COVID-19 Vaccine Information Brief

IMPORTANT/NEW COVID-19 Vaccine Information

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August 19, 2022

OVERVIEW - COVID-19 Bivalent Booster Dose Vaccine

On June 28, 2022, FDA's independent experts on the Vaccines and Related Biological Products Advisory Committee (VRBPAC) met to publicly discuss whether a change to the current vaccine strain composition of COVID-19 vaccines for booster doses is necessary for the 2022 fall and winter seasons. The advisory committee voted in favor of including a SARS-CoV-2 Omicron component in COVID-19 vaccines that would be used for boosters in the United States beginning in fall 2022. FDA subsequently clarified intent to authorize bivalent boosters including a BA.4/5 valence specifically.

Pfizer-BioNTech and Moderna have both developed bivalent omicron-adapted mRNA COVID-19 vaccines targeting BA.4 and BA.5 Omicron subvariants. **It is anticipated the bivalent COVID-19 vaccines will only be authorized as a single dose in people who have completed a primary vaccination series** but would not vary by number or type of prior booster doses received. Initial bivalent COVID-19 vaccine booster doses will include:

- Pfizer for individuals 12 years of age and older
- Moderna for individuals 18 years of age and older

The US Government (USG) has arranged to purchase Pfizer and Moderna bivalent booster doses, provided the vaccines are authorized by FDA and recommended by CDC. The USG has purchased enough booster doses to ensure a robust and complete national vaccination campaign. To prepare for

the potential Emergency Use Authorization (EUA) of a Moderna and Pfizer omicron-adapted mRNA COVID-19 vaccine, the Centers for Disease Control (CDC) and Prevention will allow for vaccine pre-ordering. This will ensure the timely distribution and administration of both products pending FDA approval and ACIP recommendations are received. Both the Moderna and Pfizer bivalent vaccines will have the same storage and handling parameters as the original vaccine products.

Vaccinations for Pfizer-BioNTech and Moderna bivalent booster doses cannot begin until after FDA EUA approval and ACIP recommendations are signed by the CDC Director.

BIVALENT OMICRON-ADAPTED mRNA COVID-19 VACCINE PRE-ORDERING SURVEY

- An additional Vaccine Allocation Survey for ONLY Pfizer and Moderna bivalent COVID-19 vaccines was sent Wednesday, August 17, 2022.
- Each county in Iowa was allocated Pfizer and Moderina vaccine doses in the initial roll out.
- During this roll out, minimum order quantities will be:
    - Moderna vaccine orders must be in 100 dose increments
    - Pfizer vaccine orders must be in 300 dose increments
- LPHAs will determine COVID-19 vaccination providers to receive vaccine to administer to the bivalent booster doses.
- Based on the total amount of vaccine requested, it may be necessary to reduce LPHA requests for vaccines.
- After this initial roll out, Iowa will receive ongoing vaccine allocations to support bivalent booster vaccination.

Vaccine Orders/Distribution

- Doses that are pre-ordered will begin being processed for delivery following EUA. Expected delivery schedules will be dependent on the actual EUA date and whether it falls before or after Labor Day.

PFIZER BIVALENT COVID-19 VACCINE FORMULATION

- The Pfizer-BioNTech bivalent omicron-adapted mRNA COVID-19 vaccine for individuals 12 years of age and older will be a new product configuration with new packaging and a new national drug code (NDC).
- The packaging configuration will be 6-dose vials in cartons of 10 vials each (60 doses total) with a minimum order quantity of 300.
- Ultra-cold freezer storage (-90°C to -60°C) until expiry.
- NO FREEZER STORAGE.
- Refrigerate (2°C to 8°C) up to 10 weeks without puncturing.
- Once open, doses in vials should be used within 12 hours.

MODERNA BIVALENT VACCINE FORMULATION

- The Moderna bivalent omicron-adapted mRNA COVID-19 vaccine for individuals 18 years of age and older will be a new product configuration with new packaging and a new national drug code (NDC).
- The packaging configuration will be 5-dose vials in cartons of 10 vials each (50 doses total) with a minimum order quantity of 100.
- **NO ULTRA-COLD FREEZER STORAGE.**
- Freezer storage (-25°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.

IMPORTANT: ADULT COVID-19 VACCINE INVENTORY CONSIDERATIONS

Current inventory for Pfizer Adult - Gray cap (12 yrs of age and older) and Moderna Adult - Red cap (12 yrs of age and older) monovalent mRNA vaccines will ONLY be needed for the primary series in individuals who have no history of COVID-19 vaccination. Limited amounts of these products will be available for future orders.

