Summary Document for Interim Clinical Considerations

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

	Pfizer-BioNTech		Moderna	Janssen
Preferential recommendation	mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna) are preferred over Janssen COVID-19 Vaccine for the primary series and booster doses.			
Age groups	5 through 11 years of age	12 years of age and older	18 years of age and older	18 years of age and older
Vaccine type	mRNA	mRNA	mRNA	Replication-incompetent adenovirus type 26 vector
Dose	10 µg (orange cap)	• 30 µg (purple cap) • 30 µg (gray cap)	• 100 µg (primary series and additional primary dose) • 50 µg (booster dose)	5×10^{10} viral particles
Dosage (volume)	0.2 mL	0.3 mL	• 0.5 mL (primary series and additional dose for moderately or severely immunocompromised persons) • 0.25 mL (booster dose)	0.5 mL
Primary series doses	2	2	2	1
Additional doses for moderately or severely immunocompromised persons	1	1	1	n/a Only mRNA vaccines are approved for additional doses
Booster doses	n/a	1	1	1
		mRNA vaccines are preferred		
COVID-19 vaccination schedule	COVID-19 Vaccine Interim COVID-19 Immunization Schedule for Ages 5 Years and Older (cdc.gov) https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-5yrs-older.pdf			

All currently authorized or approved COVID-19 vaccines

Pre-vaccination counseling	■ Prior to vaccination: ■ Provide the vaccine-specific Fact Sheet for Recipients and Caregivers Pfizer-BioNTech (https://www.fda.gov/media/144413/download), Moderna (https://www.fda.gov/media/144637/download), Janssen (https://www.fda.gov/media/146304/download). ■ Inform vaccine recipients mRNA vaccines are preferred over Janssen COVID-19 Vaccine. ■ Counsel COVID-19 vaccine recipients, parents, or guardians about expected reactions post-vaccination (e.g., pain and swelling at the injection site, fever, fatigue, headaches). ■ Inform persons receiving mRNA COVID-19 vaccines, especially males ages 12-39 years, of the rare risk of myocarditis and/or pericarditis following receipt of mRNA 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. ■ Inform persons 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.

* A 3-week (Pfizer-BioNTech) or 4-week (Moderna) interval between the first and second dose continues to be the recommended interval for people who are moderately or severely immunocompromised, persons ages 65 years and older, and others who need rapid protection due to increased concern about community transmission. The small risk of myocarditis associated with mRNA COVID-19 vaccines, particularly in males ages 12-39 years, might be reduced and peak antibody responses and vaccine effectiveness may be increased with a longer interval; up to 8 weeks between doses.

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All currently authorized or approved COVID-19 vaccines	
Interchangeability of vaccines	■ In general, the same mRNA vaccine product should be used for all doses in the primary series. In exceptional situations, for people 18 years of age or older, such as a contraindication to a second dose of mRNA vaccine or when the previous product cannot be determined or is not available, another FDA-approved or -authorized COVID-19 vaccine may be used (administer at a minimum of 28 days). ■ Only Pfizer-BioNTech vaccine products can be used in persons 5-17 years of age. The Pfizer-BioNTech formulation for children ages 5-11 years (orange cap) is not interchangeable with the Pfizer-BioNTech formulation for persons ages 12 years and older (purple or gray cap). ■ Any FDA-authorized or -approved COVID-19 vaccine can be used for the booster dose; mRNA vaccines are preferred. When a different product is used the eligible population and dosing intervals are those of the vaccine used for the primary series (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Interchangea).†
Coadministration with other vaccines	■ COVID-19 vaccines may be administered without regard to timing of other vaccines, including simultaneous administration. ■ Administer each injection in a different injection site.
Contraindications	■ Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine ■ History of a known diagnosed allergy to a component of the COVID-19 vaccine ■ Contraindication to one type of COVID-19 vaccine (mRNA) is a precaution to other types of COVID-19 vaccines (Janssen) ■ For the Janssen COVID-19 Vaccine, TTS following receipt of a previous Janssen vaccine (or other COVID-19 vaccines not currently authorized in the United States that are based on adenovirus vectors, e.g., AstraZeneca)
Precautions	■ Immediate (within 4 hours exposure) non-severe allergic reaction to a previous dose or known (diagnosed) allergy to a component of the vaccine ■ Immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"]) ■ For mRNA COVID-19 vaccines, history of myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine ■ For Janssen COVID-19 Vaccine, a history of GBS

