages 6 months—4 years, 0.3 mL/3 mcg (yellow cap; yellow label).

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

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

See section 5a for list of immunocompromising conditions.

	munocompromising condi				
COVID-19 Vaccination History Prior to Updated (2023-2024 Formula) Vaccine†	Updated (2023-2024 Formula) Vaccine	Number of Updated (2023- 2024 Formula) Vaccine Doses Indicated‡§	Dosage (mL/mcg)	Vaccine Vial Cap and Label Colors¶	Interval Between Doses
	Moderna	3	0.5 mL/ 50 mcg	Dark blue cap; Blue label	Dose 1 and Dose 2: 4 weeks  Dose 2 and Dose 3: At least 4 weeks
			OR		
Unvaccinated	Novavax	2	0.5 mL/ 5 mcg rS protein and 50 mcg Matrix-M adjuvant	Blue cap; Blue label	Dose 1 and Dose 2: 3 weeks
			OR		
	Pfizer-BioNTech	3	0.3 mL/ 30 mcg	Gray cap; Gray label	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	Dark blue cap; Blue label	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	Dark blue cap; Blue label	At least 4 weeks after last dose
1 dose any Pfizer- BioNTech	Pfizer-BioNTech	2	0.3 mL/ 30 mcg	Gray cap; Gray label	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	Gray cap; Gray label	At least 4 weeks after last dose

3 or more doses any mRNA vaccine	Moderna	1	0.5 mL/ 50 mcg	Dark blue cap; Blue label	At least 8 weeks after last dose	
	Novavax	1	0.5 mL/ 5 mcg rS protein and 50 mcg Matrix-M adjuvant	Blue cap; Blue label	At least 8 weeks after last dose	
			OR			
	Pfizer-BioNTech	1	0.3 mL/ 30 mcg	Gray cap; Gray label	At least 8 weeks after last dose	
	Moderna	1	0.5 mL/ 50 mcg	Dark blue cap; Blue label	At least 8 weeks after last dose	
1 or more doses	OR					
Novavax or Janssen, including in combination with any Original monovalent or bivalent COVID-19 vaccine doses	Novavax	1	0.5 mL/ 5 mcg rS protein and 50 mcg Matrix-M adjuvant	Blue cap; Blue label	At least 8 weeks after last dose	
	OR					
	Pfizer-BioNTech	1	0.3 mL/ 30 mcg	Gray cap; Gray label	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 2023–2024 Novavax COVID-19 vaccine does not provide for a specific vaccination schedule for people who are moderately or severely immunocompromised. People ages 12 years and older who are moderately or severely immunocompromised have the option to receive 1 additional dose of an updated 2023–2024 Moderna COVID-19 Vaccine, 0.5 mL/50 mcg (dark blue cap; blue label), an updated 2023–2024 Novavax COVID-19 Vaccine; or an updated 2023–2024 Pfizer-BioNTech COVID-19 Vaccine, 0.3 mL/30 mcg (gray cap; gray label) at least 2 months following the last recommended updated 2023–2024 vaccine dose. Further additional dose(s) may be administered by a pharmacist with a prescription issued by a healthcare provider. Any further additional doses should be administered at least 2 months after the last updated 2023–2024 COVID-19 vaccine dose.

§Administration of additional doses is as follows:

- People ages 12–64 years who are moderately or severely immunocompromised may receive 1 additional dose of any updated 2023–2024 COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech) at least 2 months after the last dose of an updated 2023–2024 COVID-19 vaccine as indicated in Table 2C. Pharmacist may administer further additional dose(s) with a prescription issued by a healthcare provider. Any further additional doses should be administered at least 2 months after the last updated 2023–2024 COVID-19 vaccine dose.
- People ages 65 years and older who are moderately or severely immunocompromised should receive 1 additional dose of any updated 2023–2024 COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech) at least 2 months after the last dose of an updated 2023–2024 vaccine as indicated in Table 2C. Pharmacist may administer further additional dose(s) with a prescription issued by a healthcare provider. Any further additional doses should be administered at least 2 months after the last updated 2023–2024 COVID-19 vaccine dose.

