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COVID-19 Vaccine Information Brief

September 9, 2022

IMPORTANT/NEW COVID-19 Vaccine Information

- Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States
- COCA Call - Recommendations For Bivalent Covid-19 Booster Doses In People Ages 12 Years and Older
- COVID-19 Vaccine Allocation and Ordering Cadence - **Additional Bivalent Survey the week of September 12, 2022**
- Moderna and Pfizer Bivalent COVID-19 Vaccines Authorized for Booster Dose
- COVID-19 Up To Date Vaccination Definition
- Timing Considerations for People with Current or Prior SARS-CoV-2 Infection
- Coadministration of COVID-19 Vaccines with Other Vaccines
- Coadministration of Influenza with COVID-19 Vaccines
- Moderna COVID-19 Bivalent Vaccine
- Moderna COVID-19 Vaccine Fact Sheets
- Moderna COVID-19 Bivalent Vaccine Educational Series
- Pfizer COVID-19 Bivalent Vaccine
- Pfizer-BioNTech Fact Sheets
- Pfizer COVID-19 Vaccine Medical Updates
- Novavax for Adolescents: Updated Recommendations
- Novavax Office Hours
- COVID-19 Vaccination Cards
- V-SAFE After Vaccination Health Checker

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

CDC released updated clinical guidance related to mRNA vaccines. The updated guidance can be found at Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States | CDC. Summary of the recent changes include:

- New booster recommendation for people ages 12 years and older to receive 1 bivalent mRNA booster after completion of a monovalent primary series; it replaces all prior booster recommendations for this age group

    - Recommendations for use of a bivalent Moderna booster dose in people ages 18 years and older
    - Recommendations for use of a bivalent Pfizer-BioNTech booster dose in people ages 12 years and older
- Updated guidance for observation periods following COVID-19 vaccination
- Updated guidance on COVID-19 vaccination and multisystem inflammatory syndrome (MIS) in children (MIS-C) and in adults (MIS-A)

Important Considerations

- **Appointments for monovalent Pfizer-BioNTech or Moderna boosters in people 12 years of age and older must be rescheduled for when the bivalent COVID-19 vaccines are available.**
- **Monovalent mRNA COVID-19 vaccines are no longer authorized as booster doses for individuals ages 12 years and older,** meaning monovalent booster doses can no longer be given to people ages 12 years and older, even if the person had not previously received a monovalent booster dose.
- Everyone ages 12 years and older is recommended to receive 1 age-appropriate bivalent mRNA booster dose after completion of any FDA approved or FDA-authorized monovalent primary series or last monovalent booster dose.
    - People cannot get a bivalent booster without first completing at least a primary series
    - Age-appropriate homologous and heterologous boosters allowed; there is no preference
- **Any monovalent mRNA COVID-19 vaccine booster administered to people aged ≥12 years after FDA's authorization of bivalent boosters must be reported as a vaccine administration error to VAERS. In this situation, organizations or providers may submit a single, aggregate VAERS report describing the error, how it happened, and how many people were affected. If any vaccine recipient developed an adverse event, an individual VAERS report should also be submitted.**
- At this time, no changes to schedules for children ages 6 months through 11 years.

Individuals ages 12 years and older are recommended to receive an age-appropriate bivalent mRNA booster dose at least two months after receipt of a primary series or prior monovalent booster dose. Either Pfizer-BioNTech COVID-19 bivalent vaccine (12 years and older) or Moderna COVID-19 bivalent vaccine (18 years and older) can be used based on the patient's age at time of administration.

COCA CALL - RECOMMENDATIONS FOR BIVALENT COVID-19 BOOSTER DOSES IN PEOPLE AGES 12 YEARS AND OLDER

During this COCA Call, presenters will discuss CDC's new guidance on bivalent COVID-19 booster doses for people ages 12 years and older, including those who are moderately or severely immunocompromised.
Date: September 13, 2022
Time: 1:00 - 2:00pm
Link: https://emergency.cdc.gov/coca/calls/2022/callinfo_091322.asp

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COVID-19 VACCINE ALLOCATION AND ORDERING CADENCE

The Department will continue to survey Local Public Health Agencies (LPHAs) biweekly to determine each county's desired COVID-19 vaccine allocation. The schedule below outlines survey dates for the remainder of 2022. Additional surveys may be necessary if supplemental allocations of vaccines are received from the federal government.

