Summary Document for Interim Clinical Considerations

for Use of COVID-19 Vaccines Currently Authorized or Approved in the United States

COVID-19 vaccine products* currently approved or authorized in the United States

Pfizer-BioNTech

Age indication	Vaccine composition	Vaccine vial cap color	Label border color	Dilution required	Primary series		Booster doses	
					Dose	Injection volume	Dose	Injection volume
6 months–4 years	Monovalent (Doses 1 and 2 primary series)	Maroon	Maroon	Yes	Doses 1 and 2: 3 µg/0.2 mL		A bivalent booster dose is ONLY authorized for children who previously completed a primary series with monovalent vaccine Booster Dose: 3µg/ 0.2mL	
6 months–4 years	Bivalent (Dose 3 primary series or booster dose†)	Maroon	Maroon	Yes	Dose 3: 3 µg/0.2 mL			
5–11 years	Monovalent	Orange	Orange	Yes	10 µg	0.2 mL	NA	NA
5–11 years	Bivalent	Orange	Orange	Yes	NA	NA	10 µg	0.2 mL
12 years and older	Monovalent	Gray	Gray	No	30 µg	0.3 mL	NA	NA
12 years and older	Bivalent	Gray	Gray	No	NA	NA	30 µg	0.3 mL

Moderna

Age indication	Vaccine composition	Vaccine vial cap color	Label border color	Dilution required	Primary series		Booster doses	
					Dose	Injection volume	Dose	Injection volume
6 months–5 years	Monovalent	Dark blue	Magenta	No	25 µg	0.25 mL	NA	NA
6 months–5 years	Bivalent	Dark pink	Yellow	No	NA	NA	10 µg	0.2 mL
6–11 years	Monovalent	Dark blue	Purple	No	50 µg	0.5 mL	NA	NA
6–11 years	Bivalent	Dark blue	Gray	No	NA	NA	25 µg	0.25 mL
12 years and older	Monovalent	Red	Light blue	No	100 µg	0.5 mL	NA	NA
12 years and older	Bivalent	Dark blue	Gray	No	NA	NA	50 µg	0.5 mL

* **NOTE**: Some COVID-19 monovalent vaccine products are expired or expiring soon. Healthcare professionals should: Always check expiration dates prior to administration. **NEVER administer expired vaccine.** CDC recommends providers check vaccine expiration dates weekly; all expired vaccine doses must be removed from the storage unit, and discarded according to the manufacturer's guidance, state, and federal regulations. Other COVID-19 vaccine products are available for those persons seeking vaccination and who have not completed a primary series, see Clinical Guidance for COVID-19 Vaccination | CDC

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COVID-19 vaccine products currently approved or authorized in the United States Continued

Janssen Janssen COVID-19 Vaccine is authorized for adults ages 18 years and older for the primary series (1 dose) and 1 booster dose in certain limited situations due to safety considerations. For more information, see Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendix A

Age indication	Vaccine composition	Vaccine vial cap color	Label border color	Dilution required	Primary series		Booster doses	
					Dose	Injection volume	Dose	Injection volume
18 years and older	Monovalent	Blue	No Color	No	5×10^{10} viral particles	0.5 mL	5×10^{10} viral particles	0.5 mL

Novavax

Age indication	Vaccine composition	Vaccine vial cap color	Label border color	Dilution required	Primary series		Booster doses‡	
					Dose	Injection volume	Dose	Injection volume
12 years and older	Monovalent	Royal blue	No Color	No	5 *µg* rS and 50 *µg* of Matrix-M™ adjuvant	0.5 mL	5 *µg* rS and 50 *µg* of Matrix-M™ adjuvant	0.5 mL

‡ Booster doses are only indicated for recipients 18 years and age and older in limited situations, see: Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States

All currently authorized or approved COVID-19 vaccines

COVID-19 vaccination schedule	■ See the Interim COVID-19 Immunization Schedule for Ages 6 Months or Older
Pre-vaccination counseling	Prior to vaccination: ■ Provide the vaccine-specific Fact Sheet for Recipients and Caregivers ■ Screen for contraindications and precautions. CDC's Prevaccination Screening Form and Guidance document can be found at, U.S. COVID-19 Vaccine Product Information | CDC. ■ Inform vaccine recipients mRNA or Novavax COVID-19 vaccines are recommended over Janssen COVID-19 Vaccine. ■ Counsel vaccine recipients, parents, or guardians about expected reactions post-vaccination (e.g., pain and swelling at the injection site, fever, fatigue, headache). ■ Inform COVID-19 vaccine recipients, especially males ages 12-39 years, of the rare risk of myocarditis and pericarditis following receipt of COVID-19 vaccines and the benefit of COVID-19 vaccination in reducing the risk of severe outcomes from COVID-19.§ Counseling should also include the need to seek care if symptoms of myocarditis or pericarditis occur after vaccination, particularly in the week following vaccination. For more information see: COVID-19 vaccination and myocarditis and pericarditis. ■ Inform vaccine recipients interested in or receiving Janssen COVID-19 Vaccine of the risk and symptoms of thrombosis with thrombocytopenia syndrome (TTS), as well as the need to seek immediate medical care should symptoms develop after receiving Janssen vaccine. For more information see: Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendix A. Guidance for use of Janssen COVID-19 Vaccine.

