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# Standing Order for Administering COVID-19 Vaccines Addendum

Update as of March 31, 2022

This addendum includes the following:

1. Updated guidance that people ages 12 years and older who are moderately or severely immunocompromised may choose to receive a second booster dose using an mRNA COVID-19 vaccine at least 4 months after the first booster dose
2. Updated guidance that adults ages 50 years and older who are **not** moderately or severely immunocompromised may choose to receive a second booster dose using an mRNA COVID-19 vaccine at least 4 months after the first booster dose.
3. Updated guidance that people ages 18-49 years who are **not** moderately or severely immunocompromised and who received Janssen COVID-19 Vaccine as both their primary series dose and booster dose may receive a second booster dose using an mRNA COVID-19 vaccine at least 4 months after the first Janssen booster dose
4. Further clarification of safety issues including those related to multisystem inflammatory syndrome in children (MIS-C) and adults (MIS-A) and myocarditis

## Guidance for COVID-19 Vaccination for people ages 12 years and older who are Moderately or Severely immunocompromised

People with immunocompromising conditions or people who take immunosuppressive medications or therapies are at increased risk for severe COVID-19. Because the immune response following COVID-19 vaccination may differ in moderately or severely immunocompromised people, specific guidance for this population is provided. **Use of mRNA vaccines is preferred**.

mRNA COVID-19 vaccines:

A 3-dose primary series is recommended for people ages 5 years and older who are moderately or severely immunocompromised **at the time of vaccination**, (refer to Table 1). The same mRNA vaccine product should be used for all doses of the primary series (see Interchangeability of COVID-19 vaccine products).

***Pfizer-BioNTech COVID-19 Vaccine (5 years and older):*** The second dose is administered 3 weeks after the first dose; the third dose is administered at least 4 weeks after the second dose.

***Moderna COVID-19 Vaccine (18 years and older):*** The second dose is administered 4 weeks after the first dose; the third dose is administered at least 4 weeks after the second dose. The dose is 100 mcg (0.5 ml) for all doses in the primary series.

Janssen COVID-19 vaccine:

A **primary Janssen vaccine dose** is recommended for people ages 18 years and older who are moderately or severely immunocompromised, followed by a **second (additional) dose using an mRNA COVID-19 vaccine** at least 4 weeks later (see Table 2 for additional information). If Moderna COVID-19 vaccine is used for the second dose, administer a 100 mcg (0.5 ml) dose.

## Booster doses for people with moderate or severe immunocompromise

Booster doses are recommended for people 12 years of age and older after completion of primary vaccination.

mRNA COVID-19 vaccine primary series:

A single booster dose is recommended at least 3 months after the third dose in the primary series, **for a total of four doses**, preferably with an mRNA COVID-19 vaccine. If Moderna vaccine is used for the booster dose, a 50 mcg (0.25 mL) dose should be used.

A second booster dose using an mRNA vaccine could benefit people who are moderately or severely immunocompromised ages 12 years and older, as they are at increased risk for severe COVID-19. People ages 12 years and older may choose to receive a second booster dose using an age-appropriate mRNA vaccine if it has been at least 4 months after the first booster does, **for a total of 5 doses**.

Janssen COVID-19 primary series:

A booster dose is recommended at least 2 months after the second (additional) dose, **for a total of 3 doses** (1 Janssen vaccine dose followed by 1 additional mRNA vaccine dose, then 1 booster dose, preferably with an mRNA COVID-19 vaccine).

**Special situation:** Many recipients of Janssen COVID-19 Vaccine may have received a booster dose (Pfizer-BioNTech, Moderna [50 µg], or Janssen vaccine), without having had the second (additional) mRNA vaccine dose. In this situation, regardless of type and timing of vaccine received as the second dose, administer a Pfizer-BioNTech vaccine or a Moderna vaccine (100 µg [0.5 mL, red cap vial]) as the third (additional) dose at least 2 months after dose 2.

