Updated – 5/10/2023

Frequently Asked Questions

Q: Are we correct in understanding that for all kids 6 years and older, who are NOT immunocompromised, they need only ONE bivalent dose? There is no more "primary series and boosters"?
A: Yes. Everyone 6 years and older should have **ONE bivalent mRNA dose**. They are considered up to date if/when they have the one bivalent mRNA dose. Regardless of vaccination history – whether they have had zero past monovalent vaccines, or 5 past monovalent vaccines, they should get ONE bivalent dose. If they have already had one bivalent dose, they are up to date and do not need to take any action unless they are 65 years or older or immunocompromised.

Q: Are COVID Vaccines interchangeable?
A: CDC recommends children ages 6 months–5 years who are unvaccinated and recommended to receive more than 1 bivalent mRNA vaccine dose for initial vaccination receive all doses from the same manufacturer. However, as detailed below, FDA authorization allows for administration of a mixed product series for initial vaccination in some age groups.
Authorization to use COVID-19 vaccines interchangeably from different manufacturers varies by vaccination history, age, and product as follows:

- People ages 6 months–4 years who are unvaccinated or previously received 1 or more doses of a monovalent mRNA vaccine are authorized to receive only bivalent mRNA vaccine dose(s) from the same vaccine manufacturer.
- People age 5 years who are unvaccinated or previously received 1 or more doses of monovalent Moderna COVID-19 Vaccine are authorized to receive either bivalent Moderna or bivalent Pfizer-BioNTech COVID-19 vaccine.
- People age 5 years who are unvaccinated or previously received 1 or more doses of monovalent Pfizer-BioNTech COVID-19 are authorized to receive only bivalent Pfizer-BioNTech COVID-19 Vaccine.
- People ages 6 years and older who are unvaccinated or previously received 1 or more doses of any monovalent COVID-19 vaccine are authorized to receive either bivalent Moderna or bivalent Pfizer-BioNTech COVID-19 vaccine.
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A Vaccine Adverse Event Reporting System (VAERS) report is required following administration of a vaccine in an unauthorized manner.

In the following exceptional situations, a different age-appropriate COVID-19 vaccine may be administered when FDA authorization requires that a vaccine from the same manufacturer be used. A VAERS report is not required for these exceptional situations:

- Same vaccine not available
- Previous dose unknown
- Person would otherwise not complete the vaccination series
- Person starts but unable to complete a vaccination series with the same COVID-19 vaccine due to a contraindication

Recommended actions for vaccine administration errors or exceptional situations follow below. The COVID vaccination schedules for People who are **not** moderately or severely immunocompromised and People who are moderately or severely immunocompromised and Appendix D should be consulted for age-specific information.

Q: Is immunocompromised status for COVID-19 vaccination based on self-attestation?
A: Yes, that is correct. Patients can self-attest to their moderately or severely immunocompromised status. Providers should not deny COVID-19 vaccination to a person due to lack of such documentation. For further information, see CDC Interim Clinical Considerations for Use of COVID-19 Vaccines.

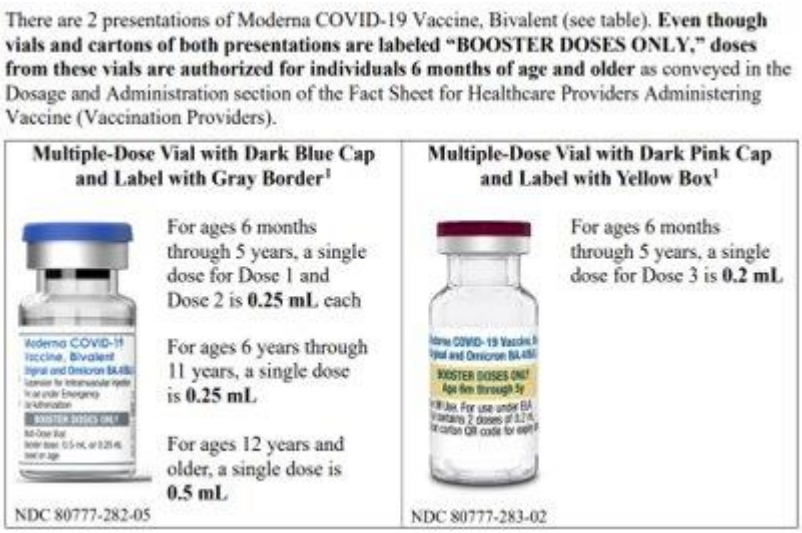
Q: Is the 15-minute post-vaccination observation period still recommended?
A: Yes. COVID-19 vaccine providers should consider observing vaccine recipients for 15 minutes. For further information, including considerations for 30-minute observation periods, please see CDC Interim Clinical Considerations for Use of COVID-19 Vaccines.

