

## **SECRETARIAL DIRECTIVE ON AVAILABILITY OF BOOSTER DOSES OF COVID-19 VACCINES**

December 10, 2021

Effective December 10, 2021, the Secretarial Directives on Eligibility to Receive Particular COVID-19 Vaccine Boosters, dated September 25, 2021 and October 22, 2021 and Secretarial Directive on Availability of Booster Doses of COVID-19 Vaccines dated November 21, 2021, are replaced with the following:

The Centers for Disease Control and Prevention (CDC) has determined that, as part of the broad range of prevention and mitigation strategies, vaccines are an important tool to help stop the COVID-19 pandemic. To that end, CDC has continued to consider available science, including SARS-CoV-2 epidemiology, evidence related to the effectiveness of currently available Food and Drug Administration (FDA) approved or authorized COVID-19 vaccines, and any risks of severe disease, hospitalization, and death to certain populations.

On November 19, 2021, FDA amended the Emergency Use Authorizations (EUAs) for the two mRNA vaccines (the Pfizer-BioNTech COVID-19 Vaccine and the Moderna COVID-19 Vaccine) to expand the population that is eligible to receive homologous or heterologous booster doses following primary vaccination.<sup>1</sup> Prior to those authorizations, individuals who had completed primary vaccination with an mRNA vaccine at least six months previously were authorized to receive a single booster dose if they fell into the following categories: individuals 65 years of age and older; individuals 18 through 64 years of age at high risk of severe COVID-19; and individuals 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2. The November 19, 2021 amendments to the EUAs expanded the population that is eligible to receive a booster dose to include all individuals aged 18 years and older, provided the booster dose is administered at least six months after completion of primary vaccination with an mRNA vaccine. On December 9, 2021, FDA amended the EUA for the Pfizer-BioNTech COVID-19 vaccine to authorize booster doses for adolescents 16 through 17 years of age at least six months after completion of primary vaccination with the Pfizer-BioNTech COVID-19 vaccine.

On November 19, 2021, FDA also amended the EUA for the Janssen COVID-19 Vaccine to authorize use of the vaccine as a single heterologous booster dose for all adults aged 18 years and older who completed primary vaccination with an FDA-authorized or approved mRNA COVID-19 vaccine.<sup>2</sup> Previously, individuals who received mRNA vaccines for primary vaccination were not eligible to receive the Janssen COVID-19 Vaccine as a heterologous booster unless they fell into the risk-based categories described above. Individuals aged 18 and older who received the Janssen COVID-19 Vaccine for primary vaccination remain eligible to

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<sup>1</sup> See Updated Letter of Authorization for Pfizer-BioNTech COVID-19 Vaccine (<https://www.fda.gov/media/150386/download>) and Updated Letter of Authorization for Moderna COVID-19 Vaccine (<https://www.fda.gov/media/144636/download>).

<sup>2</sup> See Updated Letter of Authorization for Janssen COVID-19 Vaccine (<https://www.fda.gov/media/146303/download>).

receive a heterologous booster of the Pfizer-BioNTech Vaccine or the Moderna COVID-19 Vaccine two months after completing primary vaccination.

On November 19, 2021, based on CDC's review of the available data, and taking into account data and information that were presented to and considered by the Advisory Committee on Immunization Practices (ACIP), the Director of the CDC recommended:

- A single COVID-19 vaccine booster dose for persons aged 18 years and older who received an mRNA COVID-19 vaccine primary series based on individual benefit and risk, at least six months after the primary series, under the FDA's EUA.
- A single COVID-19 vaccine booster dose for persons aged 50 years and older who received an mRNA COVID-19 vaccine, at least six months after the primary series, under the FDA's EUA.

Further, on November 29, 2021, the Director of CDC revised the November 19, 2021 CDC recommendation that all persons 18 through 49 years of age "may" get a booster to urging that all persons 18 years of age and older "should" receive a COVID-19 vaccine booster dose at the appropriate interval.

On December 9, 2021, following the FDA authorization of the revised Pfizer-BioNTech COVID-19 vaccine EUA, the Director of CDC recommended that adolescents 16 through 17 years of age may receive a Pfizer-BioNTech COVID-19 vaccine booster at least six months after completion of the Pfizer-BioNTech vaccine primary series.

The Department of Health and Human Services (HHS) concurs with CDC's recommendations for the administration of COVID-19 vaccine booster doses.

Accordingly, pursuant to Section 319 of the Public Health Service Act (42 U.S.C. §247d), the Secretary of HHS hereby **DIRECTS** as follows:

**As previously recommended, all CDC COVID-19 Vaccination Program enrolled providers shall make immediately available and administer, upon request:**

- **A booster dose of the Pfizer-BioNTech COVID-19 Vaccine, the Moderna COVID-19 Vaccine, or the Janssen COVID-19 Vaccine to all persons aged 18 years and older at least six months after completion of primary vaccination with an mRNA COVID-19 vaccine (i.e., Pfizer-BioNTech COVID-19 Vaccine or Moderna COVID-19 Vaccine), under the parameters of the EUAs issued by FDA.**
- **A single COVID-19 vaccine booster dose of the Pfizer-BioNTech COVID-19 vaccine, the Moderna COVID-19 vaccine, or the Janssen COVID-19 vaccine to all persons aged 18 years and older at least two months after receipt of the primary vaccination dose of the Janssen (Johnson & Johnson) COVID-19 vaccine, under the FDA's EUA.**

**Individuals aged 18 years and older who are eligible to receive a homologous booster dose of any of the currently FDA-authorized or approved COVID-19 vaccines may instead receive a single heterologous booster dose of the Pfizer-BioNTech COVID Vaccine, the Moderna COVID-19 Vaccine, or the Janssen COVID-19 Vaccine, under the parameters of the EUAs issued by FDA.**

**In addition, as of December 10, 2021, all CDC COVID-19 Vaccination Program enrolled providers shall make immediately available and administer, upon request:**

- **A booster dose of the Pfizer-BioNTech COVID-19 Vaccine to all persons 16 through 17 years of age at least six months after completion of primary vaccination with the Pfizer-BioNTech COVID-19 Vaccine, under the parameters of the EUAs issued by FDA. Only the Pfizer-BioNTech COVID-19 Vaccine may be administered for this booster dose; heterologous administration is not allowed for this age group.**

All CDC COVID-19 Vaccination Program enrolled providers must comply with this Directive as specified in updated CDC COVID-19 vaccination provider requirements posted at: <https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html>.

This Directive also applies to all awardees and recipients of HHS grant and cooperative agreement funds, including grants to states and U.S. territories that have been awarded to support, implement, and expand COVID-19 vaccination programs nationwide.

This Directive should be read and implemented consistent with other existing direction from HHS and CDC, including the COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations (Playbook) guidance document; prior directives from the HHS Secretary and supplements and addenda to vaccine distribution and vaccine prioritization; the CDC Provider Agreement and related guidance; and any workplan, application, jurisdiction vaccination plan, or other submission from an awardee or recipient of CDC grants or cooperative agreements related to COVID-19 vaccine activities. To the extent that this Directive directly conflicts with those documents, this Directive shall be read to replace and supersede those documents.

I thank you for your attention to this matter, as well as for your efforts in the COVID-19 response.

/s/

Xavier Becerra  
Secretary