

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)	<ul style="list-style-type: none"> ■ 30 µg (purple cap) ■ 30 µg (gray cap) 	<ul style="list-style-type: none"> ■ 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	<ul style="list-style-type: none"> ■ 0.5 mL (primary series and additional dose for moderately or severely immunocompromised persons) ■ 0.25 mL (booster dose) 	0.5 mL
Immunization Schedule	<ul style="list-style-type: none"> ■ COVID-19 vaccination is recommended for persons 5 years of age and older. ■ For most people a primary series is 2 doses of an mRNA vaccine (Pfizer-BioNTech and Moderna) or a single dose of Janssen COVID-19 Vaccine. NOTE: mRNA vaccines (Moderna, Pfizer-BioNTech) are preferred in most situations over Janssen COVID-19 Vaccine. ■ For persons who are moderately or severely immunocompromised 5 years of age and older, a 3-dose primary series of an mRNA vaccine (Moderna, Pfizer-BioNTech) is recommended. An mRNA vaccine is preferred, but a single primary Janssen vaccine dose can be used for persons 18 years of age and older followed by a 2nd dose of an mRNA at least 4 weeks later. ■ A booster dose is recommended for persons 12 years of age and older. Some persons may choose to receive a 2nd booster dose: ■ See the Interim COVID-19 Immunization Schedule for Ages 5 Years of Age or older at https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-5yrs-older.pdf 			

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<p>Pre-vaccination counseling</p>	<p>Prior to vaccination:</p> <ul style="list-style-type: none"> 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). Screen for contraindications and precautions. CDC's Prevacination Screening Form and Guidance document can be found at www.cdc.gov/vaccines/covid-19/info-by-product/index.html. 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. For more information see: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#safety-mRNA. 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. For more information see: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#considerations-Janssen.
<p>Interchangeability of vaccines</p>	<ul style="list-style-type: none"> In general, the same mRNA vaccine product should be used for all doses in the primary series. In exceptional situations for persons 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#Interchangeable).†
<p>Coadministration with other vaccines</p>	<ul style="list-style-type: none"> COVID-19 vaccines may be administered without regard to timing of other vaccines, including simultaneous administration. Administer each injection in a different injection site.
<p>Contraindications</p>	<p>History of:</p> <ul style="list-style-type: none"> 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 vaccine (or other COVID-19 vaccines not currently authorized in the United States that are based on adenovirus vectors, e.g., AstraZeneca)‡

* See Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States at: www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#recommendations for detailed guidance.

† 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.

‡ 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 COVID-19 vaccine.

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Precautions	<ul style="list-style-type: none"> ■ Allergy-related contraindication to one type of COVID-19 vaccine (mRNA) is a precaution to other types of COVID-19 vaccines (e.g. Janssen) ■ 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 ■ History of multisystem inflammatory syndrome in children (MIS-C) or multisystem inflammatory syndrome in adults (MIS-A) ■ Moderate or severe acute illness, with or without fever ■ History of 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 Guillain-Barré syndrome[§]
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Considerations for all FDA-authorized or -approved COVID-19 vaccines

Persons receiving HCT and CAR-T-cell therapy	<ul style="list-style-type: none"> ■ 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	<ul style="list-style-type: none"> ■ Whenever possible, COVID-19 vaccines should be administered at least 2 weeks before initiation or resumption of immunosuppressive therapies
SARS-CoV-2 infection <ul style="list-style-type: none"> ■ Current infection ■ History of previous infection 	<p>COVID-19 vaccination is recommended for everyone ages 5 years and older, regardless of a history of symptomatic or asymptomatic SARS-CoV-2 infection.</p> <ul style="list-style-type: none"> ■ 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 first or second COVID-19 vaccine booster 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: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#infection
Persons with history of multisystem inflammatory syndrome (MIS-C and MIS-A) from SARS-CoV-2 infection	<ul style="list-style-type: none"> ■ 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. Additional information at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#infection
Persons who received passive antibody therapy (convalescent plasma/monoclonal antibodies)	<ul style="list-style-type: none"> ■ 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	<ul style="list-style-type: none"> ■ 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.

[§] 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 an mRNA COVID-19 vaccine.

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Considerations for all FDA-authorized or -approved COVID-19 vaccines

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.
- For most children 5 years of age and older, a 2-dose primary series is recommended. A 3-dose primary series is recommended for children in this age group who are moderately or severely immunocompromised.
- 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.
- For more information see: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#safety-mRNA>

Considerations for Janssen COVID-19 Vaccine

Persons with a history of Guillain-Barré 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.
- For more information see: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#considerations-Janssen>

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.
- 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)

- 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 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/interim-considerations-us.html#appendix-a>

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 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 (<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