

From: DPH.Immunizations@ct.gov <noreply@everbridge.net>

Sent: Friday, December 9, 2022 2:55 PM

Subject: CDC Recommends Updated Bivalent Vaccine for Everyone 6 Months and Older



DEPARTMENT OF PUBLIC HEALTH

CDC Recommends Updated Bivalent Vaccine for Everyone 6 Months and Older

December 9, 2022

This communication is being sent to all key contacts at provider organizations administering COVID-19 vaccine— please read this message in its entirety. Please feel free to share it with others in your organization who may benefit from the update. Note that all our communications are archived on our web site.

Dear Connecticut COVID-19 Vaccine Providers,

Yesterday the [FDA expanded the age authorization for both Moderna and Pfizer-BioNTech bivalent COVID-19 vaccines](#). The [Centers for Disease Control and Prevention \(CDC\) has now expanded the use of updated, bivalent COVID-19 vaccine to include children ages 6 months through 5 years of age](#).

Moderna bivalent recommendation

- Children 6 months through 5 years of age who received the original (monovalent) Moderna COVID-19 Vaccine are now eligible to receive a single booster of the updated (bivalent) Moderna COVID-19 Vaccine two months after completing a primary series with the monovalent Moderna COVID-19 Vaccine.

Pfizer bivalent recommendation

- Children 6 months through 4 years of age who have not yet begun their three-dose primary series of the Pfizer-BioNTech COVID-19 Vaccine or have not yet received the third dose of their primary series will now receive the updated (bivalent) Pfizer-BioNTech COVID-19 vaccine as the third dose in their primary series following two doses of the original (monovalent) Pfizer-BioNTech COVID-19 Vaccine.
- Children 6 months through 4 years of age who have already completed their three-dose primary series with the original (monovalent) Pfizer-BioNTech COVID-19 Vaccine will not be eligible for a booster dose of an updated bivalent vaccine at this time. Children in this age group who already completed their primary series would still be expected to have protection against the most serious outcomes from the currently circulating omicron variant.
- The monovalent Pfizer-BioNTech COVID-19 Vaccine is no longer authorized for use as the third dose of the three-dose primary series in children 6 months through 4 years of

age. The monovalent Pfizer-BioNTech COVID-19 Vaccine remains authorized for administration as the first two doses of the three-dose primary series.

- Appointments for monovalent Pfizer-BioNTech third doses in children less than 5 years of age must be rescheduled for when locations have the age-appropriate bivalent COVID-19 vaccines available.

[Interim Clinical Considerations](#) for healthcare providers are expected to be updated later today and other [associated materials](#) will be updated shortly.

A COCA call about these guidance changes is scheduled for Tuesday, December 13, 2022, 2:00 PM – 3:00 PM ET: https://emergency.cdc.gov/coca/calls/2022/callinfo_121322.asp

COVID-19 vaccine providers in Connecticut may begin administration of doses in line with the FDA emergency use authorization and CDC recommendations as soon the vaccine arrives.

Providers can now order both the Moderna and Pfizer bivalent vaccines using the standard weekly ordering practice through the [submissions portal](#).

See previous communication on vaccine presentations for this expanded age group [here](#).

- In order to continue offering primary series vaccines in addition to bivalent boosters, providers will need to keep multiple COVID-19 vaccine products in their inventory. CDC recommends providers offer simultaneous administration of all age-appropriate doses of vaccines for children, adolescents, and adults for whom no contraindications exist at the time of the healthcare visit; this includes influenza vaccines.
- Pfizer has virtual training for providers on their new COVID-19 bivalent vaccine; to access dates and links for upcoming training sessions, [visit the Pfizer website](#).
- Moderna has a virtual educational webinar and interactive office hours for providers on their new COVID-19 bivalent booster vaccine; to see webinar dates and register click [here](#) and to see office hour times click [here](#).

New Shelf-Life Extensions

Pfizer

Pfizer has received shelf-life extensions of all TRIS products (i.e., all mRNA COVID-19 vaccines, including both monovalent and bivalent vaccines). Expiry is now 18 months from the date of manufacture (stored ULT frozen). Please use the [Pfizer-BioNTech COVID-19 Vaccine Expiry](#) tool to check expiration dates.

Additionally, the new FDA EUA extended ultra-cold storage time from 12 months to 18 months.

