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 recommended 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	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 primary dose) 0.25 mL (booster dose)	0.5 mL
Number of doses in primary series	2		2	1
Interval between primary series doses	3 weeks (21 days)		1 month (28 days)	N/A
Additional (3rd) primary dose for moderately or severely immunocompromised persons	Currently not authorized for this age group	Recommended at least 28 days after the 2nd dose of the primary series for moderately and severely immunocompromised people 12 years of age and older (https://www.cdc.gov/vaccines/covid-19/clinical considerations/covid-19-vaccines-us.html#considerations-covid-19-vax-immunocompromised) Use the same vaccine product as the primary series See information below about a booster dose.		Not authorized as an additional primary dose. See information below about a booster dose.
Booster dose	Currently not authorized for this age group	A booster dose, at least 6 months after the last dose of a COVID-19 mRNA vaccine primary series (i.e., after the 2nd dose or the additional [3rd] dose for moderately and severely immunocompromised persons): • Should be given to persons 18 years of age and older (Use of heterologous – mix and match – booster doses is allowed. mRNA COVID-19 vaccines are preferred.) • May be given to persons 16 and 17 years of age based on individual benefits and risks	A booster dose, at least 6 months after the last dose of a COVID-19 mRNA vaccine primary series (i.e., after the 2nd dose or the additional [3rd] dose for moderately and severely immunocompromised persons): • Should be given to persons 18 years of age and older (Use of heterologous – mix and match – booster doses is allowed. mRNA COVID-19 vaccines are preferred.)	A booster dose, at least 2 months (8 weeks) after the primary Janssen single dose: • Should be given to all persons who 18 years of age an older (Use of heterologous – mix and match – booster doses is allowed. mRNA COVID-19 vaccines are preferred.) • A moderately or severely immunocompromised person who received a primary Janssen COVID-19 Vaccine should not receive more than 1 booster dose (total of 2 doses).
		For additional information, see Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in theUnited States https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-covid19-vax-immunocopromised		
Interval between primary and booster doses	n/a	At least 6 calendar months after completing the primary series or additional primary dose (for moderately or severely immunocompromised)	At least 6 calendar months after receiving the primary series or additional primary dose (for moderately or severely immunocompromised)	At least 2 months (8 weeks) after receiving the primary dose

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All currently authorized or approved COVID-19 vaccines	
Interchangeability of vaccines	■ Primary series doses and additional primary dose (for moderately and severely immunocompromised people) should be with the same mRNA vaccine product. 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 mRNA FDA- approved or -authorized COVID-19 vaccine may be used (administer at a minimum interval of 28 days). ■ The Pfizer-BioNTech formulation for children aged 5-11 years (orange cap) is not interchangeable with the Pfizer-BioNTech formulation for people aged 12 years and older (purple cap). ■ Any FDA-approved or –authorized 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#Interchangeability).*
Coadministration with other vaccines	■ COVID-19 vaccines may be administered without regard to timing of other vaccines, including simultaneous administration.
Persons with prior or current COVID-19	■ COVID-19 vaccines can be given safely to people with prior SARS-CoV-2 infection. ■ Defer vaccination until person has recovered from the acute illness and criteria have been met for them to discontinue isolation (https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html)
Multisystem inflammatory syndrome (MIS-C and MIS-A)	■ COVID-19 vaccines can be given; however, a conversation between the patient, guardian, and clinical team to discuss benefits and risks of receiving a COVID-19 vaccine is encouraged.
Persons who received monoclonal antibodies or convalescent plasma for COVID-19 treatment or post-exposure prophylaxis	■ For post-exposure prophylaxis: defer COVID-19 vaccination for 30 days ■ For COVID-19 treatment: defer COVID-19 vaccination for 90 days
Persons with a known SARS-CoV-2 exposure	■ COVID-19 vaccine not recommended for community outbreaks or post-exposure prophylaxis. ■ People in community or outpatient setting should defer vaccination until quarantine period has ended (https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html) ■ Residents or patients in congregate settings may be vaccinated if they do not have symptoms consistent with COVID-19 (https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html)
Risk of thrombosis with thrombocytopenia syndrome (TTS)	■ All persons who elect to receive a Janssen (Johnson & Johnson) COVID-19 Vaccine should be informed about the risk and symptoms of TTS in the 2 weeks after vaccination as well as the need to seek immediate medical care should symptoms develop.
History of TTS after 1 dose of Janssen COVID-19 Vaccine	■ 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, which is not authorized or approved in the United States). ■ These people should receive a dose of an mRNA COVID-19 vaccine as a booster at least 2 months (8 weeks) following their dose of the Janssen COVID-19 Vaccine and after 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.
History of heparin-induced thrombocytopenia (HIT)	■ If within 90 days of illness, offer an mRNA vaccine, vaccinate with any FDA-authorized or approved COVID-19 vaccine, including Janssen COVID-19 Vaccine
Persons with underlying conditions	■ May receive COVID-19 vaccine
Persons receiving HCT and CAR-T-cell therapy	■ If received doses of COVID-19 vaccine prior to receiving an 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 with a history of myocarditis or pericarditis	■ If myocarditis or pericarditis occurred after a dose of an mRNA COVID-19 vaccine: • Until additional safety data are available, experts advise that people who develop mycarditis or pericarditis after a dose of an mRNA COVID-19 vaccine not receive a subsequent dose of any COVID-19 vaccine. • This decision should include a conversation between the patient and their clinical team. • A subsequent dose can be considered in certain circumstances including personal risk of severe COVID-19 and level of community transmission. Considerations can be found at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-pfizer-biontech-moderna • If a history of myocarditis or pericarditis unrelated to an mRNA COVID vaccination, may receive COVID-19 vaccine after the episode has completely resolved.