• For all age groups, the dosage for the additional doses is as follows: Moderna, 0.5 mL/50 ug; Novavax, 0.5 mL/5 mcg rS protein and 50 mcg Matrix-M adjuvant; Pfizer-BioNTech, 0.3 mL/30 ug.

¶ The updated 2023—2024 Moderna and Pfizer-BioNTech COVID-19 vaccines are also available in a prefilled, single-dose syringe for people ages 12 years and older.

- Moderna series: Children are recommended to receive an updated 2023–2024 Moderna COVID-19 Vaccine, 0.5 mL/50mcg (dark blue cap; blue label) for all doses received on or after turning age 12 years. Alternatively, they may complete the 3-dose series with an updated 2023–2024 Moderna COVID-19 Vaccine for children ages 5–11 years, 0.25 mL/25mcg (dark blue cap; green label).
- Pfizer-BioNTech series: Children are recommended to receive an updated 2023—2024 Formula Pfizer-BioNTech COVID-19 Vaccine, 0.3 mL/30 mcg (gray cap; gray label) for all doses received on or after turning age 12 years.
   Alternatively, they may complete the 3-dose series with an updated 2023—2024 Pfizer-BioNTech COVID-19 Vaccine for children ages 5–11 years, 0.3 mL/10 mcg (blue cap; blue label).

#### 4. Licensed Vaccines

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Cap/Label Color
Pfizer-BioNTech 2023- 2024 formulation <sup>1</sup>	mRNA	0.9 mL, 3 dose vial 0.3 mL, single dose vial	3-4 years 5-11 years	Yellow Cap Blue Cap
Pfizer-BioNTech COMIRNATY®³ 2023- 2024 formulation	mRNA	0.3 mL, single dose vial 0.3 mL, prefilled syringe	≥ 12 years	Gray Cap
Moderna 2023-2024 formulation <sup>2</sup>	mRNA	0.25 mL, single dose vial	3-11 years	Blue Cap/Green Label
Moderna SPIKEVAX® 2023-2024 formulation <sup>4</sup>	mRNA	2.5 mL, 5 dose vial 0.5 mL, single dose vial 0.5 mL, prefilled syringe	≥ 12 years	Blue Cap/Blue Label
NVX-CoV2373 <sup>3</sup> (NOVAVAX® 2023-2024 formulation) <sup>5</sup>	Protein subunit	2.5 mL, 5-dose vial	≥ 12 years	Royal Blue Cap

#### 5. Recommendations for Use<sup>1-8</sup>

#### A. Vaccine Schedule for Immunocompetent Individuals

#### Ages 6 months-4 years

- 1. <u>Unvaccinated:</u> 2 or 3 homologous (i.e., from the same manufacturer) updated 2023–2024 mRNA vaccine doses, depending on vaccine manufacturer (i.e., Moderna, Pfizer-BioNTech).
- Previously received an incomplete series of Original monovalent or bivalent mRNA vaccine doses: Complete the vaccination series with 1 or 2 homologous updated 2023–2024 mRNA vaccine doses, depending on vaccine manufacturer and the number of previous vaccine doses.

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

- 3. <u>Previously received all doses in the initial vaccination series with Original monovalent or bivalent</u> mRNA vaccine: 1 homologous updated 2023–2024 mRNA vaccine dose.
- 4. Special situations for children ages 6 months—4 years: COVID-19 vaccine doses from the same manufacturer should be administered whenever recommended. 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.
- 5. The **extended interval** consideration applies only to the following people who are not moderately or severely immunocompromised:
  - Ages 6 months–4 years, depending on their vaccination history
  - Ages 12 years–64 years and receiving a 2-dose Novavax series

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)

### Ages 5-11 years

 Unvaccinated or previously received any number of Original monovalent or bivalent mRNA vaccine doses: 1 dose of an updated 2023–2024 mRNA vaccine from either manufacturer (i.e., Moderna or Pfizer-BioNTech).