A second booster dose using an mRNA vaccine could benefit people who are moderately or severely immunocompromised, as they are at increased risk for severe COVID-19. These people may choose to receive a second booster dose using an mRNA COVID-19 vaccine if it has been at least 4 months after the first booster dose, **for a total of 4 doses**.

**Table 1:** COVID-19 vaccination schedule for people who are moderately or severely immunocompromised*

| Primary vaccination | Age group | Number of primary vaccine doses | Number of booster doses | Interval between 1st and 2nd dose | Interval between 2nd and 3rd dose | Interval between 3rd and 4th dose |
|---|---|---|---|---|---|---|
| Pfizer-BioNTech | 5–11 years | 3 | NA | 3 weeks | At least 4 weeks | NA |
| Pfizer-BioNTech | 12 years and older | 3 | 1* | 3 weeks | At least 4 weeks | At least 3 months* |
| Moderna | 18 years and older | 3 | 1* | 4 weeks | At least 4 weeks | At least 3 months* |
| Janssen | 18 years and older | 1 Janssen, followed by 1 mRNA | 1* | 4 weeks | At least 2 months | NA* |

*People ages 12 years and older may choose to receive a second booster dose using an mRNA COVID-19 vaccine if it has been at least 4 months after the first booster dose.

## Moderate and severe immunocompromising conditions and treatments include but are not limited to:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic cell transplant (HCT) (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts $<200/mm^3$, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor necrosis factor (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory

## Guidance for booster doses for people who are *not* Moderately or Severely immunocompromised

Booster doses for people who are **not** moderately or severely immunocompromised
All people ages 12 years and older should receive 1 booster dose of a COVID-19 vaccine after completion of the primary series, even if they were younger than age 12 years at the time of the primary series. Some adults may receive a second booster dose.

mRNA COVID-19 vaccine primary series

- Children ages 11 years and younger: Currently, COVID-19 vaccines are not authorized for use as a booster dose in this age group.
- Adolescents ages 12–17 years: A single booster dose of Pfizer-BioNTech COVID-19 Vaccine is recommended at least 5 months after the second primary series dose, for a total of 3 doses.
- Adults ages 18–49 years: A single booster dose is recommended at least 5 months after the second primary series dose, for a total of 3 doses. mRNA vaccines are preferred for the booster dose.
- Adults ages 50 years and older: A booster dose is recommended at least 5 months after the second primary series dose, for a total of 3 doses. mRNA vaccines are preferred for the first booster dose. A second mRNA booster dose could benefit people ages 50 years and older, as they are at increased risk for severe COVID-19. People ages 50 years and older may choose to receive a second booster dose using an mRNA vaccine if it has been at least 4 months after the first booster dose, for a total of 4 doses.

Janssen COVID-19 primary series

- Adults ages 18–49 years: A first booster dose is recommended at least 2 months after the single primary series dose, for a total of 2 doses. mRNA vaccines are preferred for the first booster dose. In addition, people who received Janssen COVID-19 Vaccine as both their primary series dose and first booster dose may receive a second booster dose using an mRNA vaccine at least 4 months after the first booster dose, for a total of 3 doses.
- Adults ages 50 years and older: A booster dose is recommended at least 2 months after the single primary series dose for a total of 2 doses. mRNA vaccines are preferred for the first booster dose. A second mRNA booster dose could benefit people ages 50 years and older, as they are at increased risk for severe COVID-19. People ages 50 years and older may choose to receive a second booster dose using an mRNA COVID-19 vaccine at least 4 months after the first booster dose, for a total of 3 doses.

**Interval between primary series and booster doses**

***First booster dose***: The recommended interval is based on the product received for the primary series. In most people, the interval is:

- At least 5 months after an mRNA 2-dose primary series or
- At least 2 months after a Janssen single-dose primary series

***Second booster dose***: The recommended interval between the first booster dose and the second booster is at least 4 months, regardless of primary series or first booster dose product.