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All currently authorized or approved COVID-19 vaccines	
Persons with a history of Guillain-Barré Syndrome (GBS)	■ Can receive any FDA-authorized or approved COVID-19 vaccine; however, discuss the availability of mRNA vaccines because of possible association between GBS and Janssen COVID-19 vaccination.
Pregnant or breastfeeding people or people trying to get pregnant	■ Are recommended to receive a COVID-19 vaccine primary series, additional primary dose (if indicated) and booster dose, inform of risk of TTS after receipt of Janssen COVID-19 Vaccine and the availability of other options
Children and adolescents	■ Children and adolescents aged 5-17 are ONLY eligible for Pfizer-BioNTech COVID-19 Vaccine ■ Children aged 5-11 years - 10 ug (0.2mL dosage) Pfizer-BioNTech (orange cap) ■ Adolescents 12 years of age or older - 30ug (0.3 mL dosage) Pfizer-BioNTech (purple cap) ■ Adolescents and adults 18 years and older are eligible for Janssen, Moderna, Pfizer-BioNTech (purple cap) COVID-19 vaccine products. ■ Additional primary doses are not recommended at this time for children younger than12 years of age who are moderately or severely immunocompromised. ■ Booster doses are not recommended for people younger than16 years of age https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-covid19-vax-booster ■ Because of the risk of syncope, especially in adolescents, recipients should be observed for 15 minutes after vaccination
Persons vaccinated outside the United States	■ People who received all recommended doses of an FDA-authorized or FDA-approved COVID-19 vaccine are considered fully vaccinated. If only 1 dose of a 2-dose vaccine has been received, provide the second dose as close to the recommended time as possible. • People who are moderately and severely compromised should receive an additional dose at least 28 days after completion of their primary series. • People who completed a primary series (and additional primary dose for moderately or severely immunocompromised people), follow booster guidance on page 1. ■ People who received all of the recommended doses of a World Health Organization Emergency Use Listing (WHO-EUL) COVID-19 vaccine not FDA-approved or FDA-authorized, or people who completed a heterologous (mix and match) series composed of any combination of FDA-approved, FDA-authorized, or WHO-EUL COVID-19 vaccines are considered fully vaccinated. • Should receive an additional primary dose of Pfizer-BioNTech COVID-19 Vaccine (30 µg formulation [purple cap]) at least 28 days after completion of the second vaccine dose of the primary series, if moderately or severely immunocompromised and at least 12 years of age. • Should receive a single booster dose of Pfizer-BioNTech COVID-19 Vaccine at least 6 months after completing their primary series, if at least 16 years of age (including moderately or severely immunocompromised people who received an additional primary dose) ■ People who received only the first dose of a multidose WHO-EUL COVID-19 primary series that is not FDA-approved or FDA-authorized, or who received all or some of the recommended doses of a COVID-19 vaccine primary series that is not listed for emergency use by WHO: • Should be offered a complete FDA-authorized or FDA-approved COVID-19 vaccine primary series, with a minimum interval of at least 28 days since recipient of the last dose of vaccine. • Are considered fully vaccinated after completion of primary vaccination and are not recommended to receive an additional primary dose or booster dose at this time.
Contraindications	■ Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the COVID-19 vaccine ■ Contradiction to one type of COVID-19 vaccines (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 COVID-19 Vaccine (or other COVID-19 vaccines not currently authorized in the United States that are based on adenovirus vectors)
Precaution	■ 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"])
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

* Although CDC provides considerations for a mixed series in exceptional circumstances for a primary or additional primary dose (https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Interchangeability), this is still considered an administration error that requires VAERS reporting. Heterologous booster doses are allowed and are not considered a vaccine error.