

CLINICAL SERVICE GUIDE

COVID-19 Vaccine

Additional Dose Update

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Kentucky Public Health
Prevent. Promote. Protect.

Federal Updates

FDA Amendment

- The FDA updated the Pfizer and Moderna COVID-19 vaccine EUAs to authorize an additional dose of mRNA vaccines for specific immunocompromised populations

CDC/ ACIP Interim Recommendation

- An additional dose of mRNA Covid 19 vaccine (Pfizer 12+ or Moderna 18+) recommended following the primary series in immunocompromised people

CSG Additional Dose Updates

A third dose of mRNA COVID-19 vaccine administered at least 28 days following the first two doses of the same vaccine is recommended for:

- individuals at least 18 years of age for Moderna or
- at least 12 years of age 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.

Who falls under “immunocompromised”?

People with medical conditions or people receiving treatments that are associated with *moderate to severe immune compromise*. (This includes about 2.7% of US adults.)

- Receiving active cancer treatment for tumors or cancers of the blood
- Received an organ transplant and are taking medicine to suppress the immune system
- Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids or other drugs that may suppress your immune response

Additional Dose vs Booster Dose

- **Additional dose** after an initial primary vaccine series: administration of an additional vaccine dose when the initial immune response following a primary vaccine series is likely to be *insufficient*.
- **Booster dose**: a dose of vaccine when the initial *sufficient* immune response to a primary vaccine series is likely to have waned over time. *The need for and timing of a COVID-19 booster dose has not yet been established.*

Future need for booster doses for general public?

- Yesterday (8/18/2021) the CDC and White House announced an anticipated plan to begin providing booster doses to the general public starting 9/20/2021.
- This is contingent on FDA authorization and ACIP approval. ACIP will be meeting in the coming weeks to review updated vaccine effectiveness data.
- Anticipated schedule would be 8 months after completion of primary series, though schedule would be determined by FDA/ACIP.
- **No booster doses should be given to the general public at this time.**

Considerations

- Additional dose should be the same mRNA vaccine as primary series
- The EUA amendment for an additional dose does not apply to Janssen COVID-19 vaccine or to individuals who received Janssen COVID-19 as a primary series.
- ACIP recommends that individuals self-attest their immunocompromised status in order to reduce barriers to vaccination.
- Note that “fully vaccinated” status is still considered to be 2 weeks after two doses (primary series) of mRNA COVID-19 vaccine, or 2 weeks after one dose on Janssen COVID-19 vaccine, even for immunocompromised individuals.

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