

Pfizer-BioNTech and Moderna COVID-19 vaccines – Emergency use authorization updated for additional dose for certain immunocompromised individuals

- On August 12, 2021, the [FDA approved](#) an amendment to the emergency use authorizations (EUAs) for both the [Pfizer-BioNTech COVID-19 vaccine](#) and the [Moderna COVID-19 vaccine](#) to allow for the use of an additional dose in certain immunocompromised individuals.
- The authorizations for these vaccines have been amended to allow for an additional, or third, dose to be administered at least 28 days following the two-dose regimen of the same vaccine to individuals 18 years of age or older (ages 12 or older for Pfizer-BioNTech) who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.
- On August 13, the [CDC's Advisory Committee on Immunization Practices \(ACIP\)](#) held a meeting to discuss the updated vaccine EUAs in immunocompromised patients.
 - The Committee voted unanimously in favor of recommending an additional (third) dose of the Pfizer-BioNTech (≥ 12 years) or Moderna (≥ 18 years) vaccine following a primary series in immunocompromised people.
- The updated EUA for the Pfizer-BioNTech vaccine was supported by a single arm study in 101 individuals who had undergone various solid organ transplant procedures (heart, kidney, liver, lung, pancreas). A third dose of the Pfizer-BioNTech COVID-19 was administered to 99 of these individuals approximately 2 months after they had received a second dose.
 - Among the 59 patients who had been seronegative before the third dose, 44% were seropositive at 4 weeks after the third dose. All 40 patients who had been seropositive before the third dose were still seropositive 4 weeks later. The prevalence of anti-SARS-CoV-2 antibodies was 68% four weeks after the third dose.
- The updated EUA for the Moderna COVID-19 vaccine was supported by a randomized-controlled study in 120 individuals who had undergone various solid organ transplant procedures (heart, kidney, kidney-pancreas, liver, lung, pancreas). A third dose of the Moderna COVID-19 vaccine was administered to 60 individuals approximately 2 months after they had received a second dose; saline placebo was given to 60 individuals for comparison.
 - Significant increases in levels of SARS-CoV-2 antibodies occurred four weeks after the third dose in 55.0% of the Moderna COVID-19 vaccine group and 17.5% of the placebo group.
- Currently, the FDA is not authorizing an additional dose of COVID-19 vaccine in the general population who are fully vaccinated and there is no recommendation yet for using booster doses in non-immunocompromised individuals