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 (Use for 1st and 2nd Dose)*	Maroon	Maroon	Yes	Doses 1 and 2: 3 µg/0.2 m		A booster dose is not authorized for children who received a 3-dose primary series regardless which vaccine (monovalent or bivalent) was administered for Dose 3.	
6 months–4 years	Bivalent (Use for 3rd 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

* A monovalent Pfizer-BioNTech vaccine is used for the first and second primary doses; a bivalent Pfizer-BioNTech vaccine is used for the third primary dose.

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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 in certain limited situations due to safety considerations. For guidance on retrospective record review, scheduling and administration of Janssen vaccine 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 mRNA and Novavax vaccine recipients, especially males ages 12-39 years, of the rare risk of myocarditis and pericarditis following receipt of these 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.

‡ See Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States for detailed guidance.

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All currently authorized or approved COVID-19 vaccines	
Interchangeability of vaccines	■ In general, the same COVID-19 monovalent vaccine product (Pfizer-BioNTech, Moderna, Novavax) should be used for all doses in the primary series. In exceptional situations when the previous product cannot be determined/not available or if a person is unable to complete a series with the same COVID-19 vaccine due to a contraindication any age-appropriate mRNA COVID-19 vaccine may be used (administer at a minimum interval of 28 days). ■ For booster vaccination, any homologous or heterologous age-appropriate mRNA vaccine can be used. Recommendations vary based on age and primary series product. See, Timing, spacing, age transitions, and coadministration of COVID-19 vaccines | CDC.§
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 Moderna, Novavax, or Pfizer-BioNtech 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 an mRNA or Novavax COVID-19 vaccine ■ For Janssen COVID-19 Vaccine, a history of Guillain-Barré syndrome††

§ For booster vaccination, homologous or heterologous mRNA booster is recommended.

¶ 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 ad 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 booster dose 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 should wait 2 weeks after COVID-19 vaccination before receiving tixagevimab/cilgavimab (EVUSHELD) for pre-exposure prophylaxis.
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 mRNA vaccines and Novavax	
Persons with a history of myocarditis or pericarditis	■ Development of myocarditis or pericarditis after a dose of an mRNA or Novavax COVID-19 vaccine is a precaution to a subsequent dose of any COVID-19 vaccine. ■ If after a risk assessment the decision is made to administer a subsequent COVID-19 vaccine dose, the person should wait until after their episode has resolved. ■ For information on potential use of Janssen COVID-19 Vaccine in this situation, see Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendix A | CDC ■ Persons who have a history of myocarditis or pericarditis unrelated to mRNA or Novavax 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 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 (monovalent or bilvalent vaccine as indicated) for subsequent doses.
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's 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 pericarditis after mRNA or Novavax COVID-19 Vaccine ■ Cases of Multisystem Inflammatory Syndrome ■ Cases of COVID-19 that result in hospitalization or death