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Health Alert

Please distribute to all appropriate staff

To: Glenn County Clinicians and Health Care Providers
From: Glenn County Public Health
Date: September 13, 2022

RE: COVID-19 Bivalent Booster Vaccine, Eligibility, Timing and Ordering

Key Messages

- [On September 3, 2022, The Western States Scientific Review Workgroup voted to recommend the use of the Moderna and Pfizer Bivalent Boosters.](#) This was in agreement with the federal Advisory Committee on Immunization Practices' (ACIP) recommendations.
- 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 of the BA.4/BA.5 lineages of the omicron variant of SARS-CoV-2.
- People ages 12 years and older are recommended to receive 1 age-appropriate bivalent mRNA booster dose at least 2 months after completion of any FDA-approved or FDA-authorized monovalent primary series or previously received monovalent booster dose(s).
- The 15-minutes post-vaccination observation period previously recommended by the CDC is now **optional**.
- The new bivalent booster recommendation replaces all prior booster recommendations. Monovalent mRNA vaccines are no longer authorized as a booster dose for people ages 12 and older.
- For enrolled Glenn County myCAVax providers, ordering is available. There is a limited quantity available but allocations are expected to increase into next week.

Changes in Eligibility & Recommendations

- **Moderna Bivalent Booster** is authorized and recommended for those **18 years** and older at least 2 months after completion of the primary series or the most recent booster dose of an FDA approved or authorized monovalent (original) COVID-19 vaccine.
- **Pfizer Bivalent Booster** is authorized and recommended for those **12 years** and older at least 2 months after completion of the primary series or the most recent booster dose of an FDA approved or authorized monovalent (original) COVID-19 vaccine.
- People cannot get a bivalent booster without first completing at least a primary series.
- The bivalent booster does not need to be from the same manufacturer as the patient's primary series or previous boosters. Age-appropriate homologous and heterologous boosters allowed.
- The bivalent booster recommendation **replaces** previous booster recommendations for people 12 years and older.

Deauthorization of Monovalent Boosters

- [The FDA deauthorized monovalent mRNA boosters for Pfizer 12+ and Moderna 18+.](#)
- Children ages 5-11 years are recommended to continue receiving 1 monovalent mRNA booster if eligible.
- Only monovalent vaccines are approved or authorized for primary series doses.

Vaccine Ordering

For enrolled Glenn County myCAVax providers, ordering will be available for both Pfizer and Moderna bivalent vaccines. CDPH has been notified by CDC that there will be a delay in receiving additional allocations of the Moderna Bivalent Booster vaccine. Glenn County Public Health has a limited quantity on hand for emergency distributions, but allocations are expected to increase in the next few weeks. Please contact Amanda Pitts at 530-934-6588 or apitts@countyofglenn.net for questions about orders.

- The current minimum order size for Moderna 18+ Bivalent Booster is 100 doses and the Pfizer 12+ Bivalent Booster is 300 doses.
- Third-Party Redistributor small orders for Pfizer are anticipated to be available in mCAVax starting September 19th.

Vaccine Storage and Handling

Colors and labeling of the Pfizer/Moderna Bivalent Boosters are similar to current products, gray and blue, increasing opportunity for errors. Please ensure staff review the vaccine details and are trained to properly identify the different vaccines.

Pfizer Bivalent Booster

- Ensure label states: Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)
- Gray cap and a label with a gray border
- 6 doses per vial
- Does NOT require diluent
- Volume per dose: 0.3 mL; dose: 30 mcg

- Storage: Refrigerator (2°C to 8°C) for up to 10 weeks; may be stored in an ultra-low temperature freezer (-90°C to -60°C) until expiration. Minimize exposure to light. Do not store frozen.
- If not previously thawed at 2°C to 8°C, allow vaccine to thaw at room temperature (up to 25°C) for 30 minutes before use.
- May be stored between 8°C to 25°C up to 12 hours prior to the first puncture.
- After the first puncture, vial may be stored between 2°C to 25°C for up to 12 hours.
- Vials should be discarded 12 hours after first puncture.

Moderna Bivalent Booster

- Ensure label states: Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)
- Blue cap with a label with a gray border
- 5 doses per vial
- Does NOT require diluent
- Volume per dose: 0.5 mL; dose: 50 mcg
- Storage: Freezer (-50°C to -15°C) until expiration; refrigerator (2°C to 8°C) for up to 30 days. Minimize exposure to light.
- Thaw between 2°C to 8°C for 2 hours. Let each vial stand at room temperature for 15 minutes before administering. Alternatively, thaw between 15°C to 25°C for 45 minutes.
- Vials may be stored between 8°C to 25°C for a total of 24 hours. Vials should be discarded 12 hours after the first puncture. Total storage at 8°C to 25°C must not exceed 24 hours.