The regular vaccine allocation survey on August 22, 2022 will include a limited amount of Pfizer Adult - Gray cap (12 yrs of age and older) and Moderna Adult - Red cap (12 yrs of age and older) monovalent mRNA vaccines to order.

- As much as possible, all healthcare providers should plan to use existing inventory prior to requesting additional doses of these products. LPHAs and healthcare providers should collaborate to redistribute COVID-19 vaccine inventory to prevent vaccine wastage.
- Limited quantities of these vaccines (Pfizer Adult - Gray cap (12 yrs of age and older) and Moderna Adult - Red cap (12 yrs of age and older) will be available to order moving forward. LPHAs must consider this when completing all future COVID-19 Vaccine Allocation Surveys.

Moderna Adult/Adolescent COVID-19 - Spikevax Vaccine Orders

The Moderna COVID-19 vaccine for adults, the Biologics License Application [BLA] labeled product known as Spikevax, will be used to fill a portion of all Moderna adult vaccine orders beginning the week of August 22, 2022.

- The Department has received a portion of the Moderna adult/adolescent COVID-19 threshold as Spikevax vaccine.
- The minimum order quantity of the Moderna vaccine will be 100 doses, consistent with the minimum order size of the EUA labeled product.
- The availability and amount of Spikevax vaccine will be limited.

The Department will send local public health agencies (LPHAs) the Vaccine Allocation Survey on Monday, August 22, 2022. The Department will fulfill as much of the requested Moderna adult/adolescent vaccine with Spikevax as possible. Vaccine requests above the established CDC threshold for Spikevax will be fulfilled with the EUA labeled product. LPHAs will receive the allocation in IRIS on Wednesday, August 24 and need to complete the allocation by 12:00 PM Thursday, August 25.

The FDA-approved Spikevax® (COVID-19 Vaccine, mRNA) and the Moderna COVID-19 Vaccine authorized for Emergency Use Authorization (EUA) for individuals 12 years of age and older, when prepared according to respective instructions for use, can be used interchangeably.

Moderna COVID-19 Adult Vaccine – Spikevax

The Moderna COVID-19 Vaccine was granted BLA status from the FDA and will be marketed as Spikevax for the prevention of COVID-19 in individuals 18 years of age and older. Spikevax has the same formulation as the EUA Moderna COVID-19 Vaccine and is administered as a primary series of two doses, one month apart.

- Spikevax can be used interchangeably with the EUA Moderna COVID-19 Vaccine to provide the COVID-19 vaccination series.

- Moderna COVID-19 Vaccine remains available under EUA as a two-dose primary series for individuals 12 years through 17 years of age.

Moderna is also authorized for use as a heterologous (or "mix and match") single booster dose for individuals 18 years of age and older following completion of primary vaccination with a different available COVID-19 vaccine. For example, Pfizer-BioNTech COVID-19 Vaccine and Janssen COVID-19 vaccine recipients 18 years of age and older may receive a single booster dose of the Moderna COVID-19 Vaccine.

The FDA-approved Spikevax® (COVID-19 Vaccine, mRNA) and the Moderna COVID-19 Vaccine authorized for Emergency Use Authorization (EUA) for individuals 12 years of age and older, when prepared according to respective instructions for use, can be used interchangeably.

SPIKEVAX KEY SUMMARY AND ACTION ITEMS

- It is anticipated Spikevax will be used to fill a portion of all Moderna adult vaccine orders beginning the week of August 22, 2022.
- The vaccine survey will ask LPHAs to request how many doses of adult/adolescent Moderna COVID-19 vaccine are needed for the weeks of August 22 and August 29.
- IDPH will then determine each county's allocation of Spikevax. County requests for Spikevax may be reduced and or substituted with Moderna EUA product based upon product availability.
- LPHAs will receive the allocation in IRIS on Wednesday, August 24 and need to complete the allocation by 12:00 PM Thursday, August 25.
- LPHAs will determine COVID-19 vaccination providers to receive Spikevax and Moderna EUA vaccine as allocated.
- The EUA Moderna vaccine and BLA (Spikevax) products have different labels and NDCs; however, the vaccines are identical and interchangeable, as determined by the FDA. The storage and handling guidelines are the same for both products.

Resources

- Package Insert
- Patient Package Insert
- Letter of Authorization
- Fact Sheet For Healthcare Providers Administering Vaccine
- Fact Sheet for Recipients and Caregivers