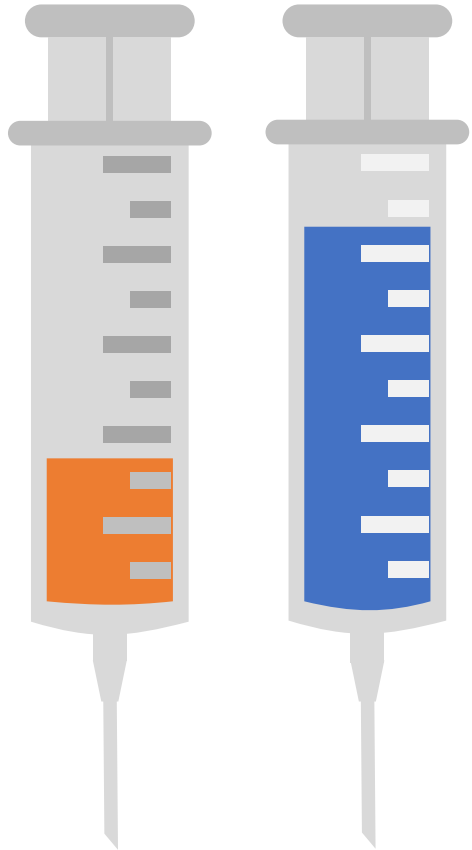


Vaccine Updates



FDA Extends Full Approval to Pfizer Vaccine for Ages 16+ ACIP/CDC Recommendation 8-30-21

*The drug will be marketed as Comirnaty (koe-mir'-na-tee), for the prevention of COVID-19 in individuals **16 years of age and older**. The full press release from the FDA is available [HERE](#).*

12-15 Years of Age remain under EUA

Administration to 12-15 year olds was not included in the EUA until May 2021 – additional time required before approval

Additional Dose Guidance under the EUA

Additional doses for moderately to severely immunocompromised individuals was recently added to the Pfizer-BioNTech EUA for all ages 12+ - and remains under EUA

[Pfizer Fact Sheet for Recipients and Caregivers](#) (updated August 23, 2021)

[Pfizer Fact Sheet for Healthcare Providers](#) (updated August 23, 2021)

MINOR'S CONSENT CHANGES

Parental Consent for Vaccines Under Emergency Use Authorization

State law (Session Law 2021-110) changed on August 20, 2021 requires health care providers to obtain **written consent** from a parent or legal guardian of a minor prior to administration of **any vaccine that that has been granted emergency use authorization and is not yet fully approved by the United States Food and Drug Administration** to an individual under 18 years of age.

- Once a vaccine has full FDA approval, pre-existing minor consent laws apply to consent to vaccination*
- **No other changes to current minor's consent law**

12-15 Years of Age - Initial 2 dose series

Pfizer is available under emergency use authorization for 12-15 year-olds with **written consent from a parent or legal guardian**

16 & 17 Years of age - initial 2 dose series

While expected and typically best practice that parental/guardian consent is obtained for COVID-19 vaccination, adolescents 16 and 17 years of age can consent for the Pfizer-BioNTech COVID-19 vaccine, if they show the decisional capacity to do so.




12-17 Years of Age - Additional doses for Immunocompromised

Pfizer is available under emergency use authorization for additional doses for 12-17 years olds with immunocompromise with **written consent from a parent or legal guardian**

Moderna and J&J COVID-19 vaccines are not currently authorized for individuals under 18 at this time.