For enrolled Glenn County myCAVax Providers

- **Required Product Training for Bivalent Boosters**
 - To ensure staff are proficient with new bivalent vaccines, CDC requires that anyone storing, handling, administering, or managing bivalent vaccines complete the required product training.
 - CDPH's Required Training Page: [COVID-19 Vaccine Training \(ca.gov\)](#)
- **Reporting inventory to VaccineFinder**
 - VaccineFinder has been updated with the new **bivalent booster vaccines**. Before receiving initial vaccine shipments, add bivalent boosters to enable inventory reporting to VaccineFinder.
 - Reminder: Report new bivalent booster dose inventory upon receipt.
- [CDPH COVID-19 Vaccine Product Guide](#)

Vaccine Administration

- **Pfizer Bivalent Booster Administration**
 - Thaw vial prior to use.
 - Before use, mix by inverting vaccine vial gently 10 times. Do not shake.
 - After mixing, the vaccine should appear as a white to off-white suspension with no visible particles.

- Do not administer if vaccine is discolored or contains particulate matter.
- After withdrawing a single 0.3 mL dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent, administer immediately through intramuscular injection.
- [See Pfizer-BioNTech COVID-19 Vaccine, Bivalent EUA for more information](#)
- **Moderna Bivalent Booster Administration**
 - Thaw vial prior to use.
 - Swirl vial gently after thawing. Do not shake.
 - The vaccine will be a white to off-white suspension. It may contain white or translucent product-related particulates.
 - Do not administer if vaccine is discolored or contains other particulate matter.
 - After withdrawing a single 0.5 mL dose Moderna COVID-19 Vaccine, Bivalent administer through intramuscular injection.
 - [See Moderna COVID-19 Vaccine, Bivalent EUA for more information](#)

Any homologous or heterologous age-appropriate mRNA vaccine can be used if a booster dose is FDA-authorized for use in a specified population. The bivalent booster does not need to be from the same manufacturer as the patient’s primary series or previous boosters.

Changes to Observation Period

The 15-minutes post-vaccination observation period previously recommended by the CDC is now **optional**.

Providers should consider an observation period for:

- 15 minutes for adolescents (risk of syncope)
- 30 minutes for those with allergy-related contraindications, allergic reactions to a previous dose of COVID-19 vaccine or anyphylaxis after a non COVID-19 vaccine

Coadministration with Influenza Vaccine

It is advised to offer influenza and COVID-19 vaccines at the same visit, if patient is eligible. Getting both vaccines is important for prevention of severe disease, hospitalization, and death and increases that chance that a person will be up to date on their vaccinations

COVID-19 Vaccine for Uninsured

Reminder: COVID-19 vaccination providers cannot charge a patient for:

- a COVID-19 vaccine
- administration fees
- copays
- coinsurance

Providers cannot deny vaccination to anyone who doesn’t have health insurance or coverage. These patients should be enrolled into [the COVID-19 uninsured group \(UIG\) by a qualified provider](#). Providers and pharmacies can consider referring these patients to qualified provider offices to be enrolled in the Medi-Cal presumptive eligibility program by calling the Medi-Nurse Line: 1-877-409-9052 for assistance in locating a Qualified provider.

EUA Fact Sheets

- EUA Provider Factsheet: [Pfizer-BioNTech COVID-19 Vaccine, Bivalent](#)
- EUA Recipient/Caregiver Factsheet: [Pfizer-BioNTech COVID-19 Vaccine, Bivalent](#)
- EUA Provider Factsheet: [Moderna COVID-19 Vaccine, Bivalent](#)
- EUA Recipient/Caregiver Factsheet: [Moderna COVID-19 Vaccine, Bivalent](#)

Questions

- Contact Amanda Pitts at (530) 934-6588 or email apitts@countyofglenn.net

Additional Resources

- [Updated Interim Clinical Considerations for the Use of COVID-19 Vaccine](#)
- [CDC Recommends the First Updated COVID-19 Booster](#)
- [CDPH Joint Statement on Authorization of Updated Moderna and Pfizer BioNTech Boosters](#)