Moderna

Expiry dates of the following Moderna products have been extended. Some of these lots are MOD 10 (ages 12+) and some are MOD 5 (ages 6-11). All of these lots are monovalent COVID-19 vaccine for primary use only. Moderna has verified the new expiry dates below and updated the [Moderna Vial Expiration Checker](#).

Lot #	Original Expiry	New Expiry (Verified)
AR4504B	11/13/2022	2/13/2023
AR5186C	11/17/2022	2/17/2023
AR7204B	11/25/2022	2/25/2023
AR7205B	11/25/2022	2/25/2023
AR7479B	11/26/2022	2/26/2023
AR8365B	12/30/2022	3/30/2023
013B22A	11/22/2022	2/22/2023
052B22A	11/23/2022	2/23/2023
064A22A	11/24/2022	2/24/2023
060B22A	11/26/2022	2/26/2023
061B22A	11/27/2022	2/27/2023
083B22A	11/28/2022	2/28/2023
068A22A	11/28/2022	2/28/2023
063B22A	12/2/2022	3/2/2023
059B22A	12/3/2022	3/3/2023
063B22-2A	12/4/2022	3/4/2023
074B22A	12/11/2022	3/11/2023
071B22A	12/12/2022	3/12/2023
072B22A	12/13/2022	3/13/2023

Thank you for all your ongoing work and support of our COVID-19 vaccine roll-out in Connecticut.

For the CT DPH Immunization Program, visit: [Contact Us](#)

For the COVID-19 webpage, visit: [COVID-19 Vaccine Program](#)

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Special Situations for COVID-19 Vaccination of Children and Adolescents

Age Transitions and Interchangeability



Moderna COVID-19 Vaccine for Children who Transition from a Younger to Older Age Group

CDC recommends vaccine recipients receive the recommended age-appropriate vaccine product and dosage **based on their age on the day of vaccination.**

- If a person moves from a younger age group to an older age group during the primary series or between the primary series and receipt of the booster dose(s), they should receive the vaccine product and dosage for the older age group for all subsequent doses.
- FDA emergency use authorization (EUA) allows for different dosing for certain age transitions, which are not considered vaccine administration errors and do not need to be reported to the Vaccine Adverse Event Reporting System (VAERS).

Children who turn from age 5 to age 6 years



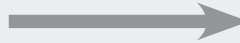
Recommended: Children who started a primary series and turned from age 5 to age 6 years before completion of the series should receive:

Dose 1 (Age 5):

0.25 mL (25 mcg) of the monovalent product authorized for children ages 6 months–5 years (dark blue cap/magenta label border)



4–8 weeks



Child turns 6

Dose 2 (Age 6):

0.50 mL (50 mcg) of the monovalent product authorized for children ages 6–11 years (dark blue cap/purple label border)



Acceptable: If the following dosing occurs, it is NOT considered an error and the primary series is considered complete.

Either dose may be:

- 0.25 mL (25 mcg) of the monovalent product authorized for children ages 6 months–5 years (dark blue cap/magenta label border), or
- 0.50 mL (50 mcg) of the monovalent product authorized for children ages 6–11 years (dark blue cap/purple label border)

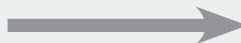
Dose 1: Age 5



OR



4–8 weeks



Dose 2: Age 6



OR



Note: Vial icons with an "M" indicate monovalent vaccine and those with a "B" indicate bivalent vaccine.

Special Situations for COVID-19 Vaccination of Children and Adolescents

Age Transitions and Interchangeability



Moderna COVID-19 Vaccine for Children who Transition from a Younger to Older Age Group (continued)

Children who turn from age 11 years to 12 years



Recommended: Children who started a primary series and turned from age 11 to age 12 years before completion of the series should receive:

Dose 1 (Age 11):
0.50 mL (50 mcg)
of the monovalent
product authorized
for children ages
6–11 years (dark
blue cap/purple
label border)



Dose 2 (Age 12):
0.50 mL (100 mcg)
of the monovalent
product authorized for
children ages 12 years
and older (red cap/
light blue label border)



Acceptable: If the following dosing occurs, it is NOT considered an error and the primary series is considered complete.
Either dose may be:

- 0.50 mL (50 mcg) of the monovalent product authorized for children ages 6–11 years (dark blue cap/purple label border), OR
- 0.50 mL (100 mcg) of the monovalent product authorized for children ages 12–17 years (red cap/light blue label border)

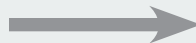
Dose 1: Age 11



OR



4-8 weeks



Dose 2: Age 12



OR



Note: Vial icons with an "M" indicate monovalent vaccine and those with a "B" indicate bivalent vaccine.

