

UPDATED CLINICAL CONSIDERATIONS FOR COVID-19 VACCINATION GUIDANCE
February 11, 2022

KEY MESSAGES AND TALKING POINTS

Topline Messages

- Today, the Centers for Disease Control and Prevention (CDC) issued updates and a clarification to [COVID-19 vaccination guidance](#) to help ensure people have optimal protection against SARS-CoV-2 (the virus that causes COVID-19) infection, severe illness, and death.
- For people who are moderately or severely immunocompromised, these updates and clarification cover the number of doses needed and the appropriate dosing schedule.
- For those who previously received passive COVID-19 antibody products, CDC simplified recommendations for vaccination after receipt of passive COVID-19 antibody products, eliminating all vaccination deferral periods after receipt of these antibody products.
- These updates follow a thorough evaluation of the latest safety and effectiveness data and evidence on COVID-19 vaccines that have already been administered in the U.S. and in other countries.

Specifically, these changes include:

- For people who are moderately or severely immunocompromised:
 - CDC clarified existing guidance to confirm that those who previously received mRNA COVID-19 vaccines (Pfizer-BioNTech or Moderna) should receive a total of **4** doses: a primary series of **3** doses of an mRNA vaccine, plus **1** booster dose of an mRNA vaccine (4th dose).
 - CDC provided new guidance that:
 - People who initiated vaccination with Johnson & Johnson’s Janssen COVID-19 vaccine should receive a total of **3** doses: **1** Johnson & Johnson’s Janssen dose, followed by **1** additional mRNA dose at least 28 days later, then **1** booster dose at least 2 months after the 2nd (additional) dose. mRNA vaccines are preferred for the booster.
 - People who received a 3-dose mRNA COVID-19 vaccination series should receive the booster dose 3 months after the primary series (instead of 5 months after the primary series).
 - **In summary, here is the updated COVID-19 vaccination schedule for people who are moderately or severely immunocompromised, with the clarification and updates highlighted:**

Primary vaccination	Age group	Number of primary and/or additional vaccine doses	Number of booster doses	Interval between 1 st and 2 nd dose	Interval between 2 nd and 3 rd dose	Interval between 3 rd and 4 th dose
Pfizer-BioNTech	5–11 years	3	N/A	21 days	≥28 days	N/A
Pfizer-BioNTech	≥12 years	3	1	21 days	≥28 days	≥3 months

Primary vaccination	Age group	Number of primary and/or additional vaccine doses	Number of booster doses	Interval between 1 st and 2 nd dose	Interval between 2 nd and 3 rd dose	Interval between 3 rd and 4 th dose
Moderna	≥18 years	3	1	28 days	≥ 28 days	≥3 months
J&J/Janssen	≥18 years	1 Janssen, followed by 1 mRNA	1	≥ 28 days	≥2 months	N/A

- The updated recommendations and clarification above will help to ensure that people who are moderately or severely immunocompromised are better protected against COVID-19, as they are at increased risk of severe COVID-19 illness and death. This is especially critical since the numbers of COVID-19 cases remain high across the United States and globally.
- People who are moderately or severely immunocompromised make up about 3 percent of U.S. adults (at least 10 million people) and include recipients of organ or stem cell transplants, people with advanced or untreated HIV infection, people currently undergoing treatment for cancer, people who are taking certain medications that weaken the immune system, and others. A complete list of conditions can be found on [CDC's website](#).
- People who are moderately or severely immunocompromised can receive all doses anywhere vaccines are offered.
 - This will help reduce barriers to access.
 - They may need to tell the pharmacist or other vaccine provider that they are immunocompromised, and proof is not needed.
 - Individuals with questions should discuss what is appropriate for them with their health care provider.
 - States, pharmacies, health centers, and all vaccine providers have been notified when and how many doses they should administer to people who are moderately or severely immunocompromised.
- In addition, CDC simplified recommendations for vaccination after receipt of passive COVID-19 antibody products, eliminating all vaccination deferral periods after receipt of these antibody products. These updates help to clarify that patients who received any passive COVID-19 antibody therapy may proceed with COVID-19 vaccination at their earliest opportunity.

