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COVID-19 Vaccine Information Brief

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IMPORTANT/NEW COVID-19 Vaccine Information

KEY SUMMARY AND ACTIONS ITEMS

- The U.S. Food and Drug Administration (FDA) amended the emergency use authorizations (EUAs) of the Moderna COVID-19 Vaccine, Bivalent and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent to authorize use as a single booster dose in younger age groups.
- Existing Moderna COVID-19 Bivalent Vaccine may immediately be administered at least two months following completion of primary or booster vaccination in children down to six years of age.
- Pre-booked Pfizer COVID-19 Bivalent Vaccine for Pediatric Ages 5-11 will begin to ship immediately and may be administered as soon as product is received.

FDA AUTHORIZES MODERNA AND PFIZER-BIONTECH BIVALENT COVID-19 VACCINES FOR USE AS A BOOSTER DOSE IN YOUNGER AGE GROUPS

The U.S. Food and Drug Administration (FDA) 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 administration at least two months following completion of primary or booster vaccination in children down to six years of age.
- Pfizer-BioNTech COVID-19 Vaccine, Bivalent is authorized for administration at least two months following completion of primary or booster vaccination in children down to five years of age.

With the FDA's authorization, the **monovalent Pfizer-BioNTech COVID-19 Vaccine is no longer authorized as a booster dose for individuals five through 11 years of age.** Both the Moderna COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine continue to be authorized for primary series administration in individuals six months of age and older.

INTERIM CLINICAL CONSIDERATIONS FOR USE OF COVID-19 VACCINES CURRENTLY APPROVED OR AUTHORIZED IN THE UNITED STATES - UPDATED

The Interim Clinical Considerations for Use of COVID-19 Vaccines have been updated. A summary of the recent changes include a new COVID-19 booster recommendations for people ages 5 years and older to receive 1 bivalent mRNA booster after completion of a monovalent primary series or previously received monovalent booster dose(s); these recommendations replace all prior booster recommendations for this age group

- Recommendations for use of a bivalent Moderna booster dose in people ages 6–17 years
- Recommendations for use of a bivalent Pfizer-BioNTech booster dose in people ages 5–11 years

Primary Series Vaccination

For primary series vaccination, three monovalent COVID-19 vaccines (listed in alphabetical order by manufacturer) are recommended: Moderna, Novavax, and Pfizer-BioNTech. ***Bivalent mRNA vaccines are not authorized or approved at this time for primary series doses.*** The same vaccine product should be used for all doses of the primary series (see Interchangeability of COVID-19 vaccine products).

Booster Vaccination

For booster vaccination, an mRNA vaccine (i.e., Moderna or Pfizer-BioNTech) is recommended. Recommendations vary based on age and primary series product. **People ages 5 years and older are recommended to receive 1 bivalent mRNA booster dose after completion of any FDA-approved or FDA-authorized monovalent primary series or previously received monovalent booster dose(s).** This new booster recommendation replaces all prior booster recommendations for this age group. **Monovalent mRNA vaccines are no longer authorized as a booster dose for people ages 5 years and older.**