Special Situations for COVID-19 Vaccination of Children and Adolescents

Age Transitions and Interchangeability



Pfizer-BioNTech COVID-19 Vaccine for Children who Transition from Age 4 Years to Age 5 Years

FDA emergency use authorization (EUA) requires children who will turn from age 4 years to 5 years during the primary series to complete the series they start, either:

- The 3-dose primary series recommended for children ages 6 months–4 years *or*
- The 2-dose primary series recommended for children ages 5 months–11 years

Because no other dosing options are authorized for this age transition, CDC's standard guidance to administer the age-appropriate vaccine product and dosage based on age on the day of vaccination does **NOT** apply.

Children who turn from age 4 to age 5 years

✓ **Authorized:** Children who turn from age 4 years to 5 years between any doses in the primary series should receive either:

- A 3-dose primary series using the:
 - Monovalent Pfizer-BioNTech COVID-19 Vaccine product authorized for children ages 6 months–4 years (maroon cap and label border) for doses 1 and 2 and
 - Bivalent Pfizer-BioNTech COVID-19 Vaccine product authorized for children ages 6 months–4 years (maroon cap and label border) for dose 3

Dose 1:
0.20 mL (3 mcg)
of the monovalent
product authorized
for children ages
6 months–4 years
(maroon cap and
label border)



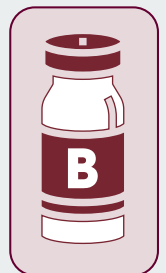
3–8 weeks

Dose 2:
0.20 mL (3 mcg)
of the monovalent
product authorized
for children ages
6 months–4 years
(maroon cap and
label border)



8 weeks

Dose 3:
0.20 mL (3 mcg)
of the bivalent
product authorized
for children ages
6 months–4 years
(maroon cap and
label border)



Or

- A 2-dose primary series using the monovalent Pfizer-BioNTech COVID-19 Vaccine product authorized for children ages 5–11 years (orange cap and label border)

Dose 1:
0.20 mL (10 mcg)
of the monovalent
product authorized
for children ages
5–11 years
(orange cap and
label border)



3–8 weeks

Dose 2:
0.20 mL (10 mcg)
of the monovalent
product authorized
for children ages
5–11 years
(orange cap and
label border)



Note: Vial icons with an "M" indicate monovalent vaccine and those with a "B" indicate bivalent vaccine.

Special Situations for COVID-19 Vaccination of Children and Adolescents

Age Transitions and Interchangeability



Children who turn from age 11 years to 12 year



Recommended: Children who started a primary series and turned from age 11 to age 12 years before completion of the series should receive:

Dose 1 (Age 11):

0.20 mL (10 mcg) of the monovalent product authorized for children ages 5–11 years (orange cap and label border)



3-8 weeks

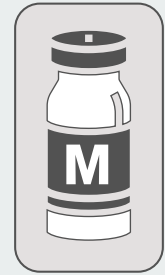


Child turns 12



Dose 2 (Age 12):

0.30 mL (30 mcg) of the monovalent product authorized for children ages 12–17 years (gray cap and label border)



Acceptable: If the following dosing occurs, it is NOT considered an error and the primary series is considered complete. **Either dose may be:**

- 0.20 mL (10 mcg) of the monovalent product authorized for children ages 5–11 years (orange cap and label border), or
- 0.30 mL (30 mcg) of the monovalent product authorized for children ages 12–17 years (gray cap and label border)

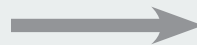
Dose 1: Age 11



OR



3-8 weeks



Dose 2: Age 12



OR



Note: Vial icons with an "M" indicate monovalent vaccine and those with a "B" indicate bivalent vaccine.

