Prevaccination Checklist for COVID-19 Vaccines

Information for Healthcare Professionals

The following guidance should be used to determine if COVID-19 vaccine can be administered or not. Using the completed prevaccination checklist, review clinical guidance based on the answers to the questions. Use this document in conjunction with:

- 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/covid-19-vaccines-us.html
- Advisory Committee on Immunization Practices on Immunization General Best Practice Guidelines at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html

COVID-19 vaccines are authorized and approved for different age groups. Administer COVID-19 vaccine intramuscularly.

For guidance on specific schedules, storage, preparation, and administration, please see:

- Interim COVID-19 Immunization Schedule for Ages 6 Months and Older at www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-6months-older.pdf
- COVID-19 Vaccination Clinical & Professional Resources for each vaccine product at www.cdc.gov/vaccines/covid-19/info-by-product/index.html

Postvaccination observation times for people without contraindications to COVID-19 vaccination

30 minutes:

- People with a history of:
  - Contraindication to another type of COVID-19 vaccine product due to allergy
  - Immediate (within 4 hours of exposure) non-severe allergic reaction to other non-COVID-19 vaccines or injectable therapies.
  - Anaphylaxis due to any cause
  - Non-severe allergic reaction to a previous dose of the same type of COVID-19 vaccine

15 minutes:

- All other people

Co-administration of COVID-19 vaccines and other vaccines

COVID-19 vaccines and other routinely administered vaccines **may be administered without regard to timing.** This includes simultaneous administration of COVID-19 vaccines and other vaccines during the same visit. Other routine vaccines can also be administered anytime before or after COVID-19 vaccination.

1. How old are you?

Clinical considerations based on the age of the recipient include:

COVID-19 vaccines products have different age indications.

- Janssen COVID-19 Vaccine can be administered to persons 18 years of age and older in certain limited situations due to safety considerations.
- Novavax COVID-19 Vaccine can be administrated to persons 12 years of age and older.
- Moderna COVID-19 Vaccine can be administered to persons ages 6 months of age and older.
- Pfizer-BioNTech COVID-19 vaccine can be administered to persons 6 months of age and older.

Use the manufacturers' fact sheets for healthcare professionals at www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines and CDC clinical materials for healthcare professionals at www.cdc.gov/vaccines/covid-19/index.html and identify correct age-appropriate product.

People receiving mRNA or Novavax COVID-19 vaccines, especially males ages 12–39 years, should be made aware of the rare risk of myocarditis and/or 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, including the possibility of cardiac sequelae. Counseling should include the need to seek care if symptoms of myocarditis or pericarditis, such as chest pain, shortness of breath, or tachycardia develop after vaccination, particularly in the week after vaccination. Extending the interval between the first and second mRNA vaccine dose to 8 weeks might reduce the risk.

Additional recipient education materials can be found at www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html

2. Are you feeling sick today?

While there is no evidence acute illness reduces vaccine efficacy or increases adverse reactions, as a precaution, **delay vaccinating patients with moderate or severe illness** until the illness has improved.

Defer vaccination of people with current SARS-CoV-2 infection. For those with

- Symptoms: defer vaccination until recovery from the acute illness and isolation has been discontinued.
- Asymptomatic infection: defer vaccination until isolation has been discontinued.

This recommendation applies regardless of whether the SARS-CoV-2 infection occurred before the recipient received an initial dose or between doses. Viral or serological testing to assess for current or prior infection solely for the purpose of vaccine-decision making is not recommended.

People with mild illnesses can be vaccinated. Do not withhold vaccination if a person is taking antibiotics.

3. Have you ever received a dose of COVID-19 vaccine?

COVID-19 vaccination is recommended for everyone 6 months of age and older. All COVID-19 primary series doses should be the same vaccine product. Booster doses, for eligible persons, may be a different age-appropriate COVID-19 vaccine than the COVID-19 vaccine product used in the primary series (i.e., mix and match may be used for boosters).

To determine previously administered COVID-19 doses, check medical records, immunization information systems, and vaccination record cards. If the vaccine product previously administered cannot be determined, is no longer available, or contraindicated, any age-appropriate COVID-19 vaccine product may be administered at least 28 days after the first dose. mRNA (Moderna, Pfizer-BioNTech) and Novavax COVID-19 vaccines are recommended for the primary series. mRNA vaccines are recommended for booster doses. Novavax COVID-19 Vaccine is not authorized for booster doses. Janssen COVID-19 Vaccine can be administered to persons 18 years of age and older in certain limited situations due to safety considerations and is not authorized for the 2nd booster dose.