**Table 2:** COVID-19 vaccination schedule for people who are not moderately or severely immunocompromised*

| Primary Series Manufacturer | Age Group | Number of doses in primary series | Number of booster doses | Interval between 1st and 2nd primary doses | Interval between primary series and booster dose |
|---|---|---|---|---|---|
| Pfizer-BioNTech | 5-11 years | 2 | NA | 3 weeks | NA |
| Pfizer-BioNTech | 12 years and older | 2 | 1† | 3-8 weeks‡ | At least 5 months† |
| Moderna | 18 years and older | 2 | 1† | 4-8 weeks‡ | At least 5 months† |
| Janssen | 18 years and older | 1 | 1† | NA | At least 2 months† |

†All people ages 12 years and older should receive 1 booster dose of a COVID-19 vaccine. Some adults may receive a second booster dose:

- Adults ages 18-49 years: Those who received Janssen COVID-19 Vaccine as both their primary series dose and booster dose may receive an mRNA COVID-19 booster dose at least 4 months after the Janssen booster dose.
- Adults ages 50 years and older: A second mRNA booster dose could benefit people ages 50 years and older, as they are at increased risk for severe COVID-19. People ages 50 years and older may choose to receive a second booster dose, if it has been at least 4 months after the first booster

‡An **8-week** interval may be optimal for some people ages 12 years and older, especially for males ages 12 to 39 years. A **shorter interval** (3 weeks for Pfizer-BioNTech; 4 weeks for Moderna) between the first and second doses remains the recommended interval for people who are moderately to severely immunocompromised; adults ages 65 years and older; and in situations in which there is increased concern about COVID-19 community levels or an individual's higher risk of severe disease.

## Myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine but before administration of a subsequent dose of COVID-19 vaccine

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 and subsequent doses should generally be avoided.

Until additional safety data are available, experts advise that people who develop myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine generally **should not** receive 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 at least after their episode of myocarditis or pericarditis has resolved (i.e., resolution of symptoms, no evidence of ongoing heart inflammation or sequelae as determined by patient's clinical team). For men ages 18 years and older who choose to receive a subsequent COVID-19 vaccine, some experts advise the use of Janssen COVID-19 Vaccine be considered instead of mRNA COVID-19 vaccines. These people should be aware of the risk of TTS. Considerations for subsequent vaccination may include:

- The myocarditis or pericarditis was considered unrelated to mRNA COVID-19 vaccination (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)
- Level of COVID-19 community transmission and personal risk of infection
- Timing of any immunomodulatory therapies; ACIP's general best practice guidelines for immunization can be consulted for more information.

## History of myocarditis or pericarditis prior to COVID-19 vaccination

People who have a history of myocarditis or pericarditis unrelated to mRNA COVID-19 vaccination (e.g., due to SARS-CoV-2 or other viruses) may receive any currently FDA-approved or FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved. This includes resolution of symptoms attributed to myocarditis or pericarditis, as well as no evidence of ongoing heart inflammation or sequelae as determined by the person's clinical team.

## People with a history of multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A)

MIS-C is a rare but severe condition in children and adolescents infected with SARS-CoV-2. MIS-A is even rarer and less well characterized. Both include a dysregulated immune response to SARS-CoV-2 infection. The risk of recurrence of a dysregulated immune response following reinfection with SARS-CoV-2, or an MIS-like illness following COVID-19 vaccination is unknown; however, it is unknown if this correlates with protection against reinfection and for how long the protection might last.

There are limited data on the safety of COVID-19 vaccines in people who have had MIS-C or MIS-A from SARS-CoV-2 infection and who have not yet received COVID-19 vaccine. A conversation between the patient, their guardian(s), and their clinical team or a specialist (e.g., specialist in infectious diseases, rheumatology, or cardiology) is strongly encouraged to assist with decisions about the use of COVID-19 vaccines in such situations.