Surveys will continue to be sent to Local Public Health Agencies on Monday and will be due back at noon on Tuesday. The allocation will be available in IRIS on Wednesday morning and will be due by Thursday at noon. **There will be an additional survey the week of September 12, 2022 for Bivalent COVID-19 vaccine only.**

Additional Vaccine Allocation Survey - Week of September 12, 2022 (Bivalent Booster Vaccine Only)

- Allocation Survey Sent - Monday, September 12, 2022
- Allocation Survey Due Back to IDPH - Wednesday, September 14, 2022 at 12:00 pm
- Allocation Posted in IRIS - Friday, September 16, 2022
- Allocation Due Back to IDPH in IRIS - Friday, September 16, 2022 at 2:00 pm

Vaccine Allocation Survey Schedule for 2022

- Week of September 12, 2022: Bivalent Vaccine only
- Week of September 19, 2022
- Week of October 3, 2022
- Week of October 17,2022
- Week of October 31, 2022
- Week of November 14, 2022
- Week of November 28, 2022
- Week of December 12, 2022 - **This will be the final vaccine allocation survey for 2022**
- Week of January 2, 2023

MODERNA AND PFIZER BIVALENT COVID-19 VACCINES AUTHORIZED FOR BOOSTER DOSE

CDC's independent advisory committee, the Advisory Committee on Immunization Practices (ACIP) voted September 1, 2022 to recommend Moderna and Pfizer-BioNTech bivalent boosters. This follows FDA's emergency use authorization (EUA) of Moderna and Pfizer-BioNTech bivalent boosters on August 31, 2022. The bivalent vaccines contain two messenger RNA (mRNA) components of SARS-CoV-2 virus, one of the original strain of SARS-CoV-2 and the other one in common between the BA.4 and BA.5 lineages of the omicron variant of SARS-CoV-2.

- Everyone ages 12 years and older is recommended to receive 1 age-appropriate bivalent mRNA booster dose after completion of any FDA approved or FDA-authorized monovalent primary series or last monovalent booster dose.

Vaccination history	→	Next dose
Primary series	At least 2 months →	1 bivalent booster dose
Primary series + 1 booster	At least 2 months →	1 bivalent booster dose
Primary series + 2 booster	At least 2 months →	1 bivalent booster dose

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COVID-19 UP TO DATE VACCINATION DEFINITION

With the arrival of updated boosters, CDC is reframing what it means to be up to date with COVID-19 vaccination. An individual is now considered up to date with COVID-19 vaccines if they have completed a COVID-19 vaccine primary series and received the most recent booster dose recommended by CDC. Vaccine recommendations are based on age, the vaccine first received, and time since last dose. People who are moderately or severely immunocompromised have different recommendations for COVID-19 vaccines.

TIMING CONSIDERATIONS FOR PEOPLE WITH CURRENT OR PRIOR SARS-COV-2 INFECTION

- At a minimum, defer any COVID-19 vaccination, including bivalent booster vaccination, at least until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.
- In addition, people who recently had SARS-CoV-2 infection may consider delaying any COVID-19 vaccination, including bivalent booster vaccination, by 3 months from symptom onset or positive test (if infection was asymptomatic).

- Individual factors such as risk of COVID-19 severe disease, COVID-19 community level, or characteristics of the predominant SARS-CoV-2 strain should be taken into account when determining whether to delay getting a COVID-19 vaccination after infection.

COADMINISTRATION OF COVID-19 VACCINES WITH OTHER VACCINES

- Routine administration of all age-appropriate doses of vaccines simultaneously is recommended 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.