Q: Which different COVID vaccines can be ordered through PA SIIS?

Brand	NDC	Description	Minimum order quantity	Label
Pfizer	59267-0304-02	COVID19-PFR-BV PFR 12+ BIVALENT (increments of 180)	180	NDC 59267-0304 Pfizer-biontech Covid-19 Vaccine, Bivalent Injection, Suspension Intramuscular Label Information - Details, Usage & Precautions (ndclist.com)
Pfizer	59267-1404-02	COVID19-PFR-BV PFR-SDV BVAL 12+ (order qty 50 only)	50	NDC 59267-0304 Pfizer-biontech Covid-19 Vaccine, Bivalent Images - Packaging, Labeling & Appearance (ndclist.com)
Pfizer	59267-0565-02	COV19-PFR-P-BV PFR-P BIVALENT 5-11 (increment 100)	100	NDC 59267-0565 Pfizer-biontech Covid-19 Vaccine, Bivalent Injection, Suspension Intramuscular Label Information - Details, Usage & Precautions (ndclist.com)
Pfizer	59267-0609-02	COV19-PFR-L5-BV PFR L5 BIVALENT (increment 100)	100	NDC 59267-0609 Pfizer-biontech Covid-19 Vaccine, Bivalent Injection, Suspension Intramuscular Label Information - Details, Usage & Precautions (ndclist.com)
Moderna	80777-0282-99	COVID19-MOD-B MOD 18+ BIVALENT (increments of 100)	100	NDC 80777-282 Moderna Covid-19 Vaccine, Bivalent Images - Packaging, Labeling & Appearancem (ndclist.com)
Moderna	80777-0283-99	COV19-MOD-L6-BV MOD L6 BIVALENT (increment 20)	20	NDC 80777-283 Moderna Covid-19 Vaccine, Bivalent Images - Packaging, Labeling & Appearance (ndclist.com)
Novavax	80631-1012-01	COVID-19 (Novavax); MDV5; 10-pack	100	

Q: Where can we find an easy-to-read flowchart of the new schedule for COVID vaccines?
A: Please find the resources below:
American Academy of Pediatrics - COVID Vaccine Dosing Quick Reference.pdf (aap.org)
CDC - Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC

Q: Do you know when to use Blue Cap/Grey Label vs. Pink Cap/Yellow Label?
A: The Moderna blue cap/grey label product is now authorized down to 6 months of age. Depending on their history, children 6 months - 5 years are now typically eligible for Moderna doses from the blue cap rather than the pink cap vials.


There are 2 presentations of Moderna COVID-19 Vaccine, Bivalent (see table). **Even though vials and cartons of both presentations are labeled "BOOSTER DOSES ONLY," doses from these vials are authorized for individuals 6 months of age and older** as conveyed in the Dosage and Administration section of the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers).

Multiple-Dose Vial with Dark Blue Cap and Label with Gray Border[1]	Multiple-Dose Vial with Dark Pink Cap and Label with Yellow Box[1]
For ages 6 months through 5 years, a single dose for Dose 1 and Dose 2 is **0.25 mL** each For ages 6 years through 11 years, a single dose is **0.25 mL** For ages 12 years and older, a single dose is **0.5 mL**	For ages 6 months through 5 years, a single dose for Dose 3 is **0.2 mL**
NDC 80777-282-05	NDC 80777-283-02

Q: Is the NEW 0.2 dose Bivalent Moderna (pink cap) available to be ordered? Is it a "different" product?
A: Yes. Bivalent Moderna (pink cap) is already available to be ordered from PA SIIS and is not considered to be a "different" product. The NDC number is 80777-283-02.

