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COVID-19 Vaccine Information Brief

September 2, 2022

IMPORTANT/NEW COVID-19 Vaccine Information

- COVID-19 Vaccine Allocation and Ordering Cadence
- Moderna and Pfizer-BioNTech Bivalent COVID-19 Vaccines Authorized for Booster Dose
- COVID-19 Vaccination Schedule for People who are NOT Moderately or Severely Immunocompromised
- COVID-19 Vaccination Schedule for People who ARE Moderately or Severely Immunocompromised
- 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
- COVID-19 Vaccination Cards
- V-SAFE After Vaccination Health Checker

Effective Immediately

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.

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. For children five through 11 years, the previous ACIP recommendation remains unchanged and a monovalent booster continues to be recommended.

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 will be utilized for the vaccine survey the week of September 5, 2022. **The survey on Tuesday, September 6, 2022, will NOT include COVID-19 Bivalent booster vaccine doses. The Department has not received additional allocations of bivalent booster vaccine from the federal government. The next opportunity to request bivalent booster vaccine is anticipated to be September 19, 2022.**

Vaccine Allocation Survey - Week of September 5, 2022

- IDPH Closed for Labor Day - Monday, September 5, 2022
- Allocation Survey Sent - Tuesday, September 6, 2022
- Allocation Survey Due Back to IDPH - Thursday, September 8, 2022 at 12:00 pm
- Allocation Posted in IRIS - Friday, September 9, 2022
- Allocation Due Back to IDPH in IRIS - Friday, September 9, 2022 at 2:00 pm

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Moderna and Pfizer-BioNTech 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.

ACIP Recommends Bivalent Boosters for the following:

- Moderna COVID-19 Vaccine, Bivalent authorized for use in people ages 18 years and older.
- Pfizer-BioNTech COVID-19 Vaccine, Bivalent authorized for use in people ages 12 years and older.
- Authorized as single booster dose administered at least 2 months after either:
    - Completion of primary vaccination with any authorized or approved monovalent COVID-19 vaccine, or
    - Receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine

Important Considerations

- 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
- At this time, no changes to schedules for children ages 6 months through 11 years.
- The bivalent booster recommendation replaces previous booster recommendations for people ages 12 years and older.
- If patients are eligible, a bivalent booster should NOT be denied based on the total number of doses previously received.

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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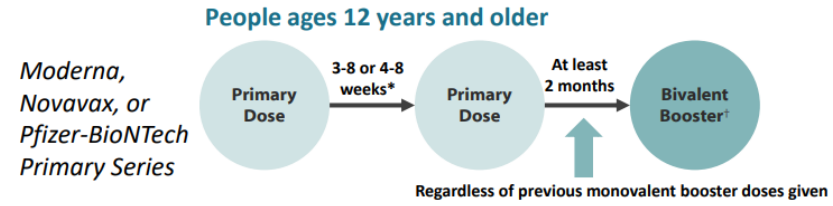
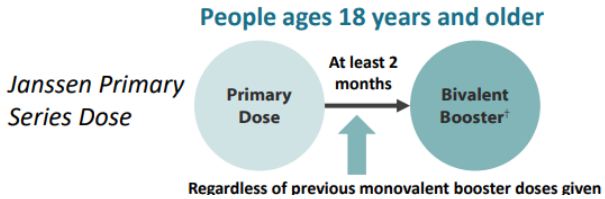
COVID-19 Vaccination Schedule for People who are NOT Moderately or Severely Immunocompromised





*3-8 interval for Novavax and Pfizer-BioNTech; 4-8 interval for Moderna

† The bivalent booster dose is administered at least 2 months after completion of the primary series.

For people who previously received a monovalent booster dose(s), the bivalent booster dose is administered at least 2 months after the last monovalent booster dose. The bivalent booster should be age appropriate; Pfizer-BioNTech is authorized for people ages 12 years and older and Moderna is authorized for people ages 18 years and older