Use the Interim Immunization Schedule for Ages 6 Months and Older to schedule doses, see www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-6months-older.pdf

Persons who received COVID-19 vaccine 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-appendix.html#appendix-b

Additional information including scheduling, immunocompromising conditions, and treatments can be found in:

Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States: www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

CDC COVID-19 clinical and professional resources: www.cdc.gov/vaccines/covid-19/index.html

4. Do you have a health condition or are you undergoing treatment that makes you moderately or severely immunocompromised?

People with immunocompromising conditions or people who take immunosuppressive medications or therapies are at increased risk for severe COVID-19 disease. COVID-19 vaccines may be administered to people with underlying medical conditions, such as HIV infection or other immunocompromising conditions, or who take immunosuppressive medications or therapies, and who have no contraindications to vaccination. People can self-report if they are moderately or severely immunocompromised. Vaccinators should not deny COVID-19 vaccination to a person due to lack of documentation of immune status.

Use the Interim Immunization Schedule for Ages 6 Months and Older to schedule doses, see www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-6months-older.pdf.

An mRNA or Novavax COVID-19 vaccine is recommended over Janssen COVID-19 Vaccine. The same vaccine product should be used for all primary series doses. If the vaccine product previously administered cannot be determined, is no longer available, or contraindicated, any age-appropriate COVID-19 vaccine may be administered at least 28 days after the first dose. An mRNA or Novavax vaccine is recommended for the primary series. The mRNA vaccines are recommended for booster doses. Novavax COVID-19 Vaccine is not authorized for booster doses. Janssen COVID-19 Vaccine can be administered to persons 18 years of age and older in certain limited situations due to safety considerations and is not authorized for the 2nd booster dose. Vaccinated people who are moderately or severely immunocompromised should be counseled about the potential for a reduced immune response to COVID-19 vaccines. They and their close contacts should continue to follow current prevention measures (www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html).

Additional information including scheduling, immunocompromising conditions, and treatments can be found in:

Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States: www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

CDC COVID-19 clinical and professional resources: www.cdc.gov/vaccines/covid-19/index.html

5. Have you received a hematopoietic cell transplant (HCT) or CAR-T-cell therapy since receiving COVID-19 vaccine?

HCT and CAR-T-cell recipients who received doses of COVID-19 vaccine before or during HCT or CAR-T-cell therapy should be revaccinated at least 3 months (12 weeks) after transplant or CAR-T-cell therapy. Additional information can be found at: Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised

6. Have you ever had an allergic reaction to:

- A previous dose OR a component of any COVID-19 vaccine

People with a severe allergic reaction* to a previous COVID-19 vaccine dose or a known (diagnosed) allergy to a component of the vaccine have a contrainidcation to the same type of COVID-19 vaccine (mRNA, Novavax, Janssen). People who had an immediate (less than 4 hours), but non-severe allergic reaction to a previous dose of COVID-19 vaccine, have a precaution to receiving the same type of COVID-19 vaccine product. Although they can receive the same product, a different COVID-19 vaccine product can also be administered.

People with a contraindication to one type of COVID-19 vaccine (e.g., mRNA) should not receive any doses of that type of vaccine and have a precaution to the other types of vaccine†.

* When vaccine recipients report a history of an immediate allergic reaction, providers should attempt to determine whether reactions reported following vaccination are consistent with immediate allergic reactions versus other types of reactions commonly observed following vaccination, such as vasovagal reaction or postvaccination side effects (which are not contraindications to receiving additional doses of that vaccine).

† People with a known allergy to polysorbate have a contraindication to both Novavax and Janssen COVID-19 vaccines and a precaution to mRNA COVID-19 vaccines. In all other cases, an allergy-related contraindication to one type of COVID-19 vaccine is a precaution to the other types.