As a Reminder

- Vaccine providers should continue to administer vaccines in accordance with the [COVID-19 vaccine provider agreement](#).
- For more information, visit:
 - <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>
 - <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html>

Q&A

Q: Can you explain this new guidance for people who are moderately or severely immunocompromised?

A: CDC clarified an existing recommendation that people who are moderately or severely immunocompromised—and who receive an mRNA (Pfizer-BioNTech or Moderna) vaccine—receive 4 doses total (a primary series of 3 doses, plus 1 booster dose).

In addition, CDC now recommends that people who are moderately or severely immunocompromised—who received the 3-dose primary mRNA COVID-19 vaccine series—receive their booster dose at least 3 months (instead of at least 5 months) after the last primary dose.

CDC also now recommends that people who are moderately or severely immunocompromised—who received a single J&J/Janssen COVID-19 vaccine primary series—receive a total of three vaccine doses: 1 J&J/Janssen dose, followed by 1 additional mRNA dose, then 1 booster dose. mRNA vaccines are preferred for the booster dose.

Q: How many doses of a Pfizer-BioNTech or Moderna (mRNA) vaccine are needed for people who are moderately or severely immunocompromised, and whose initial COVID-19 vaccine series was an mRNA vaccine?

A: Four doses total. A primary series of 3 doses, plus 1 booster dose. In terms of timing:

- For the Pfizer-BioNTech COVID-19 vaccine, the second dose for people who are moderately or severely immunocompromised is given 21 days (3 weeks) after the first dose, the third dose is given at least 28 days (4 weeks) after the second dose, and the fourth dose (booster dose) is now recommended to be given at least 3 months after the third dose.
- For the Moderna COVID-19 vaccine, the second dose for people who are moderately or severely immunocompromised is given 28 days after the first dose, the third dose is given at least 28 days after the second dose, and the fourth dose (booster dose) is now recommended to be given at least 3 months after the third dose.

Q: How many vaccine doses are recommended for people who are moderately or severely immunocompromised who received the Janssen vaccine as their initial COVID-19 vaccine?

A: Three doses total—1 J&J/Janssen dose, followed by 1 additional mRNA dose, then 1 booster dose. mRNA vaccines are preferred for the booster dose.

- The additional (second) dose is given at least 28 days (4 weeks) after the Janssen dose. The booster dose (third) dose is given at least 2 months after the additional mRNA dose.
- The additional dose must be an mRNA COVID-19 vaccine, and an mRNA COVID-19 vaccine is preferred for the booster dose due to concerns about an increased risk for thrombosis with thrombocytopenia syndrome (TTS) when using the Janssen vaccine. TTS is a rare but serious adverse event that causes blood clots or issues with clotting.

Q: What is the rationale for reducing the booster interval—from 5 months to 3 months—for people who are moderately or severely immunocompromised?

A: People who are moderately or severely immunocompromised may not develop protective immunity after a primary series, even when the recommended 3-dose mRNA vaccine primary series is used. They are also more likely to lose protective immunity over time and might need to get a booster dose sooner. Early data from several small studies show that people who are moderately or severely immunocompromised often develop increased antibody levels again after a booster dose given at an interval shorter than 5 months. There was no evidence of an increased safety concern. Currently, there is rapid spread of COVID-19 in the United States, and exposures to infected people are hard to avoid. Therefore, providing a booster dose as soon as possible makes sense for those at highest risk for severe complications.

Q: Will people who are moderately or severely immunocompromised need a doctor's note/prescription or other documentation to receive these doses?

A: No, individuals can self-identify and receive all doses anywhere vaccines are offered. This will help ensure there are not additional barriers to access for this population. If immunocompromised individuals have questions about their specific medical condition, they may discuss whether getting an additional dose is appropriate for them with their health care provider.