

## Recommendations Regarding the Updated (2023-2024) Monovalent mRNA COVID-19 Vaccines

<b>DATE:</b>	09/20/2023
<b>TO:</b>	Health Alert Network
<b>FROM:</b>	Debra L. Bogen, M.D., FAAP, Acting Secretary of Health
<b>SUBJECT:</b>	Recommendations Regarding the Updated (2023-2024) Monovalent mRNA COVID-19 Vaccines
<b>DISTRIBUTION:</b>	Statewide
<b>LOCATION:</b>	n/a
<b>STREET ADDRESS:</b>	n/a
<b>COUNTY:</b>	n/a
<b>MUNICIPALITY:</b>	n/a
<b>ZIP CODE:</b>	n/a

This transmission is a “Health Advisory,” and provides important information for a specific incident or situation; may not require immediate action.

**HOSPITALS:** PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, NURSING AND LABORATORY STAFF IN YOUR HOSPITAL; **EMS COUNCILS:** PLEASE DISTRIBUTE AS APPROPRIATE; **FQHCs:** PLEASE DISTRIBUTE AS APPROPRIATE **LOCAL HEALTH JURISDICTIONS:** PLEASE DISTRIBUTE AS APPROPRIATE; **PROFESSIONAL ORGANIZATIONS:** PLEASE DISTRIBUTE TO YOUR MEMBERSHIP; **LONG-TERM CARE FACILITIES:** PLEASE SHARE WITH ALL MEDICAL, INFECTION CONTROL, AND NURSING STAFF IN YOUR FACILITY

### SUMMARY

- The U.S. Food and Drug Administration (FDA) [announced](#) on September 11, 2023 that it had rescinded the authorization for the bivalent Pfizer-BioNTech and bivalent Moderna COVID-19 vaccines and authorized the updated (2023-2024) [monovalent mRNA Pfizer-BioNTech COVID-19 vaccine](#) and [monovalent mRNA Moderna COVID-19 vaccine](#) for all doses for individuals 6 months and older.
- COVID-19 vaccination has been proven safe and effective in significantly reducing severe outcomes of COVID-19 disease including hospitalization, death, and post viral syndromes.
- The updated (2023-2024) mRNA COVID-19 vaccines are monovalent XBB.1.5 vaccines and have been proven effective against the current circulating COVID strains in the XBB family including EG.5.1, FL.1.5.1 and BA.2.86.
- Everyone 6 months and older are recommended to receive updated (2023-2024) monovalent mRNA COVID-19 vaccine.
- Patients and providers should use [vaccines.gov](https://www.vaccines.gov) for the most up to date information regarding available vaccine providers. Uninsured adults should obtain vaccine from providers in the [Bridge Access program](#) and uninsured children should obtain vaccine from providers in the [Vaccines for Children \(VFC\)](#) program.
- If you have any questions, please call PA DOH at 1-877-PA-HEALTH (1-877-724-3258) or your local health department.

### Background

On September 11, 2023, The FDA [announced](#) that it had rescinded the authorization for the bivalent Pfizer-BioNTech and bivalent Moderna COVID-19 vaccines and authorized the updated (2023-2024) [monovalent](#)

[mRNA Pfizer-BioNTech COVID-19 vaccine](#) and [monovalent mRNA Moderna COVID-19 vaccine](#) for all doses for individuals 6 months and older. The FDA authorization for the [Novavax](#) vaccine is unchanged. On September 12, 2023 the Centers for Disease Control and Prevention (CDC) reviewed the current data on the continuing effectiveness of COVID-19 vaccines and [recommended](#) that the updated (2023-2024) monovalent mRNA COVID-19 vaccines be used for COVID-19 vaccination.

The updated (2023-2024) monovalent mRNA COVID-19 vaccines are monovalent XBB.1.5 vaccines. They have been proven effective against the COVID XBB family strains including the currently circulating EG.5.1, FL.1.5.1, and BA.2.86 strains. Also with this change, there are fewer COVID-19 vaccine products for providers to store and should reduce COVID-19 vaccine administration errors and waste.

Vaccination against COVID-19 has been proven [safe and effective](#) in significantly reducing severe outcomes of COVID-19 disease including decreasing hospitalization, death, and post viral syndromes such as long COVID. It is important that all patients 6 months and older stay up to date with their vaccines and receive a dose of the updated (2023-2024) monovalent mRNA COVID-19 vaccine.

