

## **Health Advisory**

### **Updated COVID-19 Vaccine Guidance**

**February 16, 2022**

#### **SUMMARY POINTS**

- The FDA has fully approved the Moderna COVID-19 vaccine for individuals aged  $\geq 18$  and will be marketed as “Spikevax.”
- CDC has issued Emergency Use Instructions to allow the use of Moderna (Spikevax) in certain persons 18 years and older who received primary vaccination with certain non-FDA authorized or approved COVID-19 vaccines.
- COVID-19 vaccination should no longer be deferred following use of passive antibody therapy used for treatment or post-exposure prophylaxis of COVID-19.
- Moderately to severely immunocompromised adults  $\geq 18$  should receive an additional dose of an mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) **at least 28 days** following a single dose of the Johnson & Johnson (Janssen) primary vaccine.
- People who are moderately or severely immunocompromised should receive a booster dose **at least 3 months** after the additional (third) dose of an mRNA COVID-19 vaccine or **at least 2 months** after the additional (second) dose of mRNA vaccine following a single dose of the Janssen vaccine.

Ongoing data continues to support that COVID-19 vaccinations provide protection against infection, severe illness, hospitalization, and death.

On January 31, 2022, the FDA fully approved the Moderna COVID-19 vaccine, which will now be marketed as “Spikevax” for the prevention of COVID-19 in individuals 18 years of age and older. Spikevax has the same formulation as the Moderna COVID-19 Vaccine available under EUA and is administered as a primary series of two doses, 28 days apart.

The CDC has issued Emergency Use Instructions (EUI) to provide information about use of the COVID-19 vaccine by Moderna (Spikevax) for persons 18 years and older as a primary dose(s) and/or booster dose in those with certain immunocompromising conditions or those with incomplete primary dose series who received primary vaccination with certain non-FDA authorized or approved COVID-19 vaccines. This includes individuals who were vaccinated outside of the United States or participated in certain clinical trials for a COVID-19 vaccine.

#### **Revised Guidance for COVID-19 Vaccination Following Passive Antibody Therapy**

- Previously, COVID-19 vaccination was deferred for 90 days following passive antibody therapy used for treatment of a COVID-19 infection and 30 days if used for post-exposure prophylaxis.
- The revised guidance does not recommend a deferral period for COVID-19 vaccination following use of passive antibody therapy for COVID-19 infection. COVID-19 vaccination should be prioritized.

#### **Additional Vaccine Doses for Certain Immunocompromised Persons**

- Moderately or severely immunocompromised children ages 5 – 11 should receive an additional (third) dose of the pediatric Pfizer vaccine (**orange cap**), **at least 28 days** after completing the primary series.
- Moderately or severely immunocompromised adolescents and adults ages  $\geq 12$ , should receive an additional (third) dose of the Pfizer-BioNTech vaccine (**purple or gray cap**) **at least 28 days** after receiving the second dose of a Pfizer-BioNTech vaccine.
- Moderately or severely immunocompromised adolescents and adults ages  $\geq 18$ , should receive an additional (third) dose of the Moderna vaccine **at least 28 days** after receiving the second dose of a Moderna vaccine series.
- Moderately or severely immunocompromised adults  $\geq 18$  should receive an additional dose of **an mRNA** COVID-19 vaccine (Pfizer-BioNTech or Moderna) **at least 28 days** after a single dose of the Johnson & Johnson (Janssen) vaccine.

### **Booster Doses for Immunocompromised Persons Who Received an Additional Primary Dose**

- People who are moderately or severely immunocompromised should receive a booster dose **at least 3 months** after the additional (third) dose of a primary mRNA COVID-19 vaccine series.
  - Any COVID-19 vaccine can be used for the booster dose in people ages 18 years and older, though mRNA vaccines are preferred. For people ages 12–17 years, **only** Pfizer-BioNTech can be used. Booster shots are not recommended for children ages 5-11 at this time.
- People 18 and older who are moderately or severely immunocompromised **and** received the additional (second) dose of a COVID-19 vaccine following a primary dose of the Johnson & Johnson vaccine should receive a booster dose **at least two months** later.
  - Any COVID-19 vaccine can be used for the booster dose in people ages 18 years and older, though mRNA vaccines are preferred.

### **COVID-19 Vaccination Schedule for People with Moderate to Severe Immunocompromise**

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	≥4 weeks	N/A
Pfizer-BioNTech	≥12 years	3	1	3 weeks	≥4 weeks	≥3 months
Moderna	≥18 years	3	1	4 weeks	≥4 weeks	≥3 months
Janssen	≥18 years	1 Janssen, followed by 1 mRNA	1	4 weeks	≥2 months	N/A

*Image Source:* [Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC](#)

#### **Resources:**

- [Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC](#)
- [CDC Presentation](#)
- [Spikevax and Moderna COVID-19 Vaccine | FDA](#)
- [Moderna COVID-19 Vaccine Health Care Provider Fact Sheet \(fda.gov\)](#)
- [COVID-19 Vaccine Emergency Use Instructions \(EUI\) Resources | CDC](#)