

Health Advisory

Bivalent mRNA vaccines no longer authorized; updated schedule
September 18, 2023

SUMMARY POINTS

- All individuals 6 months and over should receive a fall COVID-19 vaccine.
- Fall vaccines are monovalent XBB 1.5 vaccines. They perform well against current variants such as the XBB family, EG.5.1, FL.1.5.1, and BA.2.86.
- COVID-19 vaccination has proven safe and effective in significantly reducing severe outcomes from COVID-19 disease including, but not limited to, hospitalization, death, and post-viral syndromes such as Long-COVID or Post acute sequelae of SARS-CoV2 (PASC).
- Bivalent mRNA vaccine is no longer authorized and should be disposed of immediately.
- Immunocompromised individuals may require additional doses.

Fall mRNA vaccines are now FDA approved for all individuals 12 years of age and over; Fall mRNA vaccines for ages 6 months to 11 years are currently available under an EUA (Emergency Use Authorization). Novavax will retain its current vaccine EUA for the time being but is in discussion with the FDA regarding its own XBB vaccine approval.

In June, the FDA selected XBB 1.5 for strain composition for Fall COVID-19 vaccines. XBB 1.5 is no longer the dominant variant, but more than 90% of currently circulating viruses differ from XBB 1.5 by only a few substitutions in the receptor binding domain. The monovalent XBB 1.5 vaccine performs well against current variants such as EG.5.1, FL.1.5.1, and BA.2.86.

COVID-19 vaccines have proven safe and effective in significantly reducing severe outcomes from COVID-19 disease including, but not limited to, hospitalization, death, and post-viral syndromes such as Long-COVID or PASC.

Bivalent mRNA vaccine should be disposed of immediately. If a bivalent dose was or is given on or after September 11th, 2023, a VAERS report must be completed.

Fall vaccine recommendations

All individuals are recommended to receive a fall COVID-19 vaccine according to the guidelines below. One vaccine dose is considered sufficient for the majority of the population as nationwide combined vaccination and infection-induced [nationwide seroprevalence](#) is likely greater than 95%. Those with a recent COVID-19 infection may consider delaying vaccination by 3 months since first day of symptoms or a positive test.

Ages 5 and up

- All individuals should receive a fall vaccine, including those with a history of Novavax or Janssen vaccination, provided it has been at least 2 months since their last vaccine. Those aged 5 years and older who have received one fall vaccine dose are considered up to date, including those eligible for more than one dose.

Ages 6 months-4 years

- Unvaccinated and partially vaccinated children in this age group should receive a 2-dose series of Moderna or a 3-dose series of Pfizer-BioNTech vaccine that includes at least one fall vaccine. Fully vaccinated

children in this age group should also receive at least one fall vaccine. Consult the [CDC website](#) for specifics on vaccination in young children based on their specific vaccine history.

Immunocompromised individuals

- All individuals with certain immunocompromising conditions should complete a 3-dose series that includes at least one dose of fall vaccine.
- Individuals may receive additional doses of fall COVID-19 vaccine at the discretion of, and at intervals determined by, their clinician, provided the dose intervals are at least 2 months.
- Immunocompromising conditions include but are not limited to:
 - People who have cancer or on chemotherapy
 - Receipt of solid organ or islet transplant and taking immunosuppressive therapy
 - Moderate or severe primary immunodeficiency
 - Active treatment with high-dose steroids, alkylating agents, antimetabolites, or tumor necrosis factor blockers
 - Hematologic malignancies associated with poor response to COVID-19 vaccines regardless of current treatment status
 - Advanced HIV infection