

Pfizer/BioNTech and Moderna COVID-19 vaccines (Omicron variant XBB.1.5) – CDC recommends updated vaccine

- On September 12, 2023, the Centers for Disease Control and Prevention (CDC) convened its [Advisory Committee on Immunization Practices \(ACIP\)](#) to evaluate the 2023-2024 (monovalent, XBB containing) COVID-19 vaccines as authorized by the Food and Drug Administration (FDA) under Emergency Use Authorization (EUA) or approved by Biologics License Application (BLA). [FDA approved/authorized](#) the new vaccines on September 11, 2023.
 - BLA approved XBB.1.5 vaccines include [Moderna's Spikevax® \(2023-2024 formula\)](#) and [Pfizer's Comirnaty® \(2023-2024 formula\)](#) in individuals 12 years and older.
 - EUA authorized XBB.1.5 vaccines include [Pfizer/BioNTech's COVID-19 vaccine \(2023-2024 formula\)](#) and [Moderna's COVID-19 vaccine \(2023-2024 formula\)](#) for individuals from 6 months to 11 years of age.
 - ACIP members voted 13-1 in favor of recommending the new vaccines for their indicated populations.
- To support the Moderna COVID-19 vaccine (2023-2024 formula), [data](#) was presented showing robust neutralizing antibody titers against key COVID-19 sublineages including XBB.1.5, XBB.1.16, EG.5.1, FL.1.5.1, and BA.2.86. The safety profile of the XBB.1.5 vaccine was consistent with previously authorized vaccines.
- To support the Pfizer COVID-19 vaccine (2023-2024 formula), [data](#) was presented showing that the XBB.1.15 vaccine was equally immunogenic against key COVID-19 sublineages including XBB.1.5, EG.5.1 and BA.2.86, in a COVID-19 vaccine-experienced preclinical study.
- Novavax also has an [XBB.1.5 COVID-19 vaccine \(2023-2024 formula\)](#) under review with the FDA, but since it is not yet approved/authorized, the ACIP did not vote on it.
- Recommendations for vaccine dosing include the following:
 - Everyone ages 5 years and older recommended for a single 2023 – 2024 dose
 - Children ages 6 months–4 years should complete a multi-dose initial series (2 doses of Moderna or 3 doses of Pfizer/BioNTech mRNA COVID-19 vaccine) with at least one dose of the 2023–2024 COVID-19 vaccine
 - People who are moderately or severely immunocompromised should complete a 3- dose initial series with at least one dose of the 2023–2024 COVID-19 vaccine and may receive 1 or more additional 2023–2024 COVID-19 vaccine doses
 - Bivalent mRNA COVID-19 vaccines are no longer recommended in the U.S.
 - No additional dose recommendation at this time for individuals ≥ 65 years.
- The Pfizer/BioNTech and Moderna updated vaccines will now be available through commercial channels.
 - The Wholesale Acquisition Cost (WAC) for Moderna's vaccine is \$129 per dose and for Pfizer's vaccine is \$120 per dose.
 - The [Vaccines.gov](#) website will be updated to include information where uninsured or underinsured individuals can access vaccines through the [Bridge Access Program](#).

What's next:

- The CDC Director will need to review and endorse ACIP's recommendations before they can be adopted. Once this occurs, the new XBB.1.5 vaccines can be given to the appropriate patients.
- Pfizer/BioNTech and Moderna will begin shipping updated vaccines to administration sites.
- The FDA will review Novavax's application for its XBB.1.5 Covid-19 vaccine and if approved or authorized, then ACIP will make recommendations for its usage.



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