

FDA Announces Approval for Pediatric Bivalent Boosters

The U.S. Food and Drug Administration [amended the emergency use authorizations](#) (EUAs) of the Moderna COVID-19 Vaccine, Bivalent and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent to authorize their use as a single booster dose in younger age groups.

- The Moderna COVID-19 Vaccine, Bivalent is authorized for use as single booster dose in **individuals 6 years of age and older**.
- The Pfizer-BioNTech COVID-19 Vaccine, Bivalent is authorized for use as a single booster dose in **individuals 5 years of age and older**.

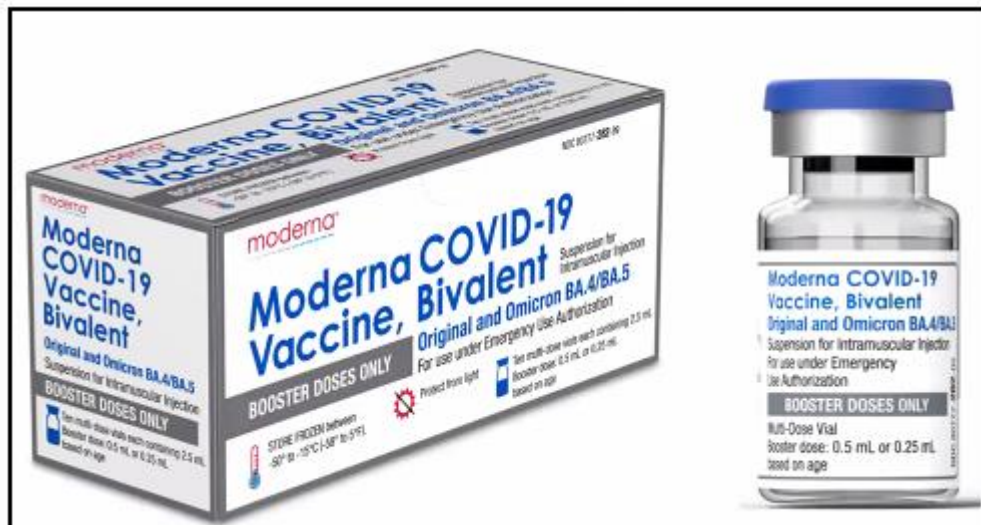
Pediatric Booster Availability

Moderna

Moderna pediatric bivalent boosters are approved using a half-dose of the bivalent vaccine currently being administered to adults. The letter to healthcare providers with important prescribing information is available at [Moderna DHCP Letter Bivalent 10122022 \(fda.gov\)](#).

Because this vaccine is currently being administered to adults, inventory already exists in the field for use with children. Administration to pediatric patients can begin immediately using existing Moderna inventory. Please review the DHCP link above to avoid administration errors in children.

Moderna Bivalent COVID-19 Vaccine Label (adult and pediatric)



Pfizer

Pre-orders of Pfizer pediatric bivalent vaccines are expected to begin delivery on Monday, October 17. Providers may begin scheduling appointments immediately in anticipation of these deliveries.

Ordering for additional pediatric bivalent vaccines is open.

Pfizer Pediatric COVID-19 Labels (monovalent and bivalent)



Peds Bivalent Booster Orders – Specifying Adult or Pediatric Intent When Ordering

- Orders of **Moderna bivalent COVID-19 vaccines** for children aged 6-11 years will be sent with two ancillary kits per minimum dose order to accommodate double the number of doses provided in each vial.
 - Providers may opt-out of receiving ancillary kits for Moderna bivalent COVID-19 vaccines, but they must still specify pediatric intent.
 - There is no way to request a single pediatric ancillary kit. However, some sites handle this by not opting out for the first order and opting out for the second.
- **Pfizer-BioNTech bivalent COVID-19 vaccines** for children aged 5-11 years require diluent, so awardees will not be able to opt-out of receiving ancillary kits nor are they required to order with intent.
- Ancillary kit opt-out continues to be available for all non-diluent kits

Monovalent Boosters No Longer Authorized

Monovalent mRNA COVID-19 vaccines are no longer authorized as booster doses for individuals 5 years of age and older. You are [up to date](#) with your COVID 19 vaccines if you have completed a COVID-19 vaccine primary series and received the most recent booster dose recommended for you by CDC. Anyone over the age of 5 is currently recommended to receive a bivalent booster.

Website Updates for Pediatric Bivalent Boosters

The Interim Clinical Considerations and FAQs for the pediatric bivalent boosters have been updated.

- ICCs: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html>
- FAQs: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/faq.html>

Peds Bivalent Booster Training

Pfizer Medical offers virtual training for providers of Pfizer-BioNTech COVID-19 vaccine primary series and bivalent Pfizer-BioNTech COVID-19 boosters for people 5 years of age and older. To access dates and links for upcoming training sessions, [visit the Pfizer website](#).

Moderna is providing daily opportunities for Q&A through Oct. 28, 2022. You may [register to attend](#) any of these sessions.

Mini-Webinars Regarding Bivalent COVID-19 Boosters

CDC is offering a series of brief webinars addressing topics around COVID-19 vaccination. These interactive, web-based training modules offer a real-world perspective on different issues around COVID-19 vaccines. Topics range from routine clinical and vaccine safety information to guidance for on-site clinic vaccination activities and having conversations with vaccine recipients. Each webinar includes self-test practice questions and lists additional resources related to the topic discussed.

