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Information for Health Care Professionals about the Screening Checklist for the COVID-19 Vaccine

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Note: For summary information on contraindications and precautions to vaccines, go to the ACIP's General Best Practice Guidelines for Immunization at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html. For CDC's complete interim considerations for the use of COVID vaccines, go to: <u>https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html</u>

1. Are you feeling sick today?

- 1. If yes, refer patient/person to the healthcare provider on site for assessment of current health status. If patient is feeling moderately or severely ill, do not vaccinate at this time. Ask the patient to return when symptoms improve.
- 2. In the last 10 days, have you had a COVID-19 test because you had symptoms and are still awaiting your test results or been told by a health care provider or health department to isolate or quarantine at home due to COVID-19 infection or exposure?
 - 1. If yes, advise patient to return to isolation or quarantine and reschedule for after isolation/quarantine ends.
 - 2. If the patient was diagnosed with COVID-19 greater than 10 days ago and has been asymptomatic for 72 hours or more, patient may be vaccinated.
 - 3. If the patient has had a test in the last 10 days, ask for the result. If positive, send them home. If negative, they can proceed to vaccination. If the result is unsure or unknown, advise the patient to return once a negative test has been confirmed or 10 days have passed since a positive test.
 - 4. Persons with a history of multisystem inflammatory syndrome in children (MIS-C) or in adults (MIS-A) should consider delaying vaccination until they have recovered from their illness and for 90 days after the diagnosis of MIS-C or MIS-A. However, patients can choose to be vaccinated. For further information on counseling a patient with a history of MIS-C or MIS-A regarding COVID-19 vaccines, please see the Centers for Disease Control and Prevention's (CDC) section on MIS-C and MIS-A in their "Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States" available at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.

3. How old will the person be on the day of vaccination?

- 1. If the person is 6 years old or older, they are up to date if they have received at least one dose of bivalent mRNA vaccine (Pfizer or Moderna).
 - i. If the person is 65 years or older, they may receive one additional bivalent dose at least 4 months after the initial bivalent dose.
 - ii. If the person is immunocompromised, they may receive an additional dose of bivalent vaccine 2 months after the initial bivalent dose. Bivalent vaccine may

be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances. Any further additional doses should be given at least 2 months after the last COVID vaccine dose.

- 2. If the patient is 6 months through 5 years of age, doses depend on the age of the child, if they were previously vaccinated, which vaccine they received, how many doses they received, and if they are immunocompromised.
 - Of Note: For children 6 months to 5 years who received one dose of Moderna monovalent vaccine, administer a Moderna bivalent 0.25 mL/25 ug dose (dark blue cap and gray label border). For children 6 months to 5 years who received 2 doses of Moderna monovalent vaccine, administer a Moderna bivalent 0.2 mL/10 ug dose (dark pink cap and yellow label border).
 - ii. For more information regarding those who are immunocompromised, see question #6 below.
- 3. For the CDC's full COVID-19 vaccine schedule for those who are NOT immunocompromised by vaccination history, see the table in Appendix A.

4. Has the person to be vaccinated ever received a dose of COVID-19 vaccine?

- If yes, look at the answers concerning which vaccine they received and how many doses. If the vaccine received is authorized for use in the U.S. (Pfizer, Moderna, Novavax, or Janssen (Johnson & Johnson):
 - i. If they are 6 years to 64 years of age and immunocompetent and received at least one dose of bivalent mRNA vaccine (Pfizer or Moderna), they are up to date and no additional doses are indicated at this time.
 - ii. If they are 65 years or older and received a dose of bivalent mRNA vaccine, they may receive one additional dose of bivalent mRNA vaccine if it has been at least 4 months after their initial bivalent dose.
 - iii. If they are 6 years or older, immunocompromised, and received a dose of bivalent mRNA vaccine, they may receive an additional dose 2 months after the initial dose. Bivalent vaccine may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances.
 - iv. If they are 6 months through 5 years of age, doses depend on the age of the child, if they were previously vaccinated, which vaccine they received, how many doses they received, and if they are immunocompromised. Of Note: For children 6 months to 5 years who received one dose of Moderna monovalent vaccine, administer a Moderna bivalent 0.25 mL/25 ug dose (dark blue cap and gray label border). For children 6 months to 5 years who received a Moderna bivalent 0.2 mL/10 ug dose (dark pink cap and yellow label border).
 - v. For the CDC's full COVID-19 vaccine schedule for those who are NOT immunocompromised by vaccination history, see the table in Appendix A.
 - vi. For more information regarding those who are immunocompromised, please see questions #6 below.
- If yes and the vaccine is not authorized for use in the U.S., but is authorized by the World Health Organization for emergency use (AstraZeneca – VAXZEVRIA, Sinovac – CORONAVAC, Serum Institute of India – COVISHIELD, Sinopharm/BIBP, COVAXIN, Nuvaxovid, or CanSino Biologics - Convidecia) they may be eligible under the CDC's

Emergency Use Instructions. See Appendix C for the CDC's COVID-19 vaccine schedule for these individuals.

