FDA approves supplemental doses of COVID-19 vaccines for some immunocompromised individuals

What you need to know

The federal Food and Drug Administration (FDA) has approved allowing a third, supplemental dose of two COVID-19 vaccines for certain immunocompromised individuals who need extra protection. The supplemental vaccines are currently approved for Pfizer (ages 12-over) or Moderna vaccines (ages 18-over). Health agencies are also studying the safety of supplemental doses of the Johnson & Johnson vaccine.

Several recent studies have shown that a third mRNA vaccine dose is safe to administer to solid-organ transplant recipients and can increase antibodies in some patients who responded poorly to the first two doses of the mRNA vaccines, leaving them more at risk despite being fully vaccinated. The U.S. Centers for Disease Control and Prevention (CDC) estimates the expanded emergency use authorization will impact about 3% of the U.S. population.

Mark Meeker, DO, FACP, CPE, vice president of community medicine, OSF HealthCare Multispecialty Group, says the expanded emergency use authorization (EAU) includes patients who have suppressed immune systems because of cancer treatment or because they underwent an organ transplant.

"They're very specific with this booster because data is still coming in. There have been studies done at university centers, studying people with solid tumors, for example, people with transplants, and they have found that the third shot really does enhance their response to the vaccine."

The FDA announcement comes as the highly contagious delta variant is represented in an increasing number of cases. The variant now represents about 87% of all new cases in the U.S. – up from 14% in early June, according to the CDC.

Here are the specific categories of patients who should contact their treating medical provider about getting a supplemental vaccine dose:

- · Receiving active cancer treatment for tumors or cancers of the blood
- Received an organ transplant and taking medicine to suppress the immune system
- Received a stem cell transplant within the last two years or are taking medicine to suppress the immune system
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids or other drugs that may suppress your immune response

The CDC Advisory Committee on Immunization Practices (ACIP) has also advised that when possible, the suppplemental dose should match the type/brand of initial doses received. Dr. Meeker says the CDC has guidance for those patients.

"Right now, based on the data we have available, the CDC is recommending that you continue the series with the first vaccine that you had received. If, however, you have trouble accessing that particular brand of vaccine – you cannot access it or there's a supply issue – then they recommend you get the other one rather than nothing at all. The third booster needs to be at least, for both of them, 28 days after that second shot."

ACIP recommended the supplemental vaccine doses, but for only the very limited group. Dr. Meeker says this does not apply to people with some chronic conditions such as diabetes. He says this initial group of patients is one for which there is the most robust data.

"We knew by the nature of their illness, or their situation, that they may not have responded adequately to the first two doses. So that was studied early on and we now have the data in that shows that is indeed the case – a lot of those

patients didn't respond well enough to the first two doses, and the third shot indeed makes a significant difference in a lot of them."

ACIP has called for more data to address the need for booster shots for other populations, including residents of long-term care facilities, adults ages 65 and older and health care providers.

Dr. Meeker points out that the supplemental vaccine doses will be available for these immunocompromised individuals through local OSF HealthCare providers, but if patients want to receive them at retail pharmacies or county public health clinics, they won't need a medical referral. But he thinks it's a good idea to check with your medical provider.

"I would highly recommend you give them a call, send them an email – however you communicate with your care team – and ask them for advice about this booster. At OSF, we have the vaccine available through all of our clinics so if you have an OSF physician for APP (advanced practice provider), you'll have access to the booster if you qualify."

OSF is also currently offering COVID-19 vaccinations on a walk-in basis with no appointment needed at select OSF Medical Group and OSF PromptCare locations.