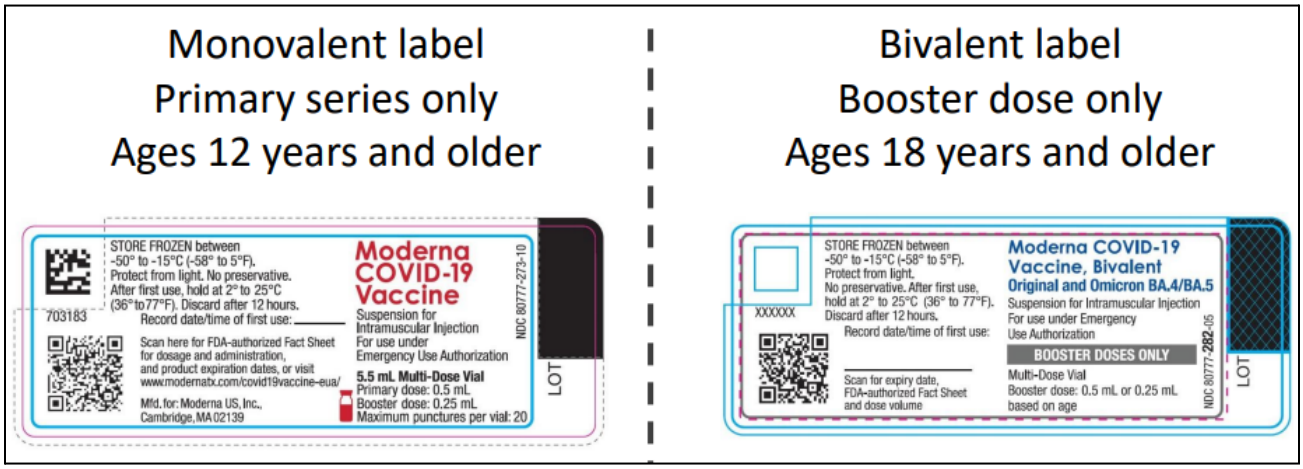
COADMINISTRATION OF INFLUENZA WITH COVID-19 VACCINES

- 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 that a person will be up to date with their vaccinations.

MODERNA COVID-19 BIVALENT VACCINE

MODERNA SHIPPING CONTAINERS

With the Fall booster campaign, a greater proportion of Moderna shipments will be using medium frozen shipping containers. **As a result, effective 9/7/22 providers will receive UPS return labels for medium frozen shipping containers, in addition to the small frozen shipping containers, so that these containers may be returned and refurbished.** Please continue to dispose of any large frozen shipping containers and packing materials. Providers are encouraged to recycle the cardboard components of the large frozen shipping containers.



	Monovalent Product	Bivalent Product
Authorized for ages	12 years and older	18 years and older
Vial cap color	Red	Dark blue
Label border color	Light blue	Gray
Dose (mRNA concentration)	100 mcg (primary dose)	50 mcg (booster dose) (25 mcg original, 25 mcg Omicron BA.4/BA.5)
Injection volume	0.5 mL	0.5 mL
Dilution required	No	No
Beyond-use date	12 hours	12 hours
Storage	Freezer (-15°C to -50°C) until expiration; Refrigerator (2°C to 8°C) up to 30 days	Freezer (-15°C to -50°C) until expiration; Refrigerator (2°C to 8°C) up to 30 days

Moderna Vaccine Storage and Handling - Same for All Vial Presentations

- **Shipping**
  - The product will ship at -20°C, like all current Moderna COVID-19 vaccines.
- **Frozen Storage**
  - Store frozen between -50°C to -15°C (-58°F to 5°F)
- **Storage after Thawing - Do not refreeze once thawed**
  - Storage at 2°C to 8°C (36°F to 46°F):
    - Vials may be stored refrigerated between 2°C to 8°C (36°F to 46°F) for up to 30 days prior to first use.
    - Once open, doses in vials should be used within 12 hours. Clinics should consider vial size (5-doses) and 12-hour time frame when scheduling children for vaccination, especially early in the program to minimize waste and optimize use of supply.

  - Storage at 8°C to 25°C (46°F to 77°F):
    - Vials may be stored between 8°C to 25°C (46°F to 77°F) for a total of 24 hours. Vials should be discarded 12 hours after the first puncture.
    - Total storage at 8°C to 25°C (46°F to 77°F) must not exceed 24 hours.

