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Health Advisory

Monovalent mRNA vaccines no longer authorized; updated schedule

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SUMMARY POINTS

- Pfizer BioNTech and Moderna monovalent vaccines are no longer approved for use by the FDA, but Novavax monovalent vaccine remains authorized for use under an EUA.
- It is recommended that all individuals aged 6 months or older receive an updated (bivalent) vaccine if they have not yet received one independent of number of monovalent doses.
- Unvaccinated children under 6 should complete a bivalent series, but unvaccinated individuals aged 6 years or older may receive just one bivalent vaccine to be considered up to date.
- Immunocompromised individuals and those aged 65 and older may be eligible for an additional updated vaccine dose.

Background

In order to simplify vaccine recommendations for the public and reduce vaccination errors and product types, the FDA and the CDC decided jointly to remove the authorization for monovalent mRNA products while retaining the authorization for bivalent mRNA products. Bivalent vaccination has proven safe and effective in significantly reducing severe outcomes from COVID-19 disease. Furthermore, the genetic composition of COVID-19 strains circulating in the U.S. has converged on the Omicron variant for over 18 months, making the monovalent vaccine less relevant.

Monovalent mRNA vaccine should be disposed of immediately. If a monovalent dose was or is given after April 18th, 2023, a VAERS report must be completed. Novavax will retain its EUA for the monovalent vaccine for the time being but is in discussion with the FDA in regard to bivalent vaccine manufacturing.

One bivalent dose is considered sufficient for the majority of the population as nationwide combined vaccination and infection-induced nationwide seroprevalence is nearly 95%.

Bivalent vaccine recommendations

Ages 6 and up
All individuals should receive a bivalent vaccine if they have not yet received one, including those with a history of Novavax or Janssen vaccination. Those aged 6 years and older who have received one bivalent dose are considered up to date, including those eligible for more than one bivalent dose.

Age 5

- Unvaccinated children who are 5 years old should receive either two doses of Moderna bivalent vaccine or one dose of the Pfizer-BioNTech bivalent.
- Vaccinated or partially vaccinated children who are 5 years old should receive at least one bivalent vaccine to be considered up to date.

Ages 6 month-4 years

- Unvaccinated children in this age group should receive a 2-dose series of Moderna bivalent or a 3-dose series of Pfizer-BioNTech bivalent vaccine.

- Children in this age group who received monovalent COVID-19 vaccine should receive at least one bivalent vaccine. Consult the CDC website as young children may need additional bivalent doses based on their specific vaccine history.

Additional bivalent vaccine doses

Ages 65 and older
Individuals 65 and over may choose to receive an additional dose of a bivalent COVID-19 vaccine at least four months after their initial dose of the bivalent COVID-19 vaccine.

Immunocompromised individuals

- Individuals ages 6 and older with certain immunocompromising conditions may choose to receive an additional dose of bivalent COVID-19 vaccine at least 2 months after their initial bivalent vaccine.
- They then may receive additional doses at the discretion of, and at intervals determined by, their clinician, provided the dose intervals are at least 2 months.
- For immunocompromised individuals 6 months to 5 years of age, eligibility for additional doses will depend upon specific vaccine history.

Immunocompromising conditions include the following:

- Active treatment for solid tumor and hematologic malignancies
- Hematologic malignancies associated with poor response to COVID-19 vaccines regardless of current treatment status
- Receipt of solid organ or islet transplant and taking immunosuppressive therapy
- Moderate or severe primary immunodeficiency
- Advanced HIV infection
- Active treatment with high-dose steroids, alkylating agents, antimetabolites, transplant related immunosuppressive drugs, cancer chemotherapeutic agents classified as immunosuppressive, tumor necrosis factor blockers,