Providers should NOT vaccinate anyone 11 or younger – not currently authorized or recommended. Not consistent with COVID-19 Provider Agreement. Studies currently going on in younger populations pertaining to dose, safety, effectiveness

COVID VACCINES IN YOUNGER CHILDREN

	16-17 years	12-15 years	5-11 years	6mo - 5yrs
	Full approval on Aug 23, 2021 (after EUA on Dec 11, 2020)	EUA approved May 10, 2021 . Additional time required before approval	Started March 2021 , expect EUA submission in Sept	Started March 2021 , ongoing
	EUA requested Jun 10 (96% effective, safe)	EUA requested Jun 10 (96% effective, safe)	Started March 2021 , expect EUA submission in fall	Started March 2021 , ongoing
	Announced in April 2021 , ongoing	Ongoing	Planned	Planned

- **Pfizer:** Dose-escalation study evaluating safety, tolerability, and immunogenicity in a two-dose schedule in 3 age groups: 5-11 years, 2-5 years, and 6 months-2 years. Expected enrollment of ~4,500 children.
- **Moderna**
 - **TeenCOVE:** 3,732 participants 12-17 years old. 0 cases in vaccinated arm. Similar safety, tolerability profile as in adult study.
 - **KidsCOVE:** Expected enrollment ~12,000 children age 6 months to 12 years
- **Dosing:** Anticipate smaller dose (e.g., 10 vs 30 micrograms) in 5-11 yr olds due to size & stronger immune response
- **AAP** urges FDA to authorize COVID-19 vaccines for children <12 as soon as possible

Additional Dose and Booster planning

BOOSTER COMMUNICATIONS: COMMUNICATING ADDITIONAL VS. BOOSTER



NC DEPARTMENT OF
HEALTH AND
HUMAN SERVICES

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COVID-19 VACCINES: What's the difference between an additional dose and a booster? If you received a two-dose vaccine (Pfizer or Moderna vaccines), here's what you should know:

ADDITIONAL DOSES

are for people who are moderately or severely immunocompromised.



Additional doses are authorized to give **28 days** after the 2nd dose of an initial mRNA (Pfizer or Moderna) vaccine.



The CDC and FDA **have provided** guidance. Doctors and pharmacists must follow CDC guidance.



Providers **can give** additional doses to moderately or severely immunocompromised patients.

BOOSTER DOSES

are to provide continued protection.



Booster doses may be authorized to give a certain period after the 2nd dose of an mRNA (Pfizer or Moderna) vaccine. Likely around **8 months**.



The CDC and FDA **have NOT provided** guidance. Doctors and pharmacists must wait for guidance.



Providers **cannot give** booster doses yet. We expect boosters might be available starting September 20.

There is currently no recommendation for additional doses or booster doses for patients who received the J&J vaccine. Evidence is being reviewed for recommendations.

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ADDITIONAL DOSES/BOOSTER PLANNING

Additional Dose

- The additional mRNA COVID-19 vaccine dose should be the same vaccine product as the initial 2-dose mRNA COVID-19 primary vaccine series (Pfizer-BioNTech or Moderna).
- If the mRNA COVID-19 vaccine product given for the first two doses is not available, the other mRNA COVID-19 vaccine product may be administered.
- A person should not receive more than three mRNA COVID-19 vaccine doses.
- Same administration rate as first 2 doses

Booster doses

- Federal DHHS put out notice as a **Planning Assumption** – Booster doses may start around Sept 20th, 8 months after initial series. NC DHHS Planning now
- Awaiting **authorization, recommendation, guidance from FDA, CDC** on need for and timing – e.g., 6 or 8 months
- Many more providers than first time - more than 3,200 enrolled providers - and good supply
- May have some mass vax, but likely more points of entry.
- Staggered doses based on date of completing of first dose

WHAT WE KNOW ABOUT UPCOMING BOOSTERS



Which vaccine manufacturers have submitted their booster packets for review?

When will FDA meet to discuss the booster packets submitted?

9/17/2021	TBD	N/A

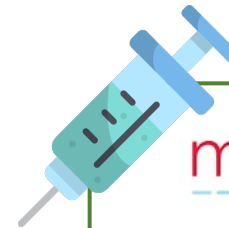


September 20 Booster Plan

The CDC will be meeting to discuss booster shot administrations tentatively set to start September 20.

Booster planning process subject to:

- **FDA authorization**
- **ACIP/CDC recommendation**



- Moderna has asked the FDA to approve the booster shots at **half the dosage given in first two shots**
- This could impact administration, ancillary kits, etc. We will continue to inform providers when the FDA makes the decision and what the impact in administration will be.