- 3. If no, administer one age-appropriate dose of a bivalent, mRNA vaccine (Pfizer or Moderna).
- 5. Have you ever had an immediate allergic reaction (e.g., hives, facial swelling, difficulty breathing, anaphylaxis) to any vaccine, injection, or shot or to any component of the COVID-19 vaccine, or a severe allergic reaction (anaphylaxis) to anything?
 - 1. If yes, then refer to the vaccination site healthcare provider for assessment of allergic reaction. Review the ingredient lists at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.
 - 2. <u>Contraindications to COVID-19 vaccine</u>:
 - i. Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
 - ii. Known diagnosed allergy to a component of the COVID-19 vaccine
 - iii. People with a known allergy to polysorbate have a contraindication to both Novavax and Janssen OVID-19 vaccines
 - iv. People with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA COVID-19 vaccines (Pfizer or Moderna)
 - 3. <u>Precautions to COVID-19 vaccine</u>: (Refer to your organization's protocol to see whether individuals with a precaution to vaccination warrant further evaluation.)
 - i. Immediate (onset within 4 hours after vaccination), but non-severe, allergic reaction after a previous dose of COVID-19 vaccine
 - ii. Immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies excluding subcutaneous immunotherapy for allergies).
 - iii. Individuals with a contraindication to one type of COVID-19 vaccine (e.g., mRNA) have a precaution to the other (e.g., Novavax protein subunit vaccine).
 - a) Consultation with an allergist-immunologist should be considered to help determine if the patient can safely receive vaccination, and vaccination of these individuals should only be undertaken in an appropriate clinical setting under the supervision of a health care provider experienced in the management of severe allergic reactions.
 - b) <u>Note</u>: These individuals should not be administered COVID-19 vaccine at State- operated vaccination sites.
 - v. For mRNA (Pfizer or Moderna),-protein subunit (Novavax), and adenovirus vector (Janssen) COVID-19 vaccines, for history of myocarditis or pericarditis after a dose of an mRNA (Pfizer or Moderna), protein subunit (Novavax), or adenovirus vector (Janssen) COVID-19 vaccine, a subsequent dose of COVID-19 vaccine should generally be avoided. (See question 9 for further information regarding this precaution.)
 - vi. For patients who are determined eligible for COVID-19 vaccination after an assessment of allergy history, a 15-minute post-vaccination observation period should be considered for the following:
 - a) Patients with a history of any allergy not listed as a contraindication or precaution.

- Any other recipients, particularly adolescents, to monitor for syncope. If syncope develops, patients should be observed until syncope resolves.
- v. For patients who are determined eligible for COVID-19 vaccination after an assessment of allergy history, a 30-minute post-vaccination observation period should be considered for the following:
 - a) Non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine
 - b) Patients with a history of an immediate allergic reaction of any severity to any other vaccine or injectable therapy
 - c) Patients with a contraindication to a different type of COVID-19 vaccine (e.g., mRNA vs. Novavax protein subunit vaccine)
- 4. More information regarding observation times can be found in the CDC's interim clinical considerations.
- 6. Are you moderately or severely immunocompromised due to one or more of the medical conditions or receipt of immunosuppressive medications or treatments listed below?
 - 1. Immunosuppressive medications or treatments:
 - i. Active treatment for solid tumor and hematologic malignancies
 - ii. Receipt of solid-organ transplant and taking immunosuppressive therapy
 - iii. Hematologic malignancies associated with poor responses to COVID-19 vaccines regardless of current treatment status (e.g., chronic lymphocytic leukemia, non-Hodgkin lymphoma, multiple myeloma, acute leukemia)
 - iv. Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
 - v. Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
 - vi. Advanced or untreated HIV infection
 - vii. Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory
 - 2. If yes:
 - Ask the patient if they would like to have a discussion with the vaccination site healthcare provider about what is known and not yet known about COVID-19 vaccine for immunocompromised people. You can tell the patient that they may have a less strong immune response to the vaccine but may still get vaccinated. Patient may be vaccinated if they choose and does not need to go to medical evaluation if they choose not to.
 - ii. If they choose to be vaccinated, then administer the mRNA COVID-19 vaccine if the person is age appropriate and without contraindications. If possible, the additional dose should be with the same mRNA vaccine product (Pfizer or Moderna) used for the initial 2 dose primary series. If the same vaccine product is not available, then the other product may be administered after counseling about the unknown risks of a mixed dose series. At this time, there is no recommendation for additional doses for those who received the Novavax COVID-19 vaccine.