PFIZER COVID-19 BIVALENT VACCINE FOR PEDIATRIC AGES 5-11 YEARS

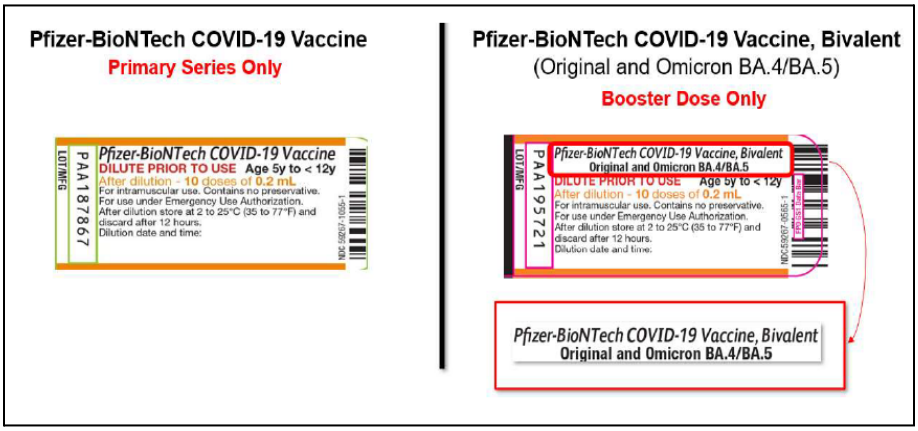
Important Considerations

A single booster dose (0.2 mL) of Pfizer-BioNTech COVID-19 Vaccine, Bivalent may be administered at least 2 months after completion of primary vaccination or receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine. The Pfizer-BioNTech COVID-19 Vaccine, Bivalent is authorized for use in individuals 5 through 11 years of age to provide a single booster dose. CDC will begin shipping the pre-booked Pfizer COVID-19 Bivalent Vaccine for Pediatric Ages 5-11 years immediately.

Age Range	Dilution Information	Doses Per Vial After Dilution	Dose Volume
5 through 11 years (Vial labels state: Age 5y to <12y)	Dilute with 1.3 mL sterile 0.9% Sodium Chloride Injection, USP prior to use	10	0.2 mL

- **Pfizer-BioNTech COVID-19 Vaccine, Bivalent Multiple Dose Vial with Orange Cap and a Label with an Orange Border**
- This is a similar vial with an orange cap as the existing Pfizer product for this age group, but with a label that identifies it as a bivalent booster.
- The monovalent vaccine will continue to be used for the PRIMARY SERIES in individuals 5 years and older.
- It is important to differentiate between the two vaccine products (monovalent vs. bivalent vaccine) to ensure the appropriate vaccine is being administered.
- Ancillary kits will include diluent for the Pfizer Pediatric (5-11 years) bivalent booster vaccine.

Label Comparison for Pfizer COVID-19 Pediatric Vaccine



Pfizer Vaccine Storage and Handling

- The product will be delivered in a newly updated product shipper at -80°C. The shipper is disposable and does not need to be returned to Pfizer. **The shipper CANNOT be used for vaccine storage.**
- Once the product arrives at the provider site, it can be stored for up to 10 weeks at 2°C to 8°C and 12 months at ultra cold temperatures of -90 to -60°C.
- Pfizer COVID-19 vaccine, bivalent cannot be stored in the freezer.
- Once open, doses in vials should be used within 12 hours.

Resources

- Pfizer-BioNTech COVID-19 Vaccine Presentations Wall Chart
- Fact Sheet For Healthcare Providers- Bivalent Booster Dose For 5-11 Years Of Age
- Fact Sheet For Recipients And Caregivers- Bivalent Booster Dose For 5-11 Years Of Age
- Healthcare Provider letter - Bivalent Booster Dose for 5-11 Years of Age

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PFIZER COVID-19 VACCINE MEDICAL UPDATES

Pfizer has expanded its training sessions to address questions about currently the recommended COVID-19 vaccine, bivalent product. The COVID-19 vaccine medical updates and site training webinars aim to educate providers and immunization staff on the proper use of the Pfizer-BioNTech COVID-19 Vaccines. For more detailed information, see dates and links for upcoming training sessions.

MODERNA COVID-19 BIVALENT VACCINE FOR SIX YEARS AND OLDER

Important Considerations

A single booster dose of Moderna COVID-19 Vaccine, Bivalent may be administered at least 2 months after completion of primary vaccination or receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.

- **For individuals 12 years of age and older, a single booster dose is 0.5 mL**
- **For individuals 6 years through 11 years of age, a single booster dose is 0.25 mL**
    - Attached are IRIS Instructions to change the Dose field in IRIS when administering a 0.25mL dose of MOderna COVID-19 bivalent vaccine from IRIS inventory.

Label for Moderna COVID-19 Vaccine, Bivalent

Vial with Dark Blue Cap **Label with Gray Border**	 NDC 80777-282-05	For ages 6 years through 11 years, a single booster dose is **0.25 mL** For ages 12 years and older, a single booster dose is **0.5 mL**

- Moderna COVID-19 Vaccine, Bivalent for individuals 6 years of age and older is supplied in a multiple-dose vial with a dark **blue** cap and a label with a gray border.