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All currently authorized or approved COVID-19 vaccines	
Interchangeability of vaccines	■ In general, the same COVID-19 monovalent vaccine product (Moderna, Novavax, Pfizer-BioNTech) should be used for all doses in the primary series with the following exception: children ages 6 months through 4 years who received 2 primary series doses of a monovalent Pfizer-BioNTech vaccine should receive a bivalent Pfizer-BioNTech vaccine as their third primary series dose. A different COVID-19 vaccine product may be administered if the previous product cannot be determined/not available, the person would otherwise not complete the primary series, or if a person is unable to complete a series with the same COVID-19 vaccine due to a contraindication ■ For booster vaccination, bivalent mRNA vaccines are recommended. Any homologous (i.e., same manufacturer for the primary series and booster dose) or heterologous (i.e., different manufacturer for the primary series and booster dose) bivalent mRNA vaccine can be used for FDA authorized age group and product. ■ For people who receive a mixed-product primary series, booster recommendations can be found in Interim Clinical Considerations and Interim COVID-19 Immunization Schedule
Coadministration with other vaccines	■ COVID-19 vaccines may be administered on the same day as other vaccines. ■ Persons, particularly adolescent or young adult males, might consider waiting 4 weeks after orthopoxvirus (monkeypox) vaccination (either JYNNEOS or ACAM2000) before receiving a dose of any COVID-19 vaccine. ■ Administer each injection in a different injection site.
Contraindications	History of: ■ Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine ■ A known diagnosed allergy to a component of the COVID-19 vaccine ■ For the Janssen COVID-19 Vaccine, TTS following receipt of a previous Janssen COVID-19 Vaccine (or other COVID-19 vaccines not currently authorized or approved in the United States that are based on adenovirus vectors, e.g., AstraZeneca)¶
Precautions	■ History of anaphylaxis after any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"]) ■ History of multisystem inflammatory syndrome in children (MIS-C) or multisystem inflammatory syndrome in adults (MIS-A) ■ History of an immediate (within 4 hours of exposure) non-severe allergic reaction after a dose of one type of COVID-19 vaccine have a precaution to the same type of COVID-19 vaccine ■ Allergy-related contraindication to one type of COVID-19 vaccine have a precaution to the other types of COVID-19 vaccines.** ■ Moderate or severe acute illness, with or without fever ■ History of myocarditis or pericarditis after a dose of any COVID-19 vaccine ■ For Janssen COVID-19 Vaccine, a history of Guillain-Barré syndrome††

¶ Additionally, people with a history of an episode of immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as spontaneous or classic HIT, should not receive Janssen COVID-19 Vaccine. These people should receive an mRNA or Novavax COVID-19 vaccine booster dose.

** People with a known allergy to polysorbate have a contraindication to both Novavax and Janssen COVID-19 vaccines.

†† People who develop GBS within 6 weeks after receipt of Janssen COVID-19 Vaccine should not receive another dose of Janssen COVID-19 Vaccine. These people should receive a of an mRNA COVID-19 vaccine for subsequent doses.

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Considerations for all FDA-authorized or -approved COVID-19 vaccines	
Persons receiving HCT and CAR-T-cell therapy	■ If received doses of COVID-19 vaccine prior to or during HCT or CAR-T cell therapy, should be revaccinated for any monovalent primary series and bivalent booster doses received before or during treatment at least 3 months (12 weeks) after transplant or CAR-T-cell therapy. There is no revaccination for monovalent booster doses.
Persons who are moderately or severely immunocompromised	■ See the Interim COVID-19 Immunization Schedule for Ages 6 Months or Older
Persons receiving immunosuppressive therapies	■ Whenever possible, COVID-19 vaccines should be administered at least 2 weeks before initiation or resumption of immunosuppressive therapies.
SARS-CoV-2 infection ■ Current infection ■ History of previous infection ■ Exposed to an infected person	COVID-19 vaccination is recommended for everyone ages 6 months and older, regardless of a history of symptomatic or asymptomatic SARS-CoV-2 infection. ■ Defer vaccination until person has recovered from acute illness and criteria have been met for them to discontinue isolation. ■ People who recently had SARS-CoV-2 infection may consider delaying their next COVID-19 dose by 3 months from symptom onset or positive test (if infection was asymptomatic). ■ Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection is not recommended for the purpose of vaccine decision-making. ■ Additional information at: Interim Clinical Considerations for Use of COVID-19 Vaccines: COVID-19 vaccination and SARS-CoV-2 infection | CDC ■ COVID-19 vaccination is not recommended for post-exposure prophylaxis.
Persons with history of multisystem inflammatory syndrome (MIS-C and MIS-A) from SARS-CoV-2 infection	■ Wait until clinical recovery and at least 90 days after an MIS-C or MIS-A diagnosis to administer COVID-19 vaccine. ■ For persons who developed MIS-C or MIS-A after COVID-19 vaccination, a conversation between the vaccine recipient, guardian, and clinical team or specialist to discuss benefits and risks of receiving a COVID-19 vaccine is encouraged. ■ Additional information at: Interim Clinical Considerations for Use of COVID-19 Vaccines COVID-19 vaccination and MIS-C and MIS-A | CDC
Persons who received passive antibody therapy (convalescent plasma/ monoclonal antibodies)	■ COVID-19 vaccination can be given at any interval following receipt of passive antibody therapy.
Persons who are pregnant, breastfeeding, trying to get pregnant, or might become pregnant in the future	■ Are recommended to be vaccinated according to the recommended schedule.