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 with a primary series at least 3 months (12 weeks) after transplant or CAR-T-cell therapy
Persons receiving immunosuppressive therapies	■ Whenever possible, COVID-19 vaccines should be administered at least 2 weeks before initiation or resumption of immunosuppressive therapies
Persons with prior or current SARS-CoV-2 infection	■ Defer vaccination until person has recovered from acute illness and criteria (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#CoV-19-vaccination) have been met for them to discontinue isolation
Persons with history of multisystem inflammatory syndrome (MIS-C and MIS-A) from SARS-CoV-2 infection	■ COVID-19 vaccines can be given. ■ For persons who have had MIS-C or MIS-A from SARS-CoV-2 infection who have not yet received COVID-19 vaccine, a conversation between the vaccine recipient, guardian, and clinical team to discuss benefits and risks of receiving a COVID-19 vaccine is encouraged. ■ Clinical recovery, including return to normal cardiac function, is an important factor when considering COVID-19 vaccination.

† Although CDC provides considerations for a mixed series in exceptional circumstances for a primary or additional dose, this is still considered an administration error that requires VAERS reporting. Heterologous booster doses are allowed (mRNA vaccines preferred) and are not considered a vaccine error.

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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 with a known SARS-CoV-2 exposure	■ COVID-19 vaccines are not recommended for post-exposure prophylaxis. ■ Persons should defer vaccination until quarantine period has ended. ■ In certain circumstances to avoid missed opportunities for vaccination, vaccination during quarantine could be considered if they do not have COVID-19 symptoms or current infection, and appropriate infection and control procedures are in place.
Persons who are pregnant, breastfeeding, trying to get pregnant, or might become pregnant in the future	■ Are recommended to receive a COVID-19 vaccine primary series, additional mRNA doses (if indicated) and a booster dose
Children and adolescents	■ Are only eligible for Pfizer-BioNTech COVID-19 Vaccine ■ Should receive the age-appropriate vaccine formulation. Follow the schedule based on their age on the day of vaccination, regardless of their size or weight. ■ Booster doses are not recommended for persons younger than 12 years of age ■ If a child, who started the series at 11 years of age turns 12 years old between doses, CDC recommends administering the age-appropriate Pfizer-BioNTech COVID-19 Vaccine (purple or gray cap) formulation for subsequent doses. However, the FDA authorization allows children who will turn from age 11 years to 12 years to receive either product (orange or purple/gray cap).
Considerations for mRNA vaccines	
Persons with a history of myocarditis or pericarditis	■ Development of myocarditis or pericarditis after a dose of an mRNA 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 receive a subsequent COVID-19 vaccine dose, the person should wait until after their episode has resolved. ■ For men ages 18 years and older who choose to receive a subsequent COVID-19 vaccine, a Janssen COVID-19 Vaccine can be considered instead of mRNA COVID-19 vaccines. ■ Persons who have a history of myocarditis or pericarditis unrelated to mRNA COVID-19 vaccination may receive any currently FDA-approved or -authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has resolved.
Considerations for Janssen COVID-19 Vaccine	
Persons with a history of Guillain-Barre syndrome (GBS)	■ A history of GBS, either before or after COVID-19 vaccination, is a precaution for receipt of Janssen COVID-19 Vaccine. An mRNA vaccine is preferred. ■ Persons who develop GBS within 6 weeks of Janssen COVID-19 vaccination should only receive an mRNA COVID-19 vaccine 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 their clinical condition has stabilized. ■ Prior to booster vaccination, a conversation between the patient and their clinical team, including hematologists or other specialists, may assist with vaccination decisions.

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Considerations for Janssen COVID-19 Vaccine	
Persons with a history of heparin-induced thrombocytopenia (HIT)	■ 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 a current FDA-authorized or -approved mRNA COVID-19 vaccine.

General COVID-19 Vaccination Information	
Persons vaccinated outside the United States	■ The recommendations for people vaccinated outside the United States depend on the vaccine(s) received for the primary series, whether the primary series was completed, and whether a booster dose was received. Current guidance can be found at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#appendix-e
Post-vaccination observation periods	**30 minutes** – people with a history of: ■ A contraindication to another type of COVID-19 vaccine product (i.e., mRNA or viral vector COVID-19 vaccines) ■ Immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine ■ Immediate allergic reaction of any severity to a non-COVID-19 vaccine or injectable therapies ■ Anaphylaxis due to any cause **15 minutes** – all other persons
SARS-CoV-2 antibody testing	■ Antibody testing 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 (https://vaers/hhs/gov). COVID-19 providers are required to report: ■ Vaccine administration errors ■ Serious adverse events ■ Cases of Multisystem Inflammatory Syndrome ■ Cases of COVID-19 that result in hospitalization or death