Vaccine Storage and Handling

- **NO ULTRA-COLD FREEZER STORAGE**
- Freezer storage (-50°C to -15°C) until expiry
- Refrigerate (2°C to 8°C) up to 30 days without puncturing
- Once open, doses in vials should be used within 12 hours

Resources

- Moderna COVID-19 Vaccine Presentations Wall Chart
- Fact Sheet For Healthcare Providers- Bivalent Booster Dose For 6 Years Of Age and Older
- Fact Sheet For Recipients And Caregivers- Bivalent Booster Dose For 6 Years Of Age and Older
- Healthcare Provider letter - Bivalent Booster Dose for 6 Years of Age and Older

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COVID-19 VACCINE RESOURCES

Below is a list of resources and upcoming informational activities related to the recommendations. *Some web resources are in process, and expected to be updated on October 13, 2022, or as soon as possible thereafter.*

- 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
- MMWR: *Interim Recommendations from the Advisory Committee on Immunization Practices for use of the bivalent COVID-19 boosters for people aged 5 years and older – United States* – November 10, 2022 - Anticipated Release Date

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COVID-19 VACCINE ALLOCATION SCHEDULE

The CDC is transitioning to a monthly COVID-19 vaccine allocation for monovalent COVID-19 vaccine. The following information outlines the vaccine allocation schedule for the remainder of 2022.
As much as possible, bivalent vaccine allocations/surveys will be incorporated into the monthly vaccine ordering schedule. If necessary, separate bivalent vaccine allocation will occur as allocations are received from the federal government.

- October 24, 2022- Bivalent only survey
- November 7, 2022
- December 5, 2022
- January 3, 2023

COVID-19 VACCINE ACCESS AND WASTAGE GUIDANCE

Iowa healthcare providers should take every opportunity to vaccinate every eligible person. As COVID-19 bivalent vaccine supply is more available, focus should shift towards ensuring vaccination of all eligible persons even at the risk of wasting unused doses. The Department supports and encourages efforts to administer vaccine to all eligible individuals. The Department recommends every effort is made to vaccinate eligible persons who present at a vaccine clinic location.

A multi-dose vial may be punctured to vaccinate one or more persons who present for vaccination. Ultimately, the remaining doses of vaccine in the vial may need to be wasted. At this point in Iowa's pandemic response, it is more critical to ensure people who want to be vaccinated with the bivalent COVID-19 vaccine are able to do so.

The CDC COVID-19 Vaccination Program Provider Agreement requires providers to report the number of doses wasted, unused, spoiled, or expired to IRIS. Healthcare providers can use the Adjusting COVID-19 Vaccine Inventory for Wastage instructions to account for wasted doses. IRIS staff are available to help manage IRIS inventory and capture vaccine wastage correctly by calling 800-374-3958.

COADMINISTRATION OF COVID-19 VACCINE WITH OTHER VACCINES

- CDC and ACIP guidance recommends routine administration of all age-appropriate doses of vaccines simultaneously as best practice for people for whom no specific contraindications exist at the time of the healthcare visit.
- Extensive experience with non-COVID 19 vaccines has demonstrated that immunogenicity and adverse event profiles are generally similar when vaccines are administered simultaneously as when they are administered alone.
- Providers should offer all vaccines for which a person is eligible at the same visit.

COADMINISTRATION OF INFLUENZA WITH COVID-19 VACCINES

- Providers should offer influenza and COVID-19 vaccines at the same visit, if eligible.
    - This includes adjuvanted or high-dose influenza vaccines; administer in separate limbs.
- With both influenza and SARS-CoV-2 circulating, getting both vaccines is important for prevention of severe disease, hospitalization, and death.
- Getting both vaccines at the same visit increases the chance a person will be up to date with their vaccinations.

COVID-19 VACCINATION CARDS

Vaccination Record Cards for many recipients of COVID-19 vaccines are now full. This is especially true for those seeking additional boosters. If a vaccination card is full, the CDC recommends completing a second card and stapling the two cards together. Individuals are encouraged to photograph both cards in case the two become separated, if possible. Both cards should be presented when vaccination history is required for travel, employment, or other purposes. Patients should bring both cards to vaccination appointments for verification of vaccination history.

V-SAFE AFTER VACCINATION HEALTH CHECKER

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after an individual receives a COVID-19 vaccination. V-safe web pages feature information on how to register and complete a v-safe health check-in (including step-by-instructions with images), troubleshooting, FAQs, and contact information for technical support.

- V-safe information sheet and poster
- V-safe after vaccination health checker website
- V-Safe Print Resources
- Vaccine Adverse Event Reporting System (VAERS)