Special Situations for COVID-19 Vaccination of Children and Adolescents

Age Transitions and Interchangeability



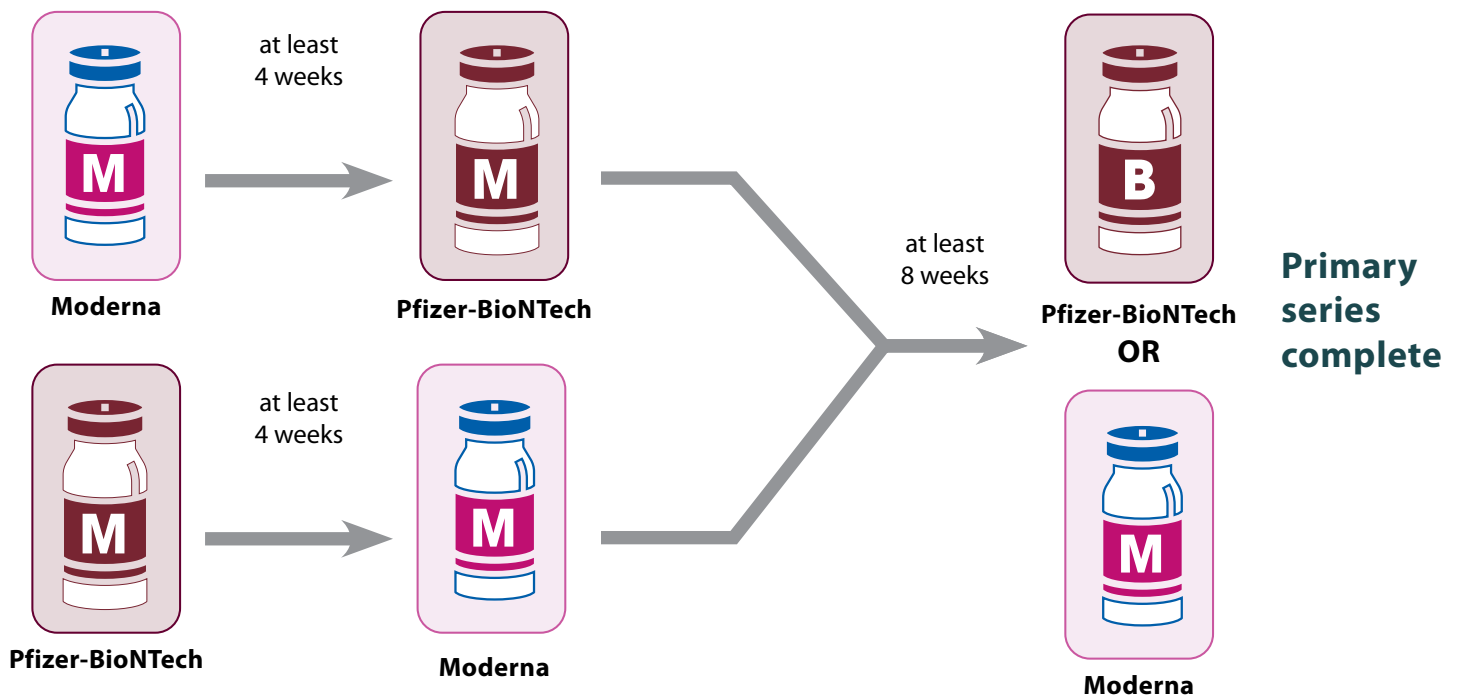
Interchangeability of Moderna and Pfizer-BioNTech COVID-19 vaccines

COVID-19 vaccine from the same manufacturer should be used for the primary series. If a different manufacturer is administered, follow the guidance below:

- If a dose of the age-appropriate product from BOTH Moderna and Pfizer-BioNTech COVID-19 is given, count both doses if the recommended interval between doses has been met.
 - If ages 6 months through 4 years, a third dose of either a monovalent Moderna vaccine or bivalent Pfizer-BioNTech vaccine should be administered at least 8 weeks after the second dose to complete the series. See examples.
 - Repeating doses is not recommended.
- This guidance applies to:
 - All eligible children, including those who are moderately or severely immunocompromised.
 - Vaccines from both manufacturers, regardless which vaccine was given first.

Examples:

Vaccination history: 1 dose of Pfizer-BioNTech and 1 dose of Moderna COVID-19 vaccines.



December 8, 2022

IMPORTANT PRESCRIBING INFORMATION

**Subject: Moderna COVID-19 Vaccine, Bivalent –
New Vial Presentation Available to Provide Booster Doses for
Ages 6 Months Through 5 Years of Age**

