Questions and Answers about Emergency Use Instructions (EUI)
Below are answers to frequently asked questions about Emergency Use Instructions (EUI). Refer to EUI for Pfizer-BioNTech COVID-19 Vaccine and Moderna COVID-19 Vaccine for additional doses.

What are Emergency Use Instructions (EUI)?
Emergency Use Instructions (EUI) allow CDC to inform healthcare providers and recipients about certain uses of medical products approved (licensed) by the U.S. Food and Drug Administration (FDA) without the FDA needing to issue an Emergency Use Authorization (EUA). The CDC Director has legal authority to create, issue, and disseminate EUI for FDA-approved medical products. EUI inform healthcare providers and recipients about such products' approved, licensed, or cleared conditions of use under circumstances that go beyond the scope of the approved labeling (package insert).

What EUI did CDC issue and why?
CDC issued EUI for use of the updated COVID-19 vaccine by Pfizer-BioNTech and updated COVID-19 vaccine by Moderna for additional doses in certain individuals. The EUI are necessary because these uses extend beyond their FDA-approved labeling. The EUI and CDC's clinical guidance help to ensure these individuals can get additional doses of the updated COVID-19 vaccine by Pfizer-BioNTech or Moderna so they can be better protected against COVID-19.

The EUI are currently issued only for Pfizer-BioNTech and Moderna COVID-19 vaccines since EUI can only apply to FDA-approved medical products. The following describes why CDC issued EUI for the Pfizer-BioNTech and Moderna COVID-19 vaccines.

Initial EUI Issuance

- CDC issuance of initial EUI for the COVID-19 vaccine by Pfizer-BioNTech on November 17, 2021
  CDC issued initial EUI for the COVID-19 vaccine by Pfizer-BioNTech[1] and updated its Interim Clinical Considerations on November 17, 2021, to ensure that certain people who were vaccinated outside of the United States, or who received certain non-FDA authorized or approved COVID-19 vaccines through participation in a clinical trial, can get an additional primary dose or booster dose of the COVID-19 vaccine by Pfizer-BioNTech. CDC issued EUI to allow additional primary doses of the COVID-19 vaccine by Pfizer-BioNTech in certain immunocompromised individuals ages 12 years and older and a heterologous booster dose in persons ages 18 years and older 6 months after completion of primary series vaccination with certain vaccines not FDA-authorized or approved.

- CDC issuance of initial EUI for the COVID-19 vaccine by Moderna on February 11, 2022
  The FDA approved the COVID-19 vaccine by Moderna (brand name Spikevax) on January 31, 2022, as a two-dose primary series for active immunization to prevent COVID-19 in persons ages 18 years and older. CDC subsequently issued EUI for the Moderna COVID-19 vaccine to allow primary, additional, and/or booster doses in persons ages 18 years and older, including those vaccinated with certain non-FDA authorized or approved COVID-19 vaccines and certain individuals with immunocompromising conditions, similar to the uses that go beyond or differ from the FDA-approved labeling as described in the EUI for the Pfizer-BioNTech COVID-19 vaccine.

[1] The COVID-19 vaccine by Pfizer-BioNTech (brand name Comirnaty) was approved by FDA in August 2021 as a 2-dose primary series for active immunization to prevent COVID-19 in persons aged ≥ 16 years. FDA also amended the EUA for the Pfizer-BioNTech COVID-19 vaccine to authorize an additional primary dose in certain immunocompromised persons aged ≥ 12 years and a homologous or heterologous booster dose in persons aged ≥ 18 years following primary vaccination with the Pfizer-BioNTech or a different FDA-authorized COVID-19 vaccine.

EUI amendments, in concert with CDC Interim Clinical Considerations, subsequent to initial issuance for the respective mRNA COVID-19 vaccines include:

- Expanded the age of heterologous booster use of COVID-19 vaccine by Pfizer-BioNTech to 16 years and older following primary series vaccination at least 6 months previously with certain vaccines not FDA-authorized or approved in the United States[2] on December 9, 2021.