- a) Previously unvaccinated immunocompromised individuals should receive the age-appropriate initial doses(s) per the recommended schedule by the CDC (see Appendix A for the CDC recommended schedule). Children 6 months-4 years for Pfizer, and 6 months-5 years for Moderna who are immunocompromised may receive an additional dose 4 weeks after completion of the primary series. For children 6 months to 4 years old, additional doses should be with the same vaccine they received for their primary series. If they received the Pfizer vaccine, then additional doses should be with the Pfizer vaccine. If they received the Moderna vaccine, then additional doses should be with the Moderna vaccine.
- b) For children 5 years of age, if they received the Pfizer vaccine for their primary series and first additional dose, they can only receive the Pfizer vaccine for further additional doses. If they received the Moderna vaccine for their primary series and first additional dose, they may receive either the Moderna or the Pfizer vaccine for further additional doses.

For people 6 years and older who are immunocompromised, received their primary series, and an additional dose, may receive an additional dose of mRNA vaccine 8 weeks after their most recent dose of bivalent mRNA vaccine. Further additional doses may be administered, informed by the clinical judgement of a healthcare provider, and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose.

7. Are you pregnant or considering becoming pregnant?

 If yes, ask the patient if they would like to have a discussion with a healthcare provider at site for counseling on the risks and benefits of COVID-19 vaccine during pregnancy. Patient may be vaccinated if they choose and does not need to go to medical evaluation if they choose.

8. Do you have a bleeding disorder, a history of blood clots or are you taking a blood thinner?

1. If yes, refer to healthcare provider to assess the patient's bleeding risk and thrombosis history. If a person with a bleeding disorder or taking a blood thinner is cleared for vaccination, then administer vaccine using a 23-gauge or smaller caliber needle and apply firm pressure on the site of vaccination, without rubbing, for at least 2 minutes after vaccination.

9. Do you have a history of myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining around the heart)?

- Evaluate if this history was in relation to a dose of an mRNA (Pfizer or Moderna), or protein subunit (Novavax) vaccine, or the viral vector vaccine from Janssen. If it was not, then the patient can receive any U.S. Food and Drug Administration (FDA) authorized COVID-19 vaccine after complete resolution of a myocarditis or pericarditis episode.
- 2. Until additional safety data are available, experts advise that people who develop myocarditis or pericarditis after a dose of an mRNA (Pfizer or Moderna) or protein subunit (Novavax) COVID-19 vaccine generally should not receive a subsequent dose of any COVID- 19 vaccine. If after a risk assessment, the decision is made to receive a subsequent COVID- 19 vaccine dose, the person should wait until at least after their

episode of myocarditis or pericarditis has resolved (i.e., resolution of symptoms, no evidence of ongoing heart inflammation or sequelae as determined by patient's clinical team). For men ages 18 years and older who choose to receive a subsequent COVID-19 vaccine following recovery from post-vaccine myocarditis, some experts advise the use of Novavax COVID-19 Vaccine be considered instead of mRNA (Pfizer or Moderna)vaccines. Decisions to proceed with vaccination should include conversations with the patient, parent/legal representative, and the clinical team, including a cardiologist. Considerations for vaccination may include:

- i. The myocarditis or pericarditis was considered unrelated to an mRNA (Pfizer or Moderna) or protein subunit (Novavax) COVID-19 vaccination (e.g., due to SARS-CoV-2 or other viruses), especially if the myocarditis or pericarditis diagnosis occurred more than 3 weeks after the most recent COVID-19 vaccine.
- ii. Personal risk of severe acute COVID-19 disease (e.g., age, underlying conditions).
- iii. Level of COVID-19 community transmission and personal risk of infection.
- iv. Timing of immunomodulatory therapeutics; ACIP's <u>general best practice</u> <u>guidelines for immunization</u> can be consulted for more information.
- 3. The CDC advises that an increased interval of 8 weeks between the 2 doses of the primary series may decrease the risk of myocarditis. However, the 3 week interval should be used for the following people:
 - i. Immunocompromised people
 - ii. High risk for severe disease
 - iii. Household members with high risk for severe disease
 - iv. High COVID-19 community levels
- 4. Individuals recommended to receive a booster should speak with their healthcare provider about which vaccine is best for their booster dose. If they choose a different vaccine booster, according to FDA and CDC guidelines, they can select from any FDA-approved or authorized COVID-10 vaccine for which they are eligible. Please see CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines for more information on booster dosing and considerations for clinicians regarding the different vaccine products.
- For the full CDC interim clinical considerations regarding a history of myocarditis and/or pericarditis, please see the CDC's COVID-19 Vaccines Currently Authorized in the United States and Clinical Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults.

10. Do you have a history of MIS-C or MIS-A (multisystem inflammatory syndrome in children or multisystem inflammatory syndrome in adults)?