The Oct. 19 webinar will focus on the bivalent booster recommendations for children ages 5-11 in lieu of a COCA call. It will be pre-recorded and posted on October 19 at: [COVID-19 Vaccine Webinar Series | CDC](#).

COVID-19 Bivalent Vaccine Inventory and Wastage Guidance

When reporting wastage for bivalent boosters in children, always report wastage in full doses based on the volume identified on the label. Never report wastage in half doses. The table below is provided to assist with wastage reporting. Additional information on the identification, disposal and reporting of wastage can be found at [Identification, Disposal, and Reporting of COVID-19 Vaccine Wastage | CDC](#)

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Product Label	Authorized For	Approved Administration	Dose Per Volume	Doses Per Vial	Max Reportable Inventory (Unopened Vials Only)	Max Reportable Wastage
Bivalent Vaccines						
Pfizer-BioNTech COVID-19 Vaccine Bivalent Booster	12 years and older	Booster	30mcg per 0.3mL	6	6	6
Pfizer-BioNTech COVID-19 Vaccine	5-11 y/o	Booster	10mcg per 0.2 mL	10	10	10

Bivalent Booster						
Moderna COVID-19 Bivalent Booster	12 years and older	Booster	50mcg per 0.5 mL	5	5	5
	6 – 11 y/o	Booster	25mcg per 0.25 mL	10	5	5

Regarding ACIP (Advisory Committee on Immunization Practices)

Why is an ACIP meeting not necessary for updated (bivalent) COVID-19 boosters for children ages 5 through 11 years?

At the [September 1, 2022 ACIP meeting](#), ACIP had the opportunity to review and discuss data about updated (bivalent) COVID-19 boosters for all age groups for which monovalent COVID-19 boosters had been previously recommended. These groups included people ages 12 years and older, as well as children ages 5 through 11 years. In order for ACIP to vote to recommend any specific vaccine product, however, FDA needs to have issued an emergency use authorization (EUA) for that product. EUAs were available on September 1, 2022 for updated (bivalent) boosters for people ages 12 years and older, but not for children ages 5 through 11. This was due to ongoing work in manufacturing and production of products for the younger age group. Manufacturing and production are complete and EUAs are now available for updated COVID-19 boosters for children ages 5 through 11 years. Since ACIP has already reviewed the relevant data—and in order to avert delays in providing updated boosters for children ages 5 through 11 years—CDC is recommending the use of these products and helping make them available to children ages 5 through 11 across the United States.

You have likely seen the [media coverage](#) of the Advisory Committee for Immunization Practices (ACIP) vote yesterday unanimously recommending that the COVID-19 vaccine be included in the Vaccines for Children (VFC) program. CDC also issued [this tweet](#) in response to the media coverage. A few points of clarification:

- This is a standard process for every routine childhood vaccine that is covered under the VFC program.
- The vote does not create a mandate. State laws [establish vaccination requirements](#) for school children.
 - Importantly, the media misunderstood the conversation that transpired at the ACIP meeting yesterday. As a reminder, jurisdictions laws may require or allow the use of ACIP recommendations when considering which vaccines to require for school attendance and/or the dosage, manner of administration, frequency, age, etc. for the vaccines. But to reiterate, the vote yesterday was on the VFC program.
- This vote simply means that once COVID-19 vaccines are commercialized and no longer available under the USG’s National COVID-19 Response, VFC providers will be able to order the vaccines through the VFC program.
- Equitable access to COVID-19 vaccines for all ages and populations remains critically important. The [VFC program](#) (Vaccines for Children) is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay.

CDC Director Dr. Rochelle Walensky signed a decision memo and released a [media statement](#) allowing Novavax monovalent COVID-19 boosters for people ages 18 years and older targeting the original COVID-19 strain, following FDA's granting of [emergency use authorization](#).

Novavax monovalent COVID-19 boosters are available for adults 18 years and older 6 months after they have completed primary series vaccination but have not previously received a COVID-19 booster—and if they cannot or will not receive an updated mRNA (bivalent) booster.

CDC recommends that everyone ages 6 months and older be [up to date](#) with COVID-19 vaccination. For those 5 years and older, you are up to date if you have completed a primary series and received the most recent booster dose recommended for you by CDC. Vaccines are highly effective at protecting people from serious illness and remains the best way to protect from severe COVID-19 hospitalization and death.

Clinical research has demonstrated the safety and effectiveness of updated COVID-19 vaccines. As occurs for all vaccines—including COVID-19 vaccines—safety monitoring will continue for them.

Resources

- [Interim Clinical Considerations](#)
- [Vaccines.gov](#)
- CDC [COVID-19 booster tool](#)
- Web resources for the public:
 - [Stay Up to Date with Your COVID-19 Vaccines | CDC](#)
 - [COVID-19 Vaccines for People who are Moderately or Severely Immunocompromised | CDC](#)
 - [Overview of COVID-19 Vaccines](#)
 - [Frequently Asked Questions about COVID-19 Vaccination | CDC](#)
 - [COVID-19 Vaccination for Children and Teens with Disabilities | CDC](#)
 - [How Do I Find a COVID-19 Vaccine or Booster?](#)
- Web resources for immunization partners:
 - [Vaccinate with Confidence](#)
 - [Guidance for Vaccinating Older Adults and People with Disabilities: Ensuring Equitable COVID-19 Vaccine Access](#)
 - [Vaccinating Older Adults and People with Disabilities at Vaccination Clinics](#)
- Mini on-demand webinar for healthcare providers – will [post](#) week of October 17, 2022
- MMWR – October 2022