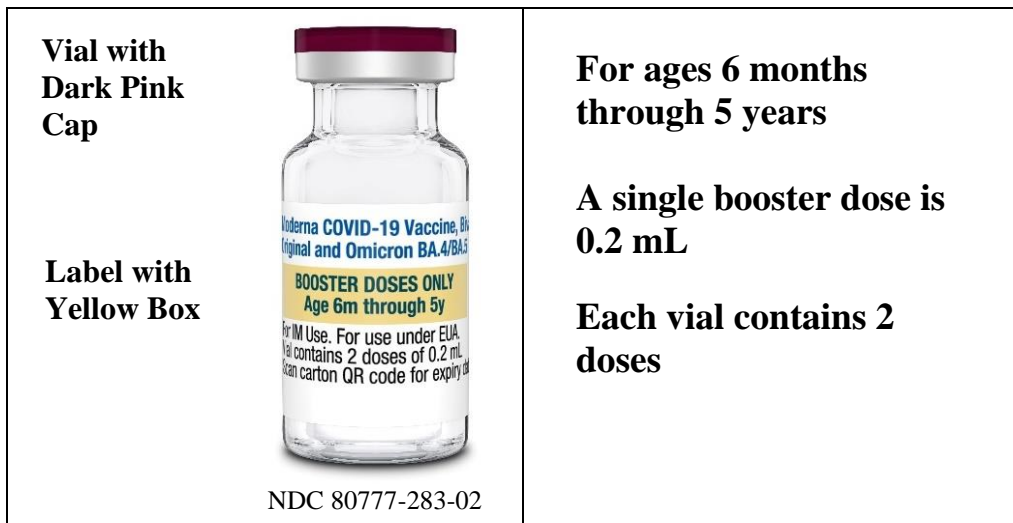
Dear Healthcare Provider:

On December 8, 2022, FDA authorized Moderna COVID-19 Vaccine, Bivalent for use as a single booster dose in individuals 6 months through 5 years of age administered at least 2 months after completion of primary vaccination with Moderna COVID-19 Vaccine.

This letter is to alert you that Moderna COVID-19 Vaccine, Bivalent for individuals 6 months through 5 years of age is supplied in a multiple-dose vial with a dark pink cap and a label with a yellow box. The volume of a single booster dose for ages 6 months through 5 years is **0.2 mL**.

It is important to carefully read the labels to differentiate between this and other Moderna COVID-19 vaccines.

The vial and label for Moderna COVID-19 Vaccine, Bivalent for use in individuals 6 months through 5 years of age are shown in the figure below.




Thaw Time and Discard Time

Thaw time and discard time for Moderna COVID-19 Vaccine, Bivalent supplied in a multiple-dose vial with a dark pink cap and a label with a yellow box for use in individuals 6 months through 5 years of age are different than those for Moderna COVID-19 Vaccine, Bivalent authorized for use in individuals 6 years of age and older and presentations of Moderna COVID-19 Vaccine authorized for use in individuals 6 months of age and older.

Specifically, for Moderna COVID-19 Vaccine, Bivalent supplied in a multiple-dose vial with a dark pink cap and a label with a yellow box for use in individuals 6 months through 5 years of age:

- Thaw before use:
 - Refrigerator: Thaw between 2°C to 8°C (36°F to 46°F) for 45 minutes. Let each vial stand at room temperature for 15 minutes before administering; or
 - Room temperature: Thaw between 15°C to 25°C (59°F to 77°F) for 15 minutes.
- After the first booster dose has been withdrawn, the vial should be held between 2°C to 25°C (36°F to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine, Bivalent vial label. Discard vial after 8 hours. Do not refreeze.

To access the most recent vaccine Fact Sheets, please scan the QR code or visit the website provided below. A copy of the Fact Sheet for Moderna COVID-19 Vaccine, Bivalent authorized for use in individuals 6 months through 5 years of age is also attached to this letter.

Website	Telephone number
<p data-bbox="245 789 760 821">www.modernatx.com/covid19vaccine-eua</p> 	<p data-bbox="1003 789 1243 856">1-866-MODERNA (1-866-663-3762)</p>

Vaccination providers must report certain information associated with the administration of the vaccine to VAERS in accordance with the authorized Fact Sheet.

Please share this letter with relevant personnel in your organization. Should you have any questions about the use of Moderna COVID-19 Vaccine, Bivalent, you can either contact the Moderna Medical Information Contact Center at 1-866-MODERNA (1-866-663-3762) or visit www.modernatx.com/covid19vaccine-eua for additional resources.

This letter is not intended as a complete description of the benefits and risks related to the use of Moderna COVID-19 Vaccine, Bivalent. Please refer to the authorized Moderna COVID-19 Vaccine, Bivalent Fact Sheet.

Sincerely,

Paul Burton

Paul Burton, MD, PhD, FACC, MRCS Chief Medical Officer, Moderna

Enclosure: Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) Moderna COVID-19 Vaccine, Bivalent - Booster Dose - 6 Months Through 5 Years of Age