- For children and adolescents with a history of MIS-C experts consider the benefits of COVID-19 vaccination for children and adolescents with a history of MIS-C (i.e., a reduced risk of severe disease including potential recurrence of MIS-C after reinfection) to outweigh a theoretical risk of an MIS-like illness or the risk of myocarditis following COVID-19 vaccination for those who meet the following criteria:
 - i. Clinical recovery has been achieved, including return to normal cardiac function
 - ii. It has been at least 90 days after the diagnosis of MIS-C
- 2. COVID-19 vaccination may also be considered for children and adolescents who had MIS-C and do not meet both criteria, at the discretion of their clinical care team (see consultation for decisions about COVID-19 vaccination). Experts view clinical recovery,

including return to normal cardiac function, as an important factor when considering COVID-19 vaccination. Additional factors, such as the risk of severe COVID-19 due to certain medical conditions, may also be considered.

- For adults with a history of MIS-A COVID-19 vaccination may be considered for adults who had MIS- A at the discretion of their clinical care team. Experts view clinical recovery, including return to normal cardiac function, as an important factor when considering COVID-19 vaccination. Additional factors, such as risk of severe COVID-19 due to age or certain medical conditions, may also be considered.
- 4. For the complete consideration for vaccination of children and adults with a history of MIS-C or MIS-A, and those who develop MIS-C or MIS-A after COVID-19 vaccination, please refer to the CDC's clinical considerations available at https://www.cdc.gov/vaccines/covid-19/clinical- considerations/interim-considerationsus.html#covid19-vaccination-misc-misa.
- 11. Have you recently received an orthopoxvirus vaccine within the last 4 weeks (e.g., JYNNEOS or ACAM2000)?
 - 1. There is not a required minimum interval between COVID-19 vaccines and orthopoxvirus vaccine, either JYNNEOS or ACAM200 vaccine regardless of which vaccine was administered first.
 - 2. JYNNEOS should be prioritized over ACAM200 when co-administering a COVID-19 vaccine and an orthopoxvirus vaccine.
 - 3. A 4 week interval may be considered for some people, particularly adolescent and young adult males due to the observed risk for myocarditis and pericarditis after receipt of ACAM200 and COVID-19 vaccine and the hypothetical risk for myocarditis and pericarditis after JYNNEOS vaccine. However, if a patient's risk for mpox or sever disease due to COVID-19 is increased, administration of mpox and COVID-19 vaccines should not be delayed.

Appendix A:

CDC's Table: 'Recommended COVID-19 vaccination schedule for people who are not moderately or severely immunocompromised by COVID-19 vaccination history, May 2023'

mRNA COVID-19 vaccines

Ages 6 months–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*
	Moderna	2	0.25 mL/25 ug	Dark blue cap; gray label border	Dose 1 and Dose 2: 4–8 weeks
Unvaccinated	Jnvaccinated <u>—</u> Pfizer BioNTech [†]	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-BioNTech	Pfizer BioNTech⁺	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-BioNTech	Pfizer BioNTech	1	0.2 mL/3 ug	Maroon	At least 8 weeks after last monovalent dose
3 doses monovalent Pfizer-BioNTech	Pfizer BioNTech	1	0.2 mL/3 ug	Maroon	At least 8 weeks after last monovalent dose
2 doses monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer- BioNTech	NA; previously received 1 bivalent vaccine 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 [‡] <i>or</i> Pfizer	2	0.25 mL/25 ug	Dark blue cap; gray label border	Dose 1 and Dose 2: 4–8 weeks
	BioNTech	1	0.2 mL/10 ug	Orange	
1 dose monovalent	Moderna <i>or</i> Pfizor	1	0.25 mL/25 ug	Dark blue cap; gray label border	4–8 weeks after monovalent dose
Wodema	BioNTech	1	0.2 mL/10 ug	Orange	At least 8 weeks after monovalent dose
2 doses monovalent	Moderna	1	0.2 mL/10 ug	Dark pink cap; yellow label border	At least 8 weeks after last monovalent dose
BioNTech	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- BioNTech	Pfizer- BioNTech	1	0.2 mL/10 ug	Orange	At least 8 weeks after last monovalent dose
2 doses monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer- BioNTech	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA
Ever received 1 dose bivalent Pfizer- BioNTech (regardless of monovalent vaccine history)	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 <i>or</i> Pfizer	1	0.25 mL/25 ug	Dark blue cap; gray label border	_
	BioNTech	1	0.2 mL/10 ug	Orange	_
1 or more doses monovalent mRNA (no	Moderna <i>or</i> Pfizer BioNTech	1	0.25 mL/25 ug	Dark blue cap; gray label border	At least 8 weeks after last monovalent dose
doses bivalent mRNA)		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 <i>or</i> Pfizer	1	0.5 mL/50 ug	Dark blue cap; gray label border	_
	BioNTech	1	0.3 mL/30 ug	Gray	—
1 or more doses monovalent mRNA (no doses bivalent mRNA) BioNTec	Moderna <i>or</i> _	1	0.5 mL/50 ug	Dark blue cap; gray label border	At least 8 weeks after last monovalent dose
	BioNTech	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

*An **8-week**<u>interval</u> between the first and second doses of Moderna and Pfizer-BioNTech COVID-19 vaccines might be optimal for some people ages 6 months–64 years, especially for males ages 12–39 years, as it might reduce the small risk of myocarditis and pericarditis associated with these vaccines.