- **Preparation for Administration**
  - The Moderna COVID-19 Vaccine, Bivalent multiple-dose vial with a dark blue cap and a label with a gray border is supplied as a frozen suspension that does not contain a preservative and must be thawed prior to administration.
  - Verify that the vial of Moderna COVID-19 Vaccine, Bivalent has a dark blue cap and a label with a gray border.
  - Each multiple-dose vial with a dark blue cap and a label with a gray border contains 5 booster doses of 0.5 mL each
    - Each dose must contain 0.5 mL of vaccine
    - If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL, discard the vial and content
  - Thaw each vial before use following the instructions below.

Thaw in Refrigerator	Thaw at Room Temperature
Thaw between 2°C to 8°C (36°F to 46°F) for 2 hours. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw between 15°C to 25°C (59°F to 77°F) for 45 minutes.

Resources

- Bivalent Booster Dear HCP Letter
- Moderna COVID-19 Vaccine, Bivalent Booster Guide PDF
- Moderna COVID-19 Vaccine Presentations Guide PDF
- Moderna COVID-19 Vaccine Dosing & Administration Quick Reference PDF
- Moderna COVID-19 Vaccine Storage & Handling Quick Reference PDF
- Moderna COVID-19 EUA HCP Website
- Moderna COVID-19 Vaccine At A Glance (cdc.gov) - **NEW**

MODERNA COVID-19 VACCINE FACT SHEETS

Material	Audience	Vaccine Purpose	Vaccine Recipient Group	Last Updated
Fact Sheet	Healthcare Providers	Primary Series	6 months through 5 years of age (magenta border)	August 31, 2022
Fact Sheet	Recipients and Caregivers	Primary Series	6 months through 5 years of age (magenta border)	June 17, 2022
Fact Sheet	Healthcare Providers	Primary Series	6 years through 11 years of age (teal and purple border)	August 31, 2022
Fact Sheet	Healthcare Providers	Primary Series	12 years and older (light blue border)	August 31, 2022
Fact Sheet	Healthcare Providers	Bivalent Booster	18 years and older (gray border)	August 31, 2022
Fact Sheet	Recipients and Caregivers	Primary Series and Bivalent Booster	12 years and older (primary series) and 18 years and older (booster) (black border)	August 31, 2022

MODERNA COVID-19 BIVALENT VACCINE EDUCATIONAL SERIES

In addition to the daily Q&A Office Hours, Moderna is providing educational webinars every Wednesday in September to detail the Moderna COVID-19 Bivalent Vaccine Booster. The information will include:

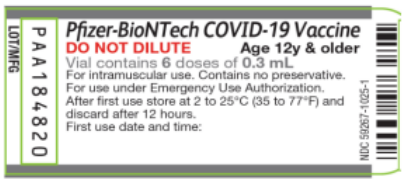
- Data supporting EUA – safety and efficacy
- ACIP Recommendations
- Storage and Handling

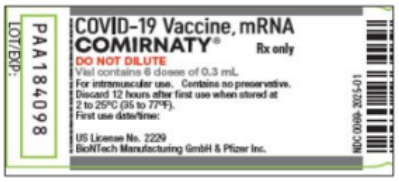
For details, see dates and links for upcoming training sessions.

PFIZER COVID-19 BIVALENT VACCINE

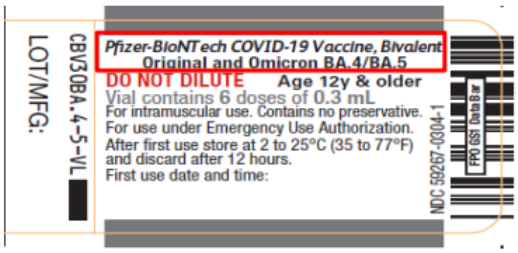
The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) for active immunization to prevent COVID-19 in individuals 12 years of age and older.