COVID-19 vaccine components

For a list of vaccine components go to www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines

Potential characteristics of allergic reactions, vasovagal reactions, and vaccine side effects following COVID-19 vaccination

In patients who experience post-vaccination symptoms, determining the etiology (including allergic reaction, vasovagal reaction, or vaccine side effects) is important to determine whether a person can receive additional doses of the vaccine. Additional information can be found at Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination at www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html

Healthcare professionals should be familiar with identifying severe allergic reactions, including anaphylaxis, and be competent in treating these events at the time of vaccine administration. Appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of a COVID-19 vaccine. See Management of Anaphylaxis at COVID-19 Vaccination Sites for additional guidance. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html

Syncope may occur in association with injectable vaccines, in particular among adolescents. Procedures should be in place to avoid falling injuries and manage syncopal reactions. All people are recommended to be observed following COVID-19 vaccination for at least 15 minutes. Patients should be seated or lying down for vaccination and during the observation period to decrease the risk for injury should they faint. If syncope develops, patients should be observed until symptoms resolve.

7. Have you ever had an allergic reaction to another vaccine (other than COVID-19 vaccine) or another injectable medication?

A history of any immediate allergic reaction (onset <4 hours of exposure) to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of COVID-19 vaccines) is a precaution to COVID-19 vaccines. This also applies if the non-COVID-19 vaccine or therapy has multiple components, one or more of which is a component of a COVID-19 vaccine, and it is unknown which component elicited the allergic reaction. Vaccine may be given, but counsel patients about unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination. Deferral of vaccination and/or consultation with an allergist-immunologist should be considered. **These individuals should be observed for 30 minutes after vaccination.**

8. Clinical Considerations:

Response	Consideration
History of myocarditis or pericarditis	■ Development of myocarditis or pericarditis after a dose of an mRNA (Moderna, Pfizer-Bio-NTech) or Novavax COVID-19 vaccine is a precaution to a subsequent dose of any COVID-19 vaccine and subsequent doses should generally be avoided. ■ 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. Considerations for subsequent COVID-19 vaccination may include: ○ The myocarditis or pericarditis was considered unrelated to vaccination with Moderna, Novavax, or Pfizer-BioNTech (e.g., due to SARS-CoV-2 or other viruses), especially if the myocarditis or pericarditis diagnosis occurred more than 3 weeks after the most recent dose of COVID-19 vaccine ○ Personal risk of severe acute COVID-19 (e.g., age, underlying conditions) ○ Timing of any immunomodulatory therapies; Consult ACIP's *General Best Practice Guidelines for Immunization* at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html ■ For information on potential use of Janssen COVID-19 Vaccine in this situation, see Appendix A at www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-a ■ Persons who have a history of myocarditis or pericarditis unrelated to mRNA (Moderna, Pfizer-Bio-NTech) or Novavax COVID-19 vaccination may receive any currently FDA-approved or -authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has resolved.
History of multisystem inflammatory syndrome; either MIS-C (children) or MIS-A (adults)	■ Persons with a history of multisystem inflammatory syndrome; either MIS-C (children) or MIS-A (adults) is a precaution to receipt of COVID-19 vaccine. ■ Considerations when conducting a risk assessment for potential COVID-19 vaccination can be found at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#covid19-vaccination-misc-misa ■ Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment Project at www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html.
History of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as heparin-induced thrombocytopenia (HIT)	■ Janssen COVID-19 vaccine is not recommended for persons with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as spontaneous or classic HIT. ■ These persons should receive an age-appropriate mRNA (ie. Moderna or Pfizer-BioNTech) or Novavax COVID-19 vaccine.
History of thrombosis with thrombocytopenia syndrome (TTS)	■ Janssen COVID-19 vaccine is contraindicated for persons with a history of TTS following a dose of Janssen COVID-19 vaccine (or other COVID-19 vaccines not currently authorized in the U.S. that are based on adenovirus vectors, e.g., AstrZeneca). ■ These persons should receive an mRNA COVID-19 vaccine.

Response	Consideration
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 or Novavax COVID-19 vaccine is recommended. ■ Persons who develop GBS within 6 weeks of Janssen COVID-19 vaccination should only receive an mRNA COVID-19 vaccine.
History of prior COVID-19 disease	■ COVID-19 vaccination is recommended for everyone ages 6 months and older, regardless of a history of symptomatic or asymptomatic SARS-CoV-2 infection. People who recently had COVID-19 disease or SARS-CoV-2 infection (within the last 3 months) may consider **delaying their first or second booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic)**. ■ Studies have shown that increased time between infection and vaccination may result in an improved immune response to vaccination. Also, a low risk of reinfection has been observed in the weeks to months following infection. Individual factors such as risk of severe disease, COVID-19 community level, or characteristics of the predominant SARS-CoV-2 strain should be considered when determining whether to delay getting a booster dose after infection. ■ **NOTE: 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.**