⁺FDA <u>Emergency Use Authorization</u> requires that children who transition from age 4 years to 5 years during the Pfizer-BioNTech vaccination series receive the 0.2 mL/3 ug dosage (maroon cap and label with a maroon border) for all doses.

⁺Children who transition from age 5 years to 6 years during the Moderna vaccination series should receive 2 doses of Moderna COVID-19 Vaccine (0.25 mL/25 ug; dark blue cap and label with a gray border).

Novavax COVID-19 Vaccine

People ages 12 years and older who previously received 1 or more doses of Novavax COVID-19 Vaccine are recommended to receive 1 bivalent mRNA vaccine dose.

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
1 or more doses of	Moderna <i>or</i> _	1	0.5 mL/50 ug	Dark blue cap; gray label border	At least 8 weeks after last monovalent dose
Novavax vaccine	BioNTech	1	0.3 mL/30 ug	Gray	At least 8 weeks after last monovalent dose

12 years and older: Novavax COVID-19 Vaccine

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).

Novavax COVID-19 Vaccine remains authorized to provide:

- A 2-dose primary series to people ages 12 years and older. The primary series doses are separated by 3–8 weeks. An 8-week interval between the first and second primary series doses might be optimal for some people ages 6 months–64 years, especially for males ages 12–39 years, as it might reduce the small risk of myocarditis and pericarditis associated with this vaccine.
- A booster dose in limited situations to people ages 18 years and older who previously completed primary vaccination using any FDA-approved or FDA-authorized COVID-19 vaccine; have not received any previous booster dose(s); and are unable (i.e., mRNA vaccine contraindicated or vaccine not available) or unwilling to receive an mRNA vaccine and would otherwise not receive a booster dose. The monovalent Novavax booster dose is administered at least 6 months after completion of any primary series.

Appendix B:

CDC's Table: "Recommended COVID-19 vaccination schedule for people who are moderately or severely immunocompromised by COVID-19 vaccination history, May 2023"

mRNA COVID-19 vaccines

Ages 6 months-4 years

		Number of			
COVID-19 vaccination	Bivalent	bivalent doses		Vaccine vial cap	
history	vaccine	indicated*	Dosage (mL/ug)	and label colors	Interval between doses
Unvaccinated	Moderna	3	0.25 mL/25 ug	Blue cap; gray	Dose 1 and Dose 2:
	or			label border	4 weeks
	Pfizer				Dose 2 and Dose 3: At
	BioNTech [†]				least 4 weeks
		3	0.2 mL/3 ug	Maroon	Dose 1 and Dose 2:
					3 weeks
					Dose 2 and dose 3:
					At least 8 weeks
1 dose monovalent	Moderna	2	0.25 mL/25 ug	Blue cap; gray	Dose 1: 4 weeks after
Moderna				label border	monovalent dose
					Dose 1 and Dose 2:
					At least 4 weeks
2 doses monovalent	Moderna	1	0.25 mL/25 ug	Blue cap; gray	At least 4 weeks after
Moderna				label border	last monovalent dose
3 doses monovalent	Moderna	1	0.2 mL/10 ug	Dark pink cap;	At least 8 weeks after
Moderna				yellow label	last monovalent dose
				border	
3 doses monovalent	-	See footnote	—	—	—
Moderna and 1 dose					
bivalent Moderna					
1 dose monovalent Pfizer-	Pfizer-	2	0.2 mL/3 ug	Maroon	Dose 1: 3 weeks after
BioNTech	BioNTech ⁺				monovalent dose
					Dose 1 and Dose 2:
					At least 8 weeks
2 doses monovalent	Pfizer-BioNTech	1	0.2 mL/3 ug	Maroon	At least 8 weeks after
Pfizer-BioNTech					last monovalent dose
3 doses monovalent	Pfizer-BioNTech	1	0.2 mL/3 ug	Maroon	At least 8 weeks after
Pfizer-BioNTech					last monovalent dose
2 doses monovalent	_	See footnote	_	—	—
Pfizer-BioNTech and 1					
dose bivalent Pfizer-					
BioNTech					
3 doses of monovalent	_	See footnote	—	_	_
Pfizer-BioNTech and 1					
bivalent Pfizer-BioNTech					
dose					

Abbreviation: NA = not authorized

*People ages 6 months–4 years who are moderately or severely immunocompromised have the option to receive 1 additional dose of a homologous bivalent mRNA vaccine at least 2 months following the last recommended bivalent mRNA COVID-19 vaccine dose. Further additional homologous bivalent dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine

dose. For Moderna, 0.2mL/10 ug (dark pink cap and label with a yellow boarder) is recommended; 0.25/25 ug (dark blue cap and label with a gray border) is also authorized. For Pfizer-BioNTech, administer 0.2 mL/3 ug (maroon cap and label with a maroon border). [†]FDA <u>Emergency Use Authorization</u> requires that children who transition from age 4 years to 5 years during the Pfizer-BioNTech vaccination series receive the 0.2 mL/3 ug dosage (supplied in vials with a maroon cap and label with a maroon border) for all doses.

