FDA Approves Second COVID Booster for People 50 and Older

Immunocompromised people ages 12 and older are also eligible for an additional shot.

March 30, 2022 By Liz Highleyman

On March 29, the Food and Drug Administration (FDA) authorized a second Pfizer-BioNTech or Moderna COVID-19 vaccine booster for people ages 50 and older, to be administered at least four months after their last shot. Immunocompromised individuals ages 12 and older may also receive an additional shot. The Centers for Disease Control and Prevention (CDC) has updated its vaccine recommendations, consistent with the authorization.

"Boosters are safe, and people over the age of 50 can now get an additional booster four months after their prior dose to increase their protection further," CDC director Rochelle Walensky, MD, MPH, said in a statement. "This is especially important for those 65 and older and those 50 and older with underlying medical conditions that increase their risk for severe disease from COVID-19 as they are the most likely to benefit from receiving an additional booster dose at this time."

The new authorization means that older adults who received the initial two-shot Pfizer-BioNTech (Comirnaty) or Moderna (Spikevax) mRNA vaccine regimen can get two boosters, for a total of four shots. The CDC also said that people of any age who received the single-shot Johnson & Johnson vaccine, who were previously advised to get a follow-up dose, are now eligible for a second mRNA booster, for a total of three shots.

People with moderate or severe immune suppression, who do not respond as well to vaccination, were advised last August to get a third mRNA shot to provide full protection (this is considered a third dose in the initial series, not a booster). Immunocompromised people ages 12 and up can now get a second Pfizer-BioNTech booster on top of that, and people ages 18 and up can get a second Pfizer or Moderna booster, for a total of five shots. (The Moderna vaccine is not approved for people under 18.) This group includes organ transplant or stem cell transplant recipients, cancer patients, people taking immunosuppressive medications and people with advanced or untreated HIV.

Terrific @nytimes 2nd booster explainer by

@apoorva_nyc https://t.co/LzKRpvrIlb I'm quoted, mostly arguing "yes". As I've said, seems like easy call for older/hi-risk folks, more of a toss-up for lower-risk. But even in latter, I see benefits marginally outweighing (tiny) risks.

— Bob Wachter (@Bob_Wachter) March 29, 2022

The FDA and CDC decisions come at a time when COVID-19 cases and hospitalizations are at a lull following this winter's omicron wave, but many experts believe a new surge may be on its way due to a new SARS-CoV-2 variant known as BA.2, which is now predominant in the United States.

Boosters temporarily raise levels of circulating antibodies against SARS-CoV-2, but these typically wane after a few months. However, the vaccines also stimulate memory B-cell and T-cell responses, which provide longer-lasting protection against severe disease.

Studies have shown that the initial mRNA two-shot series remains protective against severe illness and death, and that a first booster further reduces hospitalization, especially for older individuals. While COVID-19 vaccines lower the risk symptomatic disease—and they appear to reduce the likelihood of developing long COVID—they do not reliably prevent infection or transmission. So far, there is little evidence that a second booster provides added protection, but a recent Israeli study suggests it does.

"Current evidence suggests some waning of protection over time against serious outcomes from COVID-19 in older and immunocompromised individuals," Peter Marks, MD, PhD, director of the FDA's Center for Biologics Evaluation and Research, said in a press release. "Based on an analysis of emerging data, a second booster dose of either the Pfizer-BioNTech or Moderna COVID-19 vaccine could help increase protection levels for these higher-risk individuals."

The FDA has determined that "the known and potential benefits of a second COVID-19 vaccine booster dose with either of these vaccines outweigh their known and potential risks in these populations," the agency stated. Evidence to date shows that additional doses produce side effects similar to those of the initial series—typically mild to moderate flu-like symptoms and injection site reactions, such as temporary pain or swelling—with no new safety concerns.

Some experts lauded the decision, arguing that patients and their doctors should have the option of an additional dose as immunity wanes, but others have reservations. Among those who favor a second booster, there is debate about whether eligible individuals should get one now or wait until

a potential surge in the fall or winter. In an unusual move, the FDA's decision was made without the input of its vaccine expert advisory committee, which is scheduled to meet on April 6.

Some think the decision is premature, arguing that most healthy adults down to age 50 do not need a second booster at this time, given that the initial series and first booster remain protective against severe COVID-19. People who have recently had COVID-19 despite two or three shots do not need a second booster now, as the infection acts as a natural booster.

> With @US_FDA authorizing a 4th #COVID19 vaccine dose for 50+, our updated analysis finds that there are enough doses for 70% of people 50+ to get a 4th dose, and complete vaccination for others, but not enough for all those 50+ @joshmich @larry_levitt https://t.co/XwdDy9rQnj
>
> — Jen Kates (@jenkatesdc) March 29, 2022

Some dissenters feel health officials should focus on expanding uptake of initial vaccines and first boosters, especially for people 65 and older. To date, fewer than half of American adults have received a first booster. Some are concerned that authorization could lead to double-booster mandates. Some prefer to hold out for variant-specific boosters or new vaccines that work in different ways or that could offer protection against multiple coronaviruses. And given congressional failure to increase COVID-19 funding, there are currently enough vaccine doses to give a fourth dose to everyone over 65, but not everyone over 50.

"FDA's authorization of a second COVID-19 booster shot for individuals 50 and over provides another opportunity for people to increase their level of protection against severe disease, hospitalization and death," Daniel McQuillen, MD, president of the Infectious Diseases Society of America (IDSA) said in a statement. "IDSA calls on Congress to pass another COVID-19 supplemental funding bill to ensure that all individuals can access COVID-19 vaccines, including newly authorized boosters, as well as COVID-19 tests and therapeutics. The bill should also include the resources necessary for global COVID-19 vaccination and response in order to prevent the development and spread of new variants."

Click here for the CDC's latest vaccine and booster recommendations.
Click here for the CDC's recommendations for immunocompromised people.

Click here for more news about COVID-19 vaccines.

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