### **Bivalent Pfizer-BioNTech and bivalent Moderna vaccines are no longer authorized by the FDA and can no longer be given.**

- Any doses of bivalent Pfizer-BioNTech or bivalent Moderna COVID-19 vaccine given after September 11, 2023, should have a [VAERS](#) form completed since they were given without FDA authorization.
- All doses of bivalent Pfizer-BioNTech and bivalent Moderna vaccines should be disposed of immediately and in an appropriate manner.
- Monovalent [Novavax](#) vaccine can still be given but in most cases needs to be followed up by an updated (2023-2024) monovalent mRNA vaccine at the appropriate interval to be considered up to date with COVID-19 vaccination.
- Individuals who received the [Janssen](#) vaccine should receive a single dose of the updated (2023-2024) monovalent mRNA vaccine to be considered up to date with COVID-19 vaccination.

### **Current Updated (2023-2024) Monovalent mRNA COVID-19 Vaccine Recommendations**

- [Recommendations for all individuals 5 years and older:](#)
  - All individuals 5 years and older who have received a single dose of the updated (2023-2024) monovalent mRNA COVID-19 vaccine regardless of past history of receiving COVID-19 vaccine are now considered [up to date](#).
  - The updated (2023-2024) monovalent mRNA COVID-19 vaccines are interchangeable and which vaccine a patient should receive is not dependent upon past vaccine.
  - There should be an interval of at least 8 weeks between prior COVID-19 vaccination and the updated (2023-2024) monovalent mRNA COVID-19 vaccine.
- [Recommendations for children 6 months through 4 years:](#)
  - Children 6 months through 4 years of age who are unvaccinated may receive a 2-dose series of the updated (2023-2024) Moderna monovalent mRNA COVID-19 vaccine or a 3-dose series of the updated (2023-2024) Pfizer-BioNTech monovalent mRNA COVID-19 vaccine.
  - Children 6 months through 4 years of age who are fully or partially vaccinated with prior COVID-19 vaccines should receive the updated (2023-2024) monovalent mRNA COVID-19 vaccine but the number of doses that they receive will depend upon the vaccines given and their vaccination history.
  - The choice of which updated (2023-2024) monovalent mRNA COVID-19 vaccine given is determined by past history of vaccination.

- [Recommendations for Individuals with immunocompromising conditions:](#)
  - All individuals with certain [immunocompromising conditions](#) should complete a three dose series of COVID-19 vaccine that includes at least one dose of the updated (2023-2024) monovalent mRNA COVID-19 vaccine.
    - If an individual has already received 3 or more doses of mRNA COVID vaccine, not including the updated (2023-2024) monovalent mRNA COVID-19 vaccine, they should receive one dose of the updated (2023-2024) monovalent mRNA COVID-19 vaccine.
    - 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, and/or other biologics considered immunosuppressive or immunomodulatory.

**There are still multiple formulations of the updated (2023-2024) monovalent mRNA COVID-19 vaccines, so it is extremely important for vaccine providers to make sure that the correct vaccine is given to each patient.**

**Patients and providers should use [vaccines.gov](https://www.vaccines.gov) for the most up to date information regarding available COVID-19 vaccine providers.**

- Uninsured adults should obtain updated (2023-2024) monovalent mRNA COVID-19 vaccine from providers in the [Bridge Access program](#).
- Uninsured children should obtain updated (2023-2024) monovalent mRNA COVID-19 vaccine from providers in the [Vaccines for Children \(VFC\)](#) program.

### **Current COVID-19 Vaccination Schedule**

From the CDC: [COVID-19 Vaccination schedule](#)

If you have any questions, please call PA DOH at 1-877-PA-HEALTH (1-877-724-3258) or your local health department.

Individuals interested in receiving PA-HANs are encouraged to register at [HAN Notification Registration \(mir3.com\)](#)

Categories of Health Alert messages:

**Health Alert:** conveys the highest level of importance; warrants immediate action or attention.

**Health Advisory:** provides important information for a specific incident or situation; may not require immediate action.

**Health Update:** provides updated information regarding an incident or situation; unlikely to require immediate action.

This information is current as of September 20, 2023 but may be modified in the future.
---