Ages 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 [†]	3	0.25 mL/25 ug	Blue cap; gray	Dose 1 and Dose 2:
	or		, ,	label border	4 weeks
	Pfizer				Dose 2 and Dose 3: At
	BioNTech				least 4 weeks
		3	0.2 mL/10 ug	Orange	Dose 1 and Dose 2:
					3 weeks
					Dose 2 and dose 3: At
					least 4 weeks
1 dose monovalent Moderna	Moderna ⁺	2	0.25 mL/25 ug	Blue cap; gray	Dose 1: 4 weeks after
				label border	monovalent dose
					Dose 1 and Dose 2:
					At least 4 weeks
2 doses monovalent Moderna	Moderna ⁺	1	0.25 mL/25 ug	Blue cap; gray	At least 4 weeks after last
				label border	monovalent dose
3 doses monovalent Moderna	Moderna	1	0.25 mL/25 ug	Blue cap; gray	At least 8 weeks after last
	or			label border	monovalent dose
	Pfizer	1	0.2 mL/10 ug	Orange	At least 8 weeks after last
	BioNTech				monovalent dose
3 doses monovalent Moderna	_	See	-	-	—
and 1 dose bivalent mRNA		footnote			
1 dose monovalent Pfizer-	Pfizer-	2	0.2 mL/10 ug	Orange	Dose 1: 3 weeks after
BioNTech	BioNTech				monovalent dose
					Dose 1 and Dose 2:
					At least 4 weeks
2 doses monovalent Pfizer-	Pfizer-	1	0.2 mL/10 ug	Orange	At least 4 weeks after last
BioNTech	BioNTech				monovalent dose
3 doses monovalent Pfizer-	Pfizer-	1	0.2 mL/10 ug	Orange	At least 8 weeks after last
BioNTech	BioNTech				monovalent dose
3 doses monovalent Pfizer-	_	See	—	_	_
BioNTech and 1 dose bivalent		footnote			
Pfizer-BioNTech					

*People age 5 years who are moderately or severely immunocompromised have the option to receive 1 additional dose of a bivalent mRNA vaccine at least 2 months following the last recommended bivalent mRNA COVID-19 vaccine dose. Further additional bivalent dose(s) may be administered, informed by the clinical judgment of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose. People in this age group who previously received a dose(s) of Pfizer-BioNTech vaccine are authorized to receive only Pfizer-BioNTech vaccine.

Recipients who previously received Moderna vaccine are authorized to receive either bivalent mRNA vaccine.

If Moderna is used, 0.2mL/10 ug (dark pink cap and label with a yellow border) is recommended; 0.25/25ug (dark blue cap and label with a gray border) is also authorized.

If Pfizer-BioNTech is used, administer 0.2 ml/10 ug (orange cap and label with an orange border).

[†]Pfizer-BioNTech COVID-19 Vaccine (0.2 mL/10 ug; orange cap and label with an orange border) is also authorized in this age group with this vaccination history.

Ages 6-11 years

		Number of			
COVID-19 vaccination	Bivalent	bivalent doses		Vaccine vial cap	
history	vaccine	indicated*	Dosage (mL/ug)	and label colors	Interval between doses
Unvaccinated	Moderna ⁺	3	0.25 mL/25 ug	Blue cap; gray	Dose 1 and Dose 2:
	or			label border	4 weeks
	Pfizer-				Dose 2 and Dose 3:
	BioNTech [‡]				At least 4 weeks
		3	0.2 mL/10 ug	Orange	Dose 1 and Dose 2:
					3 weeks
					Dose 2 and dose 3:
					At least 4 weeks
1 dose monovalent	Moderna ⁺	2	0.25 mL/25 ug	Blue cap; gray	Dose 1: 4 weeks after
Moderna				label border	monovalent dose
					Dose 1 and Dose 2:
					At least 4 weeks
2 doses monovalent	Moderna ⁺	1	0.25 mL/25 ug	Blue cap; gray	At least 4 weeks after
Moderna				label border	last monovalent dose
3 doses monovalent	Moderna	1	0.25 mL/25 ug	Blue cap; gray	At least 8 weeks after
Moderna	or			label border	last monovalent dose
	Pfizer-BioNTech	1	0.2 mL/10 ug	Orange	At least 8 weeks after
					last monovalent dose
3 doses monovalent	—	See footnote	_	—	—
Moderna and 1 dose					
bivalent mRNA					
1 dose monovalent Pfizer-	Pfizer-	2	0.2 mL/10 ug	Orange	Dose 1: 3 weeks after
BioNTech	BioNTech [‡]				monovalent dose
					Dose 1 and Dose 2:
					At least 4 weeks
2 doses monovalent Pfizer-	Pfizer-	1	0.2 mL/10 ug	Orange	At least 4 weeks after
BioNTech	BioNTech‡				last monovalent dose
3 doses monovalent Pfizer-	Moderna	1	0.25 mL/25 ug	Blue cap; gray	At least 8 weeks after
BioNTech	or			label border	last monovalent dose
	Pfizer-BioNTech	1	0.2 mL/10 ug	Orange	At least 8 weeks after
					last monovalent dose
3 doses monovalent Pfizer-	_	See footnote	-	—	—
BioNTech and 1 dose					
bivalent mRNA					