Monovalent label
Primary series only
Ages 12 years and older





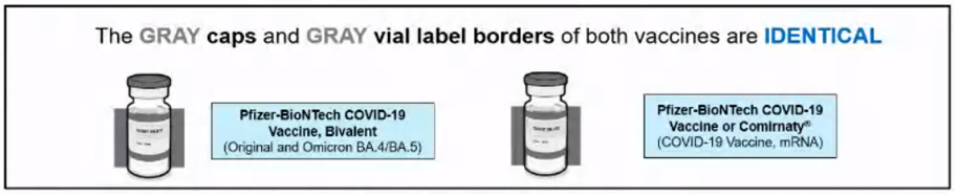
Bivalent label
Booster dose only
Ages 12 years and older



	Monovalent Product	Bivalent Product
Authorized for ages	12 years and older	12 years and older
Authorized for doses	Primary series doses	Booster doses
Vial cap color	Gray	Gray
Dose (mRNA concentration)	30 mcg	30 mcg (15 mcg original, 15 mcg Omicron BA.4/BA.5)
Vaccine composition	Monovalent—Original	Bivalent—Original and Omicron BA.4/BA.5
Injection volume	0.3 mL	0.3 mL
Dilution required	No	No
Beyond-use date	12 hours after puncture	12 hours after puncture
Storage	Ultra-cold freezer until expiration; Refrigerator (2°C-8°C) up to 10 weeks	Ultra-cold freezer until expiration; Refrigerator (2°C-8°C) up to 10 weeks

Important Considerations

The Pfizer COVID-19 Vaccine, Bivalent will be supplied in a multi-dose vial with a **GRAY** cap and **GRAY** vial label border.



- The Pfizer COVID-19, Bivalent will be used as the BOOSTER DOSE in individuals 12 years and older
- COMIRNATY and Pfizer COVID-19 EUA (Tris) vaccine will continue to be used for the PRIMARY SERIES in individuals 12 years and older.
- It is important to differentiate between the two vaccine products to ensure the appropriate vaccine is being administered.

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 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. Clinics should consider vial size (6-doses) and 12-hour time frame when scheduling children for vaccination, especially early in the program to minimize waste and optimize use of supply.

PFIZER-BIONTECH FACT SHEETS

Material	Audience	Vaccine Purpose	Vaccine Recipient Group	Last Updated
Fact Sheet	Healthcare Providers	Primary Series	6 months through 4 years, maroon cap (must dilute)	August 31, 2022
Fact Sheet	Healthcare Providers	Primary Series and Booster	5 years through 11 years of age, orange cap (must dilute)	August 31, 2022
Fact Sheet	Healthcare Providers	Primary Series	12 years of age and older, purple cap (PBS formulation, must dilute)	August 31, 2022
Fact Sheet	Healthcare Providers	Primary Series	12 years of age and older, gray cap (Tris formulation, no dilution)	August 31, 2022
Fact Sheet	Healthcare Providers	Bivalent Booster	12 years of age and older, gray border	August 31, 2022
Fact Sheet	Recipients and Caregivers	Primary Series and Bivalent Booster	12 years of age and older, purple and gray border	August 31, 2022

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.

NOVAVAX FOR ADOLESCENTS: UPDATED RECOMMENDATIONS

On August 22, 2022, CDC Director Dr. Walensky, signed a decision memo that Novavax's COVID-19 vaccine be used as another primary series option for adolescents ages 12 through 17 years. This recommendation follows FDA's emergency use authorization of Novavax for this age group. Novavax's COVID-19 vaccine, which is available now, is an important tool in the pandemic and provides a more familiar type of COVID-19 vaccine technology for adolescents. CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines has been updated with new guidance regarding adolescents and Novavax COVID-19 vaccine.

Available Novavax Resources

- Novavax COVID-19 Vaccine - Information on storage, handling, and administration
- Novavax COVID-19, Adjuvanted Vaccine: Overview and Safety - General information, including vaccine ingredients, safety data, and details on how well the vaccine works
- Novavax Fact Sheet for Healthcare Providers Administering Vaccine
- Novavax Fact Sheet for Recipients and Caregivers

NOVAVAX OFFICE HOURS

Novavax is offering weekly office hours to address questions about the currently recommended COVID-19 vaccine. Please use this link to register: https://novav.ax/officehours

COVID-19 VACCINATION CARDS

Vaccination Record Cards for many recipients of COVID-19 vaccines are now full. This is especially true for those over 50 years of age or immunocompromised individuals 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: Available in English, Spanish, Korean, Vietnamese, and Simplified Chinese
- V-safe after vaccination health checker website
- V-Safe Print Resources
- Vaccine Adverse Event Reporting System (VAERS)