- Updated the eligible age of booster use of COVID-19 vaccine by Pfizer-BioNTech to 12 years and older, booster dose interval to 5 months, vaccine use for those with incomplete primary dose series of non-FDA-authorized or approved COVID-19 vaccines and included the new FDA-approved formulation of the vaccine for persons ages 12 years and older (gray-capped multi-dose vials) on January 7, 2022.

- Updated on February 11, 2022, to allow an additional Pfizer-BioNTech COVID-19 vaccine dose in persons ages 18 years and older with certain immunocompromising conditions who received primary vaccination with the Janssen COVID-19 vaccine; revaccination of certain moderately or severely immunocompromised persons ages 12 years and older who received certain therapies (i.e., hematopoietic cell transplant (HCT) or chimeric antigen receptor (CAR)-T-cell therapy) and received COVID-19 vaccine prior to or during treatment; and the ability of healthcare providers to administer the Pfizer-BioNTech COVID-19 vaccine outside of the FDA-authorized or FDA-approved labeling and CDC recommended dosing intervals based on clinical judgment when the benefits of vaccination are deemed to outweigh the potential and unknown risks.

- Extended the dosing interval to 8 weeks[3] between the first and second primary doses of mRNA COVID-19 vaccines (i.e., Pfizer-BioNTech and Moderna COVID-19 vaccines) on February 22, 2022.

- Updated on March 29, 2022, to allow a second booster dose with mRNA COVID-19 vaccines (i.e., Pfizer-BioNTech and Moderna COVID-19 vaccines) in persons ages 18–49 years who are not moderately or severely immunocompromised and received both a primary dose and first booster dose with the Janssen COVID-19 vaccine. Additionally, clarification was added to the EUI for Moderna COVID-19 vaccine that a new booster-only formulation of the Moderna COVID-19 vaccine for persons ages 18 years and older (dark blue-capped multi-dose vials [50 µg in 0.5 mL] EUA-authorized on March 29, 2022) may be used to administer booster dose(s) as recommended in CDC's Interim Clinical Considerations.

- Updated on May 20, 2022, to allow the following for Pfizer-BioNTech and Moderna COVID-19 vaccines: revaccination for any COVID-19 vaccine dose(s) received during treatment with B-cell depleting therapies over a limited period and deferral of the second primary dose in an mRNA COVID-19 vaccine series in people who recently had SARS-CoV-2 infection by 3 months from symptom onset or positive test (if infection was asymptomatic).

- Updated on June 24, 2022, to allow the use of Moderna COVID-19 vaccine for persons ages 12

[2] FDA amended the EUA for the Pfizer-BioNTech COVID-19 vaccine on December 9, 2021 to expand the eligible population for homologous booster doses to persons aged ≥ 16 years.

[3] The original recommended interval (3 weeks for Pfizer-BioNTech; 4 weeks for Moderna) between the first and second primary doses remains the recommended interval for: people who are moderately to severely immunocompromised; adults ages 65 years and older; and others who need early protection due to increased concern about community transmission or risk of severe disease.

years and older for: a longer interval of 4–8 weeks between the first and second primary dose of Moderna COVID-19; primary dose(s), including for those with certain immunocompromising conditions or those with incomplete primary series, for persons who received primary vaccination with certain non-FDA authorized or approved COVID-19 vaccines; revaccination for any COVID-19 vaccine dose(s) received during treatment with B-cell depleting therapies over a limited period; and deferral of the second primary dose in an mRNA COVID-19 vaccine series in people who recently had SARS-CoV-2 infection by 3 months from symptom onset or positive test (if infection was asymptomatic). Also updated to indicate the COVID-19 vaccine by Moderna under EUI allows similar uses as an alternative mRNA COVID-19 vaccine to Pfizer-BioNTech, removing the restriction of ages 18 years and older on those similar uses.