*People ages 6–11 years who are moderately or severely immunocompromised have the option to receive 1 additional dose of Moderna COVID-19 Vaccine (0.25mL/25 ug; dark blue cap and label with a gray border) or Pfizer-BioNTech COVID-19 Vaccine (0.2 mL/10 ug; orange cap and label with an orange border) at least 2 months following the last recommended bivalent COVID-19 vaccine dose. Further additional dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose. [†]Pfizer-BioNTech COVID-19 Vaccine (0.2 mL/10 ug; orange cap and label with an orange border) is also authorized in this age group with this vaccination history.

^{*}Moderna COVID-19 Vaccine (0.25 ml/25 ug; dark blue cap and label with a gray border) is also authorized in this age group with this vaccination history.

Ages 12 years and older

		Number of			
COVID-19 vaccination	Bivalent	bivalent doses		Vaccine vial cap	
history	vaccine	indicated*	Dosage (mL/ug)	and label colors	Interval between doses
Unvaccinated	Moderna ⁺	3	0.5 mL/50 ug	Blue cap; gray	Dose 1 and Dose 2:
	or			label border	4 weeks
	Pfizer				Dose 2 and Dose 3:
	BioNTech [‡]				At least 4 weeks
		3	0.3 mL/30 ug	Gray	Dose 1 and Dose 2:
					3 weeks
					Dose 2 and dose 3:
					At least 4 weeks
1 dose monovalent	Moderna ⁺	2	0.5 mL/50 ug	Blue cap; gray	Dose 1: 4 weeks after
Moderna				label border	monovalent dose
					Dose 1 and Dose 2:
					At least 4 weeks
2 doses monovalent	Moderna ⁺	1	0.5 mL/50 ug	Blue cap; gray	At least 4 weeks after last
Moderna				label border	monovalent dose
3 doses monovalent	Moderna	1	0.5 mL/50 ug	Blue cap; gray	At least 8 weeks after last
Moderna	or			label border	monovalent dose
	Pfizer-BioNTech	1	0.3 mL/30 ug	Gray	At least 8 weeks after last
					monovalent dose
3 doses monovalent	_	See footnote	_	_	—
Moderna and 1 dose					
bivalent mRNA					
1 dose monovalent Pfizer-	Pfizer-	2	0.3 mL/30 ug	Gray	Dose 1: 3 weeks after
BioNTech	BioNTech [‡]				monovalent dose
					Dose 1 and Dose 2: At
					least 4 weeks
2 doses monovalent Pfizer	Pfizer-	1	0.3 mL/30 ug	Gray	At least 4 weeks after last
	BioNTech [‡]				monovalent dose
3 doses monovalent Pfizer-	Moderna	1	0.5 mL/50 ug	Blue cap; gray	At least 8 weeks after last
BioNTech	or			label border	monovalent dose
	Pfizer-BioNTech	1	0.3 mL/30 ug	Gray	At least 8 weeks after last
					monovalent dose
3 doses monovalent Pfizer-	—	See footnote	_	-	—
BioNTech and 1 dose					
bivalent mRNA					

*People ages 12 years and older who are moderately or severely immunocompromised have the option to receive 1 additional dose of Moderna COVID-19 Vaccine (0.5 mL/50 ug; dark blue cap and label with a gray border) or Pfizer-BioNTech COVID-19 Vaccine (0.3 mL/30 ug; gray cap and label with a gray border) at least 2 months following the last recommended bivalent COVID-19 vaccine dose. Further additional dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose. †Pfizer-BioNTech COVID-19 Vaccine is also authorized in this age group with this vaccination history (0.3 mL/30 ug; gray cap and label with a gray border).

‡Moderna COVID-19 Vaccine is also authorized in this age group with this vaccination history (0.5 ml/50 ug; dark blue cap and label with a gray border).

Novavax COVID-19 Vaccine

People ages 12 years and older who previously received 1 or more doses of Novavax COVID-19 vaccine are recommended to receive 1 bivalent mRNA vaccine dose.