## Considerations for starting the COVID-19 vaccine series in people with MIS-C or MIS-A

Experts consider the benefits of COVID-19 vaccination for children and adolescents (i.e., a reduced risk of severe disease including potential recurrence of MIS-C after reinfection) to outweigh a theoretical risk of an MIS-like illness or the risk of myocarditis following COVID-19 vaccination for people who meet all of the following criteria:

1. Clinical recovery has been achieved, including return to normal cardiac function;
2. It has been ≥90 days since their diagnosis of MIS-C;
3. They are in an area where the COVID-19 community level is high or otherwise have an increased risk for SARS-CoV-2 exposure and transmission; and
4. Onset of MIS-C occurred before any COVID-19 vaccination (For people diagnosed with MIS-C or MIS-A after COVID-19 vaccination see the relevant section below).

COVID-19 vaccination may also be considered for people who have not yet received COVID-19 vaccine and either have a history of MIS-C from SARS-CoV-2 infection and do not meet all the above criteria or have a history of MIS-A from SARS-CoV-2. Experts view clinical recovery, including return to normal cardiac function, as an important factor when considering COVID-19 vaccination. Additional factors when considering individual benefits and risks include:

1. An increased personal risk of severe COVID-19 (e.g., age, underlying conditions)
2. Timing of immunomodulatory therapies (ACIP's general best practice guidelines for immunization can be consulted for more information)

## People diagnosed with MIS-C or MIS-A after COVID-19 vaccination

In the rare instance a person develops MIS-C, MIS-A, or a similar clinical illness after receipt of a COVID-19 vaccine, referral to a specialist in infectious diseases, rheumatology, and/or cardiology should be considered. Assessment should include testing for current or prior SARS-CoV-2 infection. Obtaining a serum sample before any Intravenous immune globulin (IVIG) is administered is highly recommended so that the sample can be tested for SARS-CoV-2 anti-nucleocapsid antibody, which typically requires a reference laboratory. A positive anti-nucleocapsid antibody test result indicates prior SARS-CoV-2 infection. (To test for current SARS-CoV-2 infection, a molecular diagnostic or antigen test should be used). Anti-spike protein antibody testing cannot be used to determine SARS-CoV-2 infection status in a vaccinated person, because a positive test result can be induced by either COVID-19 vaccination or SARS-CoV-2 infection.

A discussion between the patient, their guardian(s), and their clinical team is strongly encouraged to assist with decisions about subsequent doses of COVID-19 vaccine for people who have onset of MIS-C or MIS-A after receiving a vaccine dose but who have not yet completed all recommended doses.

Additional considerations for MIS-C may include:

- For people who have onset of MIS-C 90 days or more after the date of their most recent COVID-19 vaccine dose, administration of subsequent COVID-19 vaccine dose(s) should be considered if the first 3 criteria in the section above ("Considerations for starting the COVID-19 vaccine series in people with MIS-C or MIS-A") are also met.
- For people who have onset of MIS-C fewer than 90 days after the date of their most recent COVID-19 vaccine dose, subsequent COVID-19 vaccine dose(s) should be deferred at this time until additional data are available.
- However, on a case-by-case basis, a provider and the family may choose to provide subsequent dose(s) if the first 3 criteria in the section above ("Considerations for starting the COVID-19 vaccine series in people with MIS-C or MIS-A") are met, and there is strong evidence that the MIS-C was a complication of a recent SARS-CoV-2 infection.

For complicated situations, not addressed by the guidance above, healthcare and public health professionals may consider requesting a consultation from the Clinical Immunization Safety Assessment COVIDvax project. An illness consistent with MIS-C or MIS-A after receivingCOVID-19 vaccine should be reported to VAERS.

For more information refer to CDC Interim Clinical Consideration for use of COVID-19 Vaccines at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html. See media statement.

This policy and procedure shall remain in effect for all patients of DPHSS until rescinded in writing by the Department.

Robert Leon Guerrero MD

**ROBERT LEON GUERRERO, MD**
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3/31/22

**DATE**