- Updated on September 2, 2022 to remove the use of Pfizer-BioNTech and Moderna COVID-19 vaccines for: Booster doses for those with certain immunocompromising conditions or those with incomplete primary series who received primary or booster vaccination with certain non-FDA authorized or approved COVID-19 vaccines, a 3-month interval for a first booster dose after an mRNA vaccine primary series for persons who are moderately or severely immunocompromised, and a second booster dose in persons ages 18–49 years without certain immunocompromising conditions who received both a primary dose and first booster dose with the Janssen COVID-19 Vaccine.

- Updated on September 12, 2023 to include additional doses of the Updated COVID-19 vaccines, 2023-2024 Formula (monovalent, XBB containing), by Pfizer-BioNTech and Moderna for people ages 12 years and older who are moderately or severely immunocompromised. Additional details are described in CDC's interim Clinical Considerations and the EUI for Pfizer-BioNTech COVID-19 Vaccine and Moderna COVID-19 Vaccine.

- Updated October 6, 2023, to include updated Novavax COVID-19 vaccines (2023-2024 Formula, monovalent, XBB containing) in CDC's interim Clinical Considerations. No updates were made to recommendations for use of Moderna or Pfizer-BioNTech vaccines.

What are the risks and benefits of receiving COVID-19 vaccines by Pfizer-BioNTech and Moderna as additional vaccine doses for individuals described in the EUI?

People who are moderately or severely immunocompromised and previously unvaccinated or in need of revaccination would be less likely to have protection from infection-induced immunity and thus the data supporting a single dose for those with evidence of pre-existing infection-induced immunity would be less applicable to this population. Therefore, the following evidence supports continuing a 3-dose initial series to ensure the optimal immune response to protect this population at high risk of severe outcomes with COVID-19 and the need for additional updated COVID-19 vaccine doses in people who are moderately to severely immunocompromised and previously vaccinated. The original Pfizer-BioNTech COVID-19 vaccine and Moderna COVID-19 vaccine randomized controlled trials from 2020 measured efficacy of a 2-dose initial series (previously called the primary series) among people without evidence of prior SARS-CoV-2 infection. Effectiveness of an additional primary series dose of the COVID-19 vaccine is inferred from immunogenicity data in immunocompromised adults who received a single additional primary series dose. Persons who are moderately or severely immunocompromised may have reduced protection after COVID-19 vaccination, compared with persons without immunocompromise. Historically, COVID-19 vaccine effectiveness has been lower and waned more quickly for adults with immunocompromise compared to adults without immunocompromise.

For data regarding safety, please see sections in the Spikevax package insert and Comirnaty package inserts.

Based on available information, it appears reasonable to anticipate that known and potential risks of additional doses of the updated COVID-19 vaccine by Pfizer-BioNTech or Moderna COVID-19 vaccine may be outweighed by their likely benefit to enhance or restore protection, which might have waned over time, especially in people who are moderately or severely immunocompromised.

Refer to the CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines for additional information.

Should providers give vaccine recipients BOTH the Emergency Use Authorization (EUA) and Emergency Use Instructions (EUI) Fact Sheet for Recipients and Caregivers before administering a dose of mRNA COVID-19 vaccine?

It is NOT necessary to provide both EUA and EUI Recipient Fact Sheets. Depending on the authorized or allowed vaccine use that is being administered, provide either the EUA or EUI Recipient and Caregiver Fact Sheet that corresponds to the vaccine being administered to the individual (i.e., based on which COVID-19 vaccine and dose being given).

How should the Emergency Use Instructions (EUI) Fact Sheet for Recipients and Caregivers be provided?

The EUI Recipient and Caregiver Fact Sheet may be provided through appropriate means (e.g., hard copy, electronic dissemination like QR code, url) similar to the ways in which the Emergency Use Authorization (EUA) Recipient Fact Sheet is provided.