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## COVID-19 Vaccine Information Brief

November 28, 2022

### IMPORTANT/NEW COVID-19 Vaccine Information

- Vaccine Allocation Survey Tuesday, November 29, 2022
  - PFIZER COVID-19 Bivalent Booster Vaccine Pre-Order for Children 6 months - 4 years
  - MODERNA COVID-19 Bivalent Booster Vaccine Pre-Order for Children 6 months - 5 years
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### Key Summary and Actions Items

- Pfizer-BioNTech and Moderna have both developed bivalent omicron-adapted mRNA COVID-19 vaccines targeting BA.4 and BA.5 Omicron subvariants for additional age indications. CDC anticipates a recommendation for bivalent COVID-19 vaccine for additional pediatric age groups in early to mid-December.
- Bivalent COVID-19 vaccine products expected to be under consideration in December include:
  - Bivalent Pfizer-BioNTech vaccine for children aged 6 months through 4 years
  - Bivalent Moderna vaccine for children aged 6 months through 5 years
- At this time, it is expected children in these age groups will be required to receive two doses of monovalent COVID-19 vaccine before receiving a dose of bivalent COVID-19 vaccine.
- Moderna's bivalent COVID-19 vaccine is expected to be authorized as a booster, and Pfizer-BioNTech's is expected to be authorized as part of the pediatric primary series, mix-and-match use is NOT expected to be authorized.
- To prepare for the potential Emergency Use Authorization (EUA) of Pfizer omicron-adapted mRNA COVID-19 vaccine for expanded age groups, the Centers for Disease Control (CDC) and Prevention will allow for pre-ordering for the Bivalent Pfizer-BioNTech vaccine for children aged 6 months through 4 years and Bivalent Moderna vaccine for children aged 6 months through 5 years.
- An additional Vaccine Allocation Survey for ONLY Bivalent Pfizer-BioNTech vaccine for children aged 6 months through 4 years and Bivalent Moderna vaccine for children aged 6 months through 5 years will be sent Tuesday November 29, 2022.
- Based on Vaccine Allocation Survey results, an allocation of Pfizer and Moderna Pediatric bivalent booster vaccines will be available in IRIS on Thursday, December 1, 2022.
  - LPHAs will determine COVID-19 vaccination providers to receive and administer this vaccine.
- Not all COVID-19 vaccination sites may receive bivalent pediatric vaccines.
  - Providers most likely to vaccinate pediatric populations should be prioritized for initial dose availability, with provider types varying by county.
- Providers are strongly encouraged to adopt strategies to minimize unnecessary wastage;

however, providers should not miss any opportunities to vaccinate every eligible person who requests a vaccination, even if it means puncturing a multidose vial to administer a vaccine without having enough people available to receive each dose in the vial.

- **Bivalent COVID-19 vaccine booster doses WILL NOT BE SHIPPED until the FDA has issued EUA approval.**

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### **COVID-19 Bivalent Booster Vaccine Allocation Survey**

The Centers for Disease Control (CDC) and Prevention will allow for vaccine pre-ordering for the Bivalent Pfizer-BioNTech vaccine for children aged 6 months through 4 years and Bivalent Moderna vaccine for children aged 6 months through 5 years.

On Tuesday, November 29, 2022, a Vaccine Allocation Survey for **ONLY** the Bivalent Pfizer-BioNTech vaccine for children aged 6 months through 4 years and Bivalent Moderna vaccine for children aged 6 months through 5 years will be sent to LPHAs.

- The Department has received a limited allocation of these bivalent booster vaccines from the federal government for pre-booking and county requests may be reduced based upon vaccine availability.
- Based on Vaccine Allocation Survey results, an allocation of the Bivalent Pfizer-BioNTech vaccine for children aged 6 months through 4 years and Bivalent Moderna vaccine for children aged 6 months through 5 years will be available in IRIS on Thursday, December 1, 2022.
- LPHAs should consider supplying pediatric vaccine to appropriate provider types in their county if enrolled as an Iowa COVID-19 vaccine provider.
- Bivalent COVID-19 vaccine booster doses WILL NOT BE SHIPPED until the FDA has issued EUA approval.

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### **PFIZER COVID-19 BIVALENT VACCINE - PEDIATRIC AGES 6 MONTHS THROUGH 4 YEARS**

#### **Important Considerations**

It is expected children aged 6 months through 4 years who received two doses of monovalent **Pfizer-BioNTech COVID-19 vaccine** will be authorized to receive a third dose of bivalent vaccine to **complete their primary series**. Children who received one dose of monovalent Pfizer-BioNTech COVID-19 vaccine would need to receive a second dose of monovalent Pfizer-BioNTech COVID-19 vaccine before receiving a dose of bivalent Pfizer-BioNTech COVID-19 vaccine. **It is expected that children aged 6 months through 4 years who received three doses of monovalent Pfizer-BioNTech COVID-19 vaccine to complete their primary series will not be authorized to receive a booster dose of bivalent COVID-19 vaccine at this time.**

Expected characteristics of Pfizer-BioNTech bivalent COVID-19 vaccine for children aged 6 months through 4 years:

- Ultra-cold freezer storage (-90°C to -60°C) until expiry
- NO FREEZER STORAGE (-25°C to -15°C)
- Refrigerate (2°C to 8°C) up to 10 weeks without puncturing
- Requires 2.2 mL diluent per vial
- Packaged in 10-dose vials in cartons of 10 vials each (100 doses total)
- Dose 3mcg/0.2mL
- Minimum order quantity of 100 doses
- Maroon cap identical to the monovalent Pfizer-BioNTech product for this age group
- New label identifying the product as a bivalent vaccine (i.e., Original and Omicron BA.4/BA.5)
- **Once punctured, each vial must be used within 12 hours**

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### MODERNA COVID-19 BIVALENT VACCINE - PEDIATRIC AGES 6 MONTHS THROUGH 5 YEARS

#### Important Considerations

It is expected children aged 6 months through 5 years who received one dose of monovalent **Moderna COVID-19 vaccine** will need to receive a second dose of monovalent Moderna COVID-19 vaccine to complete their primary series before receiving a bivalent Moderna COVID-19 vaccine dose as a booster. (Children 5 years of age who completed the monovalent Moderna primary series are currently authorized to receive a bivalent PfizerBioNTech booster.)

Expected characteristics of Moderna bivalent COVID-19 vaccine for children aged 6 months through 5 years:

- NO ULTRA-COLD FREEZER STORAGE (-90°C to -60°C)
  - Freezer storage (-50°C to -15°C) until expiry
  - Refrigerate (2°C to 8°C) up to 30 days without puncturing
  - Does not require diluent
  - **Packaged in 2-dose vials in cartons of 10 vials each (20 doses total)**
  - Dose 10 mcg/0.2mL
  - Minimum order quantity of 100 doses
  - Vial with dark pink cap and yellow border on the label
  - **Once punctured, each vial must be used within 8 hours**
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