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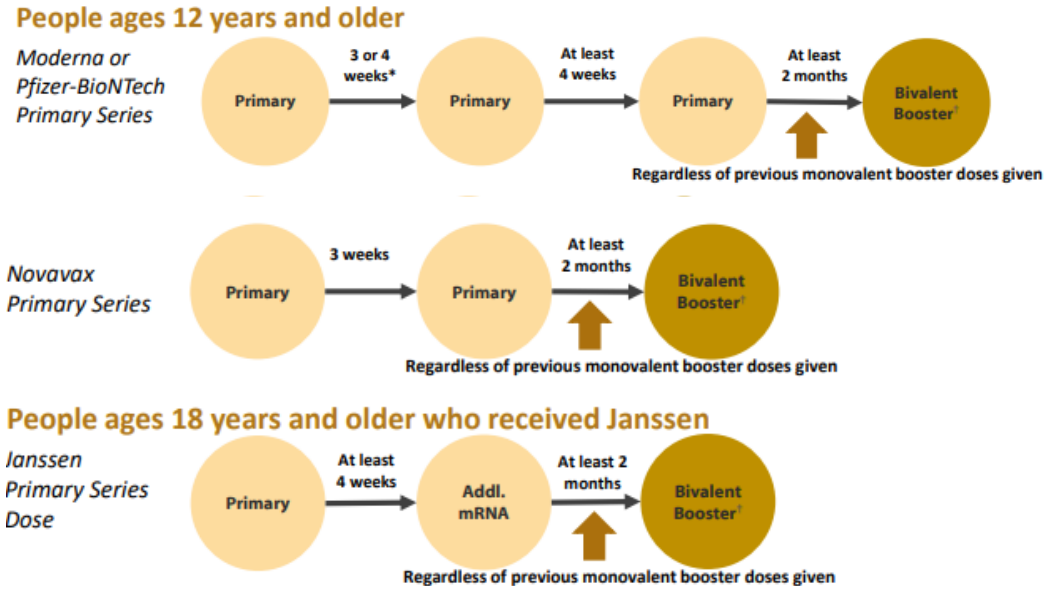
COVID-19 Vaccination Schedule for People who ARE Moderately or Severely Immunocompromised



*3-8 interval for Novavax and Pfizer-BioNTech; 4-8 interval for Moderna

† The bivalent booster dose is administered at least 2 months after completion of the primary series.

For people who previously received a monovalent booster dose(s), the bivalent booster dose is administered at least 2 months after the last monovalent booster dose. The bivalent booster should be age appropriate; Pfizer-BioNTech is authorized for people ages 12 years and older and Moderna is authorized for people ages 18 years and older.

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

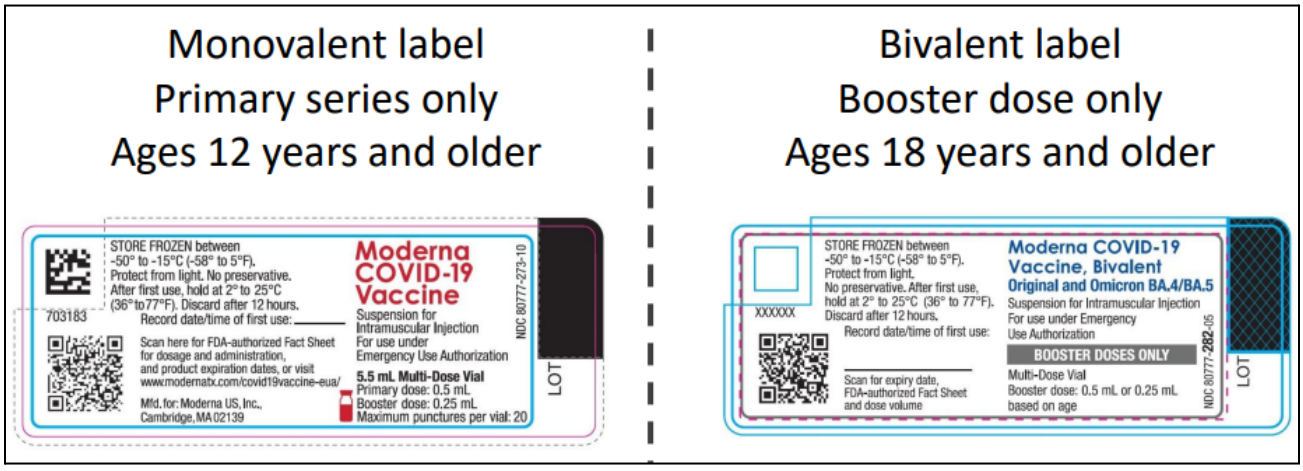
- Routine administration of all age-appropriate doses of vaccines simultaneously is recommended as best practice for people for whom no specific contraindications exist at the time of the healthcare visit.
- Extensive experience with non-COVID 19 vaccines has demonstrated that immunogenicity and adverse 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

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), for active immunization to prevent COVID-19 in individuals 18 years of age and older.



	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 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

Moderna is offering training sessions to address questions about the currently recommended COVID-19 vaccine, bivalent. The COVID-19 vaccine medical updates and site training webinars aim to educate providers and immunization staff on the proper use of the Moderna COVID-19 Vaccines. For details, see dates and links for upcoming training sessions.

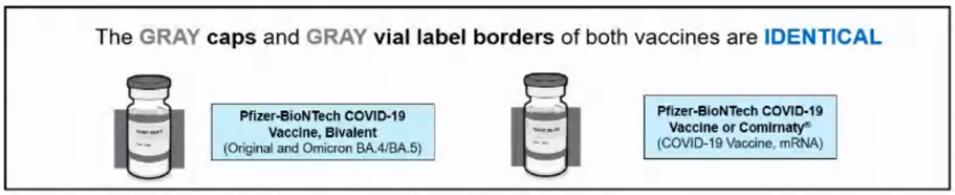
PFIZER COVID-19 BIVALENT VACCINE

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 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 (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.

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

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)