Novavax COVID-19 Vaccine

COVID 19 vaccination	Bivalant	Number of	Docago	Vaccine vial	Interval botween
history	vaccine	indicated*	(mL/ug)	colors	doses
1 or 2 doses of	Moderna	1	0.50 mL/50 ug	Dark blue cap;	At least 8 weeks after
Novavax vaccine	or			gray label	last monovalent dose
	Pfizer			border	
	BioNTech	1	0.3 mL/30 ug	Gray	At least 8 weeks after
					last monovalent dose

*People ages 12 years and older who are moderately or severely immunocompromised have the option to receive 1 additional dose of Moderna COVID-19 Vaccine (0.5 mL/50 ug; dark blue cap and label with a gray border) or Pfizer-BioNTech COVID-19 Vaccine (0.3 mL/30 ug; gray cap and label with a gray border) at least 2 months following the last recommended bivalent COVID-19 vaccine dose. Further additional dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose.

Novavax COVID-19 Vaccine remains authorized to provide:

- A 2-dose primary series to people ages 12 years and older. The primary series doses are separated by 3–8 weeks. An 8-week interval between the first and second primary series doses might be optimal for some people ages 6 months–64 years, especially for males ages 12–39 years, as it might reduce the small risk of myocarditis and pericarditis associated with this vaccine.
- A booster dose in limited situations to people ages 18 years and older who previously completed primary vaccination using any FDA-approved or FDA-authorized COVID-19 vaccine; have not received any previous booster dose(s); and are unable (i.e., contraindicated or vaccine not available) or unwilling to receive an mRNA vaccine and would otherwise not receive a booster dose. The monovalent Novavax booster dose is administered **at least 6 months** after completion of any primary series.

Appendix C: CDC's Table: "People who received COVID-19 vaccine outside the United States"

Table B. People who received COVID-19 vaccine outside the United States

Table B.1. Received a COVID-19 vaccine that is FDA-authorized

Vaccination history	Recommended actions
Received 1 or more monovalent mRNA vaccine	 Administer 1 bivalent mRNA dose.*
dose(s)	 See <u>Table 1</u> if age 6 months–5 years.
Received 1 or 2 Novavax vaccine dose(s)	 Administer 1 bivalent mRNA dose.*[†]
Received a bivalent mRNA dose	• Do not repeat.
	 See Special situation (after table footnotes).

Table B.2. Received a COVID-19 vaccine listed for emergency use by WHO but not authorized by FDA^{‡§} Received a COVID-19 vaccine listed for emergency use by WHO but not approved or authorized by FDA

Vaccination history	Recommended actions
Received all recommended primary series doses	 Administer 1 bivalent mRNA dose.*[†]
for that vaccine	
Received partial primary series for that vaccine	 Administer 1 bivalent mRNA dose.*
	• See <u>Table 1</u> if age 6 months–5 years.
Received a monovalent booster dose after	 Administer 1 bivalent mRNA dose.*
completion of primary series	
Received a bivalent mRNA booster dose after	 Do not repeat.*
completion of primary series	• See Special situation (after table footnotes).

Table B.3. Received all or some of the recommended doses of COVID-19 vaccines that are NOT FDA-authorizedor among those listed for emergency use by WHO

Received all or some of the recommended doses of COVID-19 vaccines that are NOT FDA-authorized, FDAapproved, or among those listed for emergency use by WHO

Vaccination history	Recommended actions
Received any number and combination of vaccine doses	 Do not count doses received toward vaccination in the US. Vaccinate according to the US schedule (<u>Table 1</u>). Start vaccination at least 28 days after the last dose of vaccine.

*People ages 6 months and older should receive at least 1 age-appropriate bivalent mRNA dose at least 2 months after their last monovalent vaccine dose. People ages 65 years and older have the option to receive 1 additional bivalent mRNA vaccine dose at least 4 months after the first bivalent mRNA vaccine dose.

[†]A monovalent Novavax booster dose (instead of a bivalent mRNA dose) may be used after completion of primary vaccination <u>in</u> <u>limited situations</u> in people ages 18 years and older who have not received any previous booster dose(s). The Novavax booster dose is administered at least 6 months after the last primary series dose.

[‡]COVID-19 vaccines that are listed for <u>emergency use by WHO</u>, but are not approved or authorized by FDA, have not been evaluated for efficacy or safety by CDC or ACIP.

[§]This scenario also includes people who received a heterologous primary series or booster dose composed of doses of COVID-19 vaccines listed for emergency use by WHO, at least one of which is not FDA-approved or FDA-authorized.

Special situation: Do not administer a second bivalent mRNA vaccine dose if the person previously received a bivalent Moderna or Pfizer-BioNTech mRNA vaccine dose containing the original SARS-CoV-2 strain and Omicron BA.1 variant unless the person is age 65 years or older: Those age 65 years or older have the option to receive 1 additional bivalent mRNA vaccine dose at least 4 months after the first bivalent mRNA vaccine dose.