FDA Approves Updated COVID Vaccines but Narrows Their Use

New Moderna, Pfizer and Novavax vaccines are now authorized only for people 65 and older and those with underlying health conditions.

August 29, 2025 By Liz Highleyman

[Update: On September 19, the CDC's Advisory Committee on Immunization Practices recommended that COVID-19 vaccination for people ages 6 months and older should be based on individual decision-making, emphasizing that the risk-benefit balance for people under 65 is most favorable for those at an increased risk for severe COVID.]

On August 26, the Food and Drug Administration (FDA) approved three updated COVID-19 vaccines from Moderna, Pfizer/BioNTech and Novavax but limited their authorization to people at increased risk for severe illness due to their age or underlying health conditions. This means people living with HIV and cancer patients, for example, will still be able to get the vaccines.

COVID vaccines are updated each fall to better target the latest circulating SARS-CoV-2 variants. The 2025-2026 Moderna mRNA vaccine (Spikevax) and Pfizer/BioNTech mRNA vaccine (Comirnaty) target a specific variant dubbed LP.8.1, while the Novavax protein subunit vaccine (Nuvaxovid) targets the broader Omicron strain known as JN.1.

The new vaccines are approved for adults ages 65 and older and for younger people with "at least one underlying condition that puts them at high risk for severe outcomes from COVID-19," according to the revised FDA indications. The Moderna vaccine is indicated for higher-risk individuals ages 6 months and older, the Pfizer/BioNTech vaccine for those 5 years and older, and the Novavax vaccine for those 12 years and older. At the same time, the FDA rescinded emergency use authorization of the vaccines for younger children.

When COVID vaccines were initially authorized, the Centers for Disease Control and Prevention (CDC) put out a long list of conditions that increase the risk for severe COVID, including asthma, cancer, chronic kidney, liver or lung disease, diabetes, heart conditions, HIV, certain mental health conditions, obesity, pregnancy, immune deficiency, use of immunosuppressive medications and even smoking and lack of physical activity. It is not yet clear whether the new indications apply to all of these conditions or whether people will need proof of their health status to access the vaccines.

The CDC's Advisory Committee on Immunization Practices (ACIP) normally makes recommendations about who should receive vaccines, subject to approval by the CDC director. In June, Health and Human Services Secretary Robert F. Kennedy Jr.—a longtime vaccine skeptic who has harshly criticized the mRNA COVID shots—removed all ACIP members and replaced them with ideological allies. The CDC is currently without a Senate-confirmed leader after this week's ouster of Susan Monarez, PhD, which could leave the decision in Kennedy's hands. In May, he announced that COVID vaccines would no longer be recommended for healthy children or pregnant women, a decision contradicted by the American Academy of Pediatrics and American College of Obstetricians and Gynecologists.

Prior FDA approvals and CDC guidelines for COVID boosters were broad, with ACIP recommending an updated vaccine each year for most adults and leaving it up to parents whether to repeatedly vaccinate children ages 6 months and older. In contrast, some other countries have been more restrictive. Guidelines from the U.K. National Health Service and the World Health Organization, for example, do not routinely recommend annual revaccination for healthy adults and children—similar to the new FDA indications.

I promised 4 things:

1. to end covid vaccine mandates.

2. to keep vaccines available to people who want them, especially the vulnerable.

3. to demand placebo-controlled trials from companies.

4. to end the emergency.

In a series of FDA actions today we accomplished…

— Secretary Kennedy (@SecKennedy) August 27, 2025

In a post on the social medium platform X, Kennedy stated that the FDA approvals fulfill his promise “to keep vaccines available to people who want them, especially the vulnerable.”

Likewise, FDA commissioner Marty Makary, MD, MPH, stated that “100% of adults in this country can still get the vaccine if they choose. We are not limiting availability to anyone.”

100% of adults in this country can still get the vaccine if they choose. We are not limiting availability to anyone.

https://t.co/XtYJpVFFcR

— Dr. Marty Makary (@DrMakaryFDA) August 27, 2025

Kennedy and Markary seem to be referring to the fact that physicians are allowed to prescribe vaccines and medications “off-label” beyond their FDA indications based on clinical judgement.

But critics say the narrower indications will make it more difficult to access the vaccines in practice and that they leave out some healthy people who could benefit, such as health care providers and those who live with vulnerable individuals. While older adults and people with underlying health conditions are at greatest risk for severe COVID, some healthy children and younger adults have nonetheless experienced serious illness, hospitalization and death. What’s more, some people want regular boosters to reduce the risk of long COVID.

While doctors can still prescribe the new shots, many Americans do not have an established relationship with a health care provider. Most adults get COVID vaccines at drug stores like CVS or Walgreens, which may not offer them to people who don’t fall within the FDA indications. In some states, it’s illegal for pharmacists to administer vaccines off-label or without a CDC recommendation.

In addition, insurers may not cover the vaccines for people who do not meet the FDA criteria. Under a provision of the Affordable Care Act, insurers are required to cover vaccines recommended by ACIP at no charge. Medicaid, which includes the Vaccines for Children Program, also generally follows ACIP guidance. But given the CDC’s ongoing turmoil and Kennedy’s vaccine skepticism, this recommendation, too, is likely to be narrow.

The CDC’s Bridge Access Program previously provided free COVID vaccines for many people without insurance coverage, but this program ended in 2024. Without insurance, the vaccines

typically cost around $200.

Click here for more news about COVID-19 vaccines.

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