Q: For the Moderna 6m-5yrs with the yellow label border, do ancillary kits come with syringes that can accurately measure 0.2 ml?
A: Yes. Ancillary kits containing syringes are sent with all vaccine orders except the orders for single dose vials by Pfizer.

Q: Can healthcare providers request a consultation for a complex COVID-19 vaccine safety question?
A: Yes. U.S. healthcare providers or health departments can request a consultation from CDC's Clinical Immunization Safety Assessment (CISA) COVIDvax project for any complex COVID-19 vaccine safety question that is (1) about an individual patient residing in the U.S. or vaccine safety issue and (2) not readily addressed by CDC or Advisory Committee on Immunization Practices (ACIP) guidelines.

This request can be made through CDC-INFO by:

- Calling 800-CDC-INFO (800-232-4636), or
- Submitting a request via CDC-INFO webform

For more information, visit the CDC's Clinical Immunization Safety Assessment (CISA) Project webpage.

Q: How do we dispose of vaccine related waste?
A: Please see below:

Vaccine Vials

- Always collect all vaccine vials (used and discarded) and put them in one place, separating from other waste.
- An empty, full or vial with leftover vaccine should always be put in a sharps container to prevent injury from broken glass as well as possible counterfeits.

Syringes

- Always throw the used syringes in a sharp's container.
- Syringes fall under regulated medical waste.
- The sharps container used must have FDA market clearance.

Vial packaging

- Please dispose of vial packages as regulated medical waste to reduce chances of improper use.

Reminders

1. **All sharps' containers must be:**
    - Made of a heavy-duty plastic.
    - Able to close with a tight-fitting, puncture-resistant lid, without sharps being able to come out.
    - Upright and stable during use.
    - Leak-resistant; and
    - Properly labeled to warn of hazardous waste inside the container.

2. Keep all vaccine related wastes in a secure place until they are ready to be picked up by a licensed vendor for transportation to treatment and disposal area.
3. Please note that approved medical waste vendors should be used for the disposal of medical waste including the sharps containers.
4. Using a state licensed medical waste vendor would be appropriate.

Q: Do you know if COVID-19 vaccine reporting will still be required once the public health emergency for COVID-19 ends on May 11, 2023?
A: Even after the PHE ends on May 11, the reporting requirements for COVID-19 vaccine administration data submission and inventory reporting will not change. Our jurisdiction will continue to send that vaccination data to the CDC on a regular basis. Only

change you might notice is the cadence at which data is refreshed on CDC's data tracker for COVID vaccines. Please note that at this time, procurement, and distribution of COVID vaccines is still being done through the US government. Therefore, the requirements outlined in provider agreement upon enrollment to the COVID vaccine program (which includes reporting requirements) continue to remain unchanged until further notice. However, the requirement may change once commercialization of COVID vaccines take place and providers obtain vaccines through commercial marketplace. We do not have a specific date for when commercialization will occur, but CDC has given us tentative timeline of fall (sept) of this year.

Q: When the state and federal COVID-19 Public Health Emergencies (PHEs) end, can Providers still administer COVID-19 vaccines under Emergency Use Authorization (EUA)?
A: Yes. Providers can still administer COVID-19 vaccines under Emergency Use Authorization (EUA) when the state and federal COVID-19 Public Health Emergencies (PHEs) end. The Food and Drug Administration (FDA) "EUA Declaration" remains in effect until terminated by the Health and Human Services Secretary; a date for this has not been announced. For further information, please visit FDA- Emergency Authorization FAQs

Q: With the Public Health Emergency (PHE) ending and commercialization approaching, are providers still required to complete the CDC COVID-19 training modules?
A: Yes. We will continue to make sure that providers are trained, and the trainings are available for them to use for that requirement, if needed. So long as providers are offering COVID vaccination through a publicly funded mechanism, we will continue to ensure they are properly trained – whether as part of the current CDC COVID vax program, VFC, or the upcoming bridge program. Providers can continue to use the CDC training modules for that purpose.