#### Ages 12 years and older

- 1. <u>Unvaccinated:</u> 1 dose of an updated 2023–2024 mRNA COVID-19 vaccine (i.e., Moderna, Pfizer-BioNTech) OR 2 doses of the updated 2023–2024 Novavax vaccine.
- 2. <u>Previously received 1 or more Original monovalent or bivalent mRNA vaccine doses:</u> 1 dose of any updated 2023–2024 COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
- 3. Previously received 1 or more doses of Original monovalent Novavax vaccine, alone or in combination with any Original monovalent or bivalent mRNA vaccine doses: 1 dose of any updated 2023–2024 Formula COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
- 4. Previously received 1 or more doses of Janssen vaccine, alone or in combination with any Original monovalent or bivalent mRNA vaccine or Original monovalent Novavax doses: 1 dose of any updated 2023–2024 COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
- 5. Special situation for people ages 65 years and older: People ages 65 years and older should receive 1 additional dose of any updated 2023–2024 COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech) at least 4 months following the previous dose of an updated 2023–2024 COVID-19 vaccine. For initial vaccination with the updated 2023–2024 Novavax COVID-19 Vaccine, the 2-dose series should be completed before administration of the additional dose.
- 6. The **extended interval** consideration applies only to the following people who are not moderately or severely immunocompromised:
  - Ages 6 months–4 years, depending on their vaccination history
  - Ages 12 years–64 years and receiving a 2-dose Novavax series

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)

### a. <u>Vaccine Schedule for Individuals with Moderately or Severely Immunocompromising</u> Conditions

### 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)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm3, history
  of an AIDS-defining illness without immune reconstitution, or clinical manifestations of
  symptomatic HIV)</li>
- 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.

### Ages 6 months through 4 years

- 1. <u>Unvaccinated:</u> 3 homologous (i.e., from the same manufacturer) updated 2023–2024 mRNA vaccine doses (i.e., Moderna, Pfizer-BioNTech).
- Previously received 1 or 2 Original monovalent or bivalent mRNA vaccine doses: Complete
  the 3-dose series with 2 or 1 homologous updated 2023–2024 mRNA vaccine doses,
  respectively.
- 3. <u>Previously received a combined total of 3 or more Original monovalent or bivalent mRNA vaccine doses:</u> 1 dose of a homologous updated 2023–2024 mRNA vaccine.
- 4. <u>Special situations for children ages 6 months–4 years:</u> COVID-19 vaccine doses from the same manufacturer should be administered whenever recommended. 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.

5. <u>Additional doses:</u> May receive 1 or more additional homologous updated 2023–2024 mRNA vaccine doses with a prescription issued by a healthcare provider.

#### Ages 5 through 11 years

- 1. <u>Unvaccinated:</u> 3 homologous (i.e., from the same manufacturer) updated 2023–2024 mRNA vaccine doses (i.e., Moderna, Pfizer-BioNTech).
- Previously received 1 or 2 Original monovalent or bivalent mRNA vaccine doses: Complete
  the 3-dose series with 2 or 1 homologous updated 2023–2024 mRNA vaccine doses,
  respectively.
- 3. <u>Previously received a combined total of 3 or more Original monovalent or bivalent mRNA</u> vaccine doses: 1 dose of an updated 2023–2024 mRNA vaccine from either manufacturer.
- 4. <u>Additional doses:</u> May receive 1 or more additional updated 2023–2024 mRNA vaccine doses from either manufacturer with a prescription issued by a healthcare provider.