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Considerations for all FDA-authorized or -approved COVID-19 vaccines	
Persons with a history of myocarditis or pericarditis	■ Development of myocarditis or pericarditis after a dose of any COVID-19 vaccine is a precaution to a subsequent dose of any COVID-19 vaccine. ■ Consult Interim Clinical Considerations: Myocarditis after mRNA COVID-19 Vaccines | CDC if a subsequent dose is being considered after the episode of myocarditis or pericarditis has completely resolved. ■ Persons who have a history of myocarditis or pericarditis unrelated to COVID-19 vaccination may receive any age-appropriate COVID-19 vaccine after the episode of myocarditis or pericarditis has resolved. ■ For more information, see Interim Clinical Considerations for Use of COVID-19 Vaccines: COVID-19 vaccination and myocarditis and pericarditis | CDC

Considerations for Janssen COVID-19 Vaccine	
Janssen COVID-19 Vaccine is authorized for adults ages 18 years and older for the primary series dose and 1 booster dose (following completion of primary vaccination with an FDA-authorized or FDA-approved COVID-19 vaccine) in certain limited situations due to safety considerations. For more information, see Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendix A | CDC	
Persons with a history of Guillain-Barré syndrome (GBS)	■ A history of GBS is a precaution for receipt of Janssen COVID-19 Vaccine. An mRNA or Novavax vaccine is recommended. ■ Persons who develop GBS within 6 weeks of Janssen COVID-19 vaccination should only receive an mRNA COVID-19 vaccine. See Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendix A
Persons with a history of thrombosis with thrombocytopenia syndrome (TTS)	■ It is contraindicated to administer Janssen COVID-19 Vaccine to persons with a history of TTS following receipt of the Janssen COVID-19 Vaccine or any other adenovirus vector-based COVID-19 vaccines (e.g., AstraZeneca COVID-19 Vaccine). ■ These persons should receive a dose of an mRNA COVID-19 vaccine as a booster dose at least 2 months (8 weeks) following their dose of the Janssen COVID-19 Vaccine and after their clinical condition has stabilized.
Persons with a history of heparin-induced thrombocytopenia (HIT)	■ Persons with a history of an episode of an immune-mediated syndrome characterized by TTS, such as a spontaneous or classic HIT, should not receive Janssen COVID-19 Vaccine. ■ These persons should receive an mRNA or Novavax COVID-19 vaccine.

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General COVID-19 Vaccination Information	
Persons vaccinated outside the United States	■ The recommendations for people vaccinated outside the United States depend on the number and type of vaccine(s) received for the primary series and booster doses. Current guidance can be found at: Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendix B | CDC
Post-vaccination observation periods	**15 minutes**: Vaccination providers, particularly when vaccinating adolescents, should consider observing vaccine recipients for 15 minutes after vaccination because of the risk of syncope. **30 minutes**: Vaccination providers should consider observing persons with the following medical histories for 30 minutes after vaccination to monitor for allergic reactions: ■ An allergy-related contraindication to a different type of COVID-19 vaccine ■ Non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine ■ Anaphylaxis after non-COVID-19 vaccines or injectable therapies
SARS-CoV-2 antibody testing	■ Antibody testing is not recommended for vaccine decision-making or to assess immunity following vaccination.
Reporting requirements	Adverse events that occur following COVID-19 vaccination should be reported to VAERS. COVID-19 providers are required to report: ■ Vaccine administration errors ■ Serious adverse events ■ Myocarditis or pericardiitis ■ Cases of Multisystem Inflammatory Syndrome ■ Cases of COVID-19 that result in hospitalization or death