

SECRETARIAL DIRECTIVE ON ELIGIBILITY TO RECEIVE PARTICULAR COVID-19 VACCINE BOOSTERS

October 22, 2021

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 October 20, 2021, FDA amended the emergency use authorizations (EUAs) for the COVID-19 vaccines to take the following actions: to allow for the use of a single booster dose of the Moderna COVID-19 Vaccine that may be administered at least 6 months after completion of the primary series to individuals aged 65 years of age and older, aged 18 through 64 years of age at high risk of severe COVID-19, and aged 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2; to allow for the use of a single booster dose of the Janssen (Johnson and Johnson) COVID-19 Vaccine which may be administered at least 2 months after completion of the single-dose primary regimen to individuals 18 years of age and older; to allow for the use of each of the currently authorized or approved COVID-19 vaccines as a heterologous (or “mix and match”) booster dose in eligible individuals following completion of primary vaccination with a different available COVID-19 vaccine; and to clarify that a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine may be administered at least 6 months after completion of the primary series to individuals 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2.

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 that: a single Moderna COVID-19 vaccine booster dose (which is half of the dose that is administered for a primary series dose) can be provided at least 6 months after completion of the Moderna primary series, in risk groups the CDC had previously recommended receive a Pfizer-BioNTech booster dose,¹ under the FDA’s EUA; a single Janssen (Johnson & Johnson) COVID-19 vaccine booster dose can be provided for persons aged 18 years and older, at least 2 months after receipt of the primary Janssen

¹ CDC’s previous recommendations for administration of Pfizer-BioNTech COVID-19 vaccine boosters:

- people 65 years and older, and residents in long-term care settings 18 years and older **should** receive a booster shot of Pfizer-BioNTech’s COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series
- people aged 50–64 years with [underlying medical conditions](#) **should** receive a booster shot of Pfizer-BioNTech’s COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series
- people aged 18–49 years with [underlying medical conditions](#) **may** receive a booster shot of Pfizer-BioNTech’s COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks
- people aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting **may** receive a booster shot of Pfizer-BioNTech’s COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, [based on their individual benefits and risks](#).

(Johnson & Johnson) dose, under the FDA's EUA; and among groups recommended to receive booster dose after a Pfizer-BioNTech, Moderna, or Janssen COVID-19 vaccine primary series, a single booster dose of any of the authorized or approved COVID-19 vaccines may be administered as a heterologous booster dose, under the FDA EUAs for the three vaccines.²

The Department of Health and Human Services (HHS) concurs with CDC's recommendation. 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 of October 22, 2021, when requested for an individual among the groups recommended for a booster consistent with the FDA EUA and the CDC's recommendation, all CDC COVID-19 Vaccination Program enrolled providers shall make immediately available and administer upon request:

1) for those who received the Moderna primary series, a single Moderna COVID-19 vaccine booster dose (which is half of the dose that is administered for a primary series Moderna dose) at least 6 months after completion of the Moderna primary series, in risk groups CDC has previously recommended receive a Pfizer-BioNTech booster dose, under the FDA's EUA; or

2) for those who received a primary Janssen dose, a single Janssen COVID-19 vaccine booster for all persons aged 18 years or older at least 2 months after receipt of the primary Janssen dose, under the FDA's EUA.

Among the groups recommended by CDC to receive booster vaccination after a Pfizer-BioNTech, Moderna, or Janssen COVID-19 vaccine primary series, a single booster dose of any of the currently authorized or approved COVID-19 vaccines may be provided as a heterologous booster dose, under the FDA EUAs.

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

² See <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines>

to COVID-19 vaccine activities. To the extent 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