### Ages 12 years and older

- Unvaccinated: 3 homologous (i.e., from the same manufacturer) updated 2023–2024 mRNA vaccine doses (i.e., Moderna, Pfizer-BioNTech) OR 2 updated 2023–2024 Novavax vaccine doses.
- Previously received 1 or 2 Original monovalent or bivalent mRNA vaccine doses: Complete
  the 3-dose series with 2 or 1 homologous updated 2023–2024 mRNA vaccine doses,
  respectively.
- 3. Previously received a combined total of 3 or more Original monovalent or bivalent mRNA vaccine doses: 1 dose of any updated 2023–2024 COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
- 4. Previously received 1 or more Original monovalent Novavax vaccine doses, alone or in combination with any Original monovalent or bivalent mRNA vaccine doses: 1 dose of any updated 2023–2024 COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).
- 5. Previously received 1 or more doses of Janssen vaccine, alone or in combination with any Original monovalent or bivalent mRNA vaccine or Original monovalent Novavax doses: 1 dose of any updated 2023–2024 COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech).

#### 6. Additional doses:

- People ages 12–64 years may receive 1 or more additional doses of any updated 2023–2024 COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech) with a prescription issued by a healthcare provider.
- People ages 65 years and older should receive 1 additional dose of any updated 2023-2024 COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech) at least 2 months after receipt of a previous updated 2023-2024 COVID-19 vaccine. Individuals 65 years and older may receive further additional doses of any updated 2023–2024 COVID-19 vaccine (i.e., Moderna, Novavax, Pfizer-BioNTech) with a prescription issued by a healthcare provider.

#### 6. Contraindications

a. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component. 1-5

Vaccine	Contains
Pfizer-BioNtech 2023-2024 formulation <sup>1</sup> (yellow cap and border) <sup>1</sup>	Lipids (0.04 mg ((4-hydroxybutyl)azanediyl)bis(hexane6,1-diyl)bis(2-hexyldecanoate), 0.005 mg 2[(polyethylene glycol)-2000]-N,N itetradecylacetamide, 0.01 mg 1,2-distearoyl-snglycero-3-phosphocholine, and 0.02 mg cholesterol), 9.4 mg sucrose, 0.02 mg tromethamine, and 0.12 mg tromethamine hydrochloride. The diluent (sterile 0.9% Sodium Chloride Injection, USP) contributes 1.88 mg sodium chloride per dose.
Pfizer-BioNtech 2023-2024 formulation <sup>1</sup> (blue cap and border)	Lipids (0.14 mg ((4- hydroxybutyl)azanediyl)bis(hexane6,1-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, and 0.4 mg tromethamine hydrochloride.
Pfizer-BioNtech COMIRNATY® 2023-2024 formulation³ (gray cap and border)	Lipids (0.43 mg ((4-hydroxybutyl)azanediyl)bis(hexane6,1-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 2023-2024 formulation <sup>2</sup> (dark blue cap and green border)	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.
Moderna SPIKEVAX® 2023-2024 formulation <sup>4</sup> (dark blue cap and 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.
NVA-CoV2373 (NOVAVAX® 2023-2024 formulation) <sup>5</sup>	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 vaccine contains a recombinant form of the SARS-CoV-2 spike protein produced from baculovirus infected Sf9 (fall armyworm) insect cells and Matrix-M <sup>TM</sup> 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<sup>8</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. See Appendix A for additional information.
- 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.

#### 8. Other Considerations<sup>8</sup>

- a. 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.
- b. Individuals who received monoclonal antibodies or convalescent plasma during COVID-19 treatment may be vaccinated as soon as their symptoms have resolved.
- c. 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.
- d. 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.
- e. 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.
- 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 individuals 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.
- j. Children 3 years through 4 years of age should complete a multi-dose initial series (2 doses of Moderna vaccine or 3 doses of Pfizer-BioNtech vaccine) with at least one dose of the

2023–2024 COVID-19 mRNA vaccines. Doses for adults and immunocompromised persons ≥5 years of age may receive any age-appropriate authorized product.

### 9. Side Effects and Adverse Reactions

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

Pfizer-BioNtech <sup>1,3</sup> and Moderna <sup>2,4</sup> Adverse Events	Frequency
Injection site events (pain at the injection site,	Very common, up to 93%
redness, swelling)	Noncessar un to 770/
Systemic events (fatigue, headache, muscle ache, joint pain)	Very common, up to 77%
Fever	Up to 16%
Lymphadenopathy <mark>*</mark>	Up to 20%
Serious adverse events	Uncommon, up to 1% (similar to placebo
	group)

<sup>\*</sup>Lymph node swelling in the underarm is more common after the booster dose than after the initial serie<mark>s.</mark>

Novavax <sup>5</sup> Adverse Events	Frequency
Injection site events (pain at the injection site,	Very common, up to 82%
redness, swelling)	
Systemic events (fatigue, muscle pain, headache,	Very common, up to 62%
nausea)	
Fever	Uncommon, up to 6%

#### 10. Storage and Handling

- a. Store medications according to OAR 855-041-1036.
- b. For Pfizer-BioNtech vaccine only: thaw, if needed. The single dose pre-filled glass syringe (COMIRNATY) CANNOT be frozen and stored in the refrigerator. The yellow cap formulation requires reconstitution; the blue and gray cap formulations are ready to administer.<sup>1,3</sup>
- c. For Moderna vaccine only: thaw vaccine prior to administration.<sup>2,4</sup>

Vaccine	Temp	Storage Issues	Notes
Pfizer-	-90° to -60° C	Vaccine may be stored until the	Do not freeze the single dose
BioNtech	(-130° to -76° F)	expiration date.	pre-filled glass syringe
1,3			(discard if frozen)
	2° to 8° C	Adolescent/adult 2023-2024	
	(36° to 46° F)	formulation (blue or gray cap	
		vial OR single dose pre-filled	
		plastic pre-filled syringe): store	
		in the refrigerator for up to 10	
		weeks	
		Pediatric 2023-2024	
		formulation (yellow cap):	
		before mixing, the vaccine may	
		before mixing, the vaccine may	

		be stored in the refrigerator for up to 10 weeks.	
		Adolescent/adult 2023-2024 formulation (single dose prefilled glass syringe): Store in the refrigerator until printed expiration date on carton	
	Ambient temperatures	Adolescent/adult 2023-2024 formulation (blue or gray cap vial OR single dose pre-filled	
		glass syringe OR single dose pre-filled plastic syringe): vaccine may be held at room	
		Pediatric 2023-2024 formulation (yellow cap): once mixed, vaccine may be held at room temperature for up to 12 hours	
Moderna <sup>2,4</sup>	-50° to -15° C (-58° to 5° F) 2° to 8° C (36° to 46° F)	Vaccine is viable until the expiration date.  Vaccine is viable under refrigeration for up to 30 days.	For multi-dose vials, once stopper has been punctured, all doses must be used within 12 hours.
	Ambient temperatures	Unpunctured vials of vaccine is viable for up to 24 hours at room temperature	Do not refreeze once thawed. Protect vaccine from light.
Novavax <sup>5</sup>	2°-8°C (36° to 46° F)	No expiration date is printed on vial or carton. Lookup the expiration date of the batch/Lot number at <a href="https://www.novavaxcovidvaccine.com">www.novavaxcovidvaccine.com</a> enter "United States" as the "country/region."	Once vial stopper has been punctured, store vial at 2° to 25° C (36° to 77° F) for use within 12 hours. Discard the vial 12 hours after first puncture.  Do not freeze.  Protect vaccine from light.

#### 11. References

- Pfizer-BioNTech COVID-19 Vaccine, 2023–2024 formulation. Emergency use authorization (EUA) fact sheet, 11 Sep 2023. Available at: <a href="https://www.fda.gov/media/167211/download">https://www.fda.gov/media/167211/download</a>. Accessed 14 Sep 2023.
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- Centers for Disease Control and Prevention. (2024, April 4). ACIP Vaccine Recommendations and Schedules. Centers for Disease Control and Prevention. <a href="https://www.cdc.gov/vaccines/acip/recommendations.html">https://www.cdc.gov/vaccines/acip/recommendations.html</a>. Accessed 1 March 2024.
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#### 12. Appendix

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