

# FDA authorizes COVID vaccine for middle and high school students



Credit: Jenni Girtman

Credit: Jenni Girtman

DeKalb Pediatric Center medical assistant Pheona Mack, right, administers Fred Kane, 16, his second dose of the Pfizer vaccination Thursday. The office expects long lines for the first week when 15-year-olds and younger become eligible for covid vaccines. (Jenni Girtman for The Atlanta Journal-Constitution)

The Food and Drug Administration on Monday authorized the use of the Pfizer-BioNTech vaccine in adolescents ages 12 to 15 years, a critical step in raising the level of immunity and getting the pandemic under control.

The expansion of vaccine eligibility marks a major development in the country's vaccination efforts, offering protection against COVID-19 for more children during summer activities and raising hopes of a return to something more like normalcy in schools in the fall, at least for older students. The action makes immunization accessible to all high school students and many in middle school, where students typically start sixth grade at age 11.

In Georgia, 585,882 youths, or 6% of the population, fall in this 12-to-15 age group, according to 2019 Census estimates.

"I'm very excited — super excited — that our students are going to have the opportunity to get vaccinated," said Maggie Fehrman, the interim Decatur schools superintendent. It should mean a robust reopening of school in the fall, with less social distancing in seventh grade on up, she said.

The FDA clearance comes as an amendment to the existing emergency use authorization for the Pfizer-BioNTech vaccine granted for adults late last year and then expanded in late March to those as young as 16.

But there is still one more step before the vaccine can be administered to adolescents. The Centers for Disease Control and Prevention's vaccine advisory panel is meeting Wednesday, where it is expected to review the clinical trial data and to give the full go-ahead. Preparations are underway for some providers to begin vaccinating adolescents immediately, as early as Wednesday.

President Joe Biden said there will be 20,000 pharmacy sites around the country ready to provide COVID-19 vaccines to adolescents. The president also announced plans to ship doses "in the following weeks" to pediatricians, "so parents and their children can talk to their family doctor about it and get the shot from a provider they trust the most."

The president also said that if teens are on the move this summer, they will be able to get the first dose in one place and the second somewhere else.

"This is a big deal," said Dr. Hugo Scornik, a Conyers pediatrician and president of Georgia's chapter of the American Academy of Pediatrics. "This can be transformative for schools and frees kids to do more activities they love like sports, and this gets us to closer to that level of immunity we need to get to."

Scornik said while children who catch the coronavirus tend to have milder symptoms than adults, they can, in rare instances, have severe complications. Children can also get sick and spread the disease, so vaccinating young people can break the chain of infection. People 17 and under in Georgia make up 11% of confirmed cases, 2% of hospitalizations and 0.05% of confirmed COVID-19 deaths, according to an analysis of state data.

The FDA said it determined the benefits of the vaccine for those 12 years of age and older outweigh the known and potential risks. The FDA said the most commonly reported side effects in the adolescent clinical trial participants, which typically lasted one to three days, were pain at the injection site, tiredness, headache, chills, muscle pain, fever and joint pain.

"Today's action allows for a younger population to be protected from COVID-19. . . Parents and guardians can rest assured that the agency undertook a rigorous and thorough review of all available data, as we have with all of our COVID-19 vaccine emergency use authorizations," said Acting FDA Commissioner Janet Woodcock in a press release.

Available vaccines have worked remarkably well so far for those 16 and up, not only at preventing infection but also at preventing serious illness and hospitalization, even as new variants circulate around the globe.

Pfizer got the FDA's OK last October to test its COVID-19 vaccine in adolescents. The clinical trials were needed to see not only if the vaccine was safe and effective for ages 12-15, but also to ensure that the dose was correct.

In late March, the company reported that its late-stage clinical trials showed the vaccine was 100% effective in protecting the children and had no serious side effects.

About two weeks after that, Pfizer-BioNTech asked the FDA to expand its emergency use authorization to those ages.

Pfizer-BioNTech isn't the only company seeking to lower the age limit for its vaccine. Results also are expected by the middle of this year from a study of Moderna's vaccine in 12- to 17-year-olds.

But there are challenges ahead, not only logistical issues but also concerns and hesitancy about vaccination that could undermine immunization rates at some schools.

Explore [Emory partnering in Moderna COVID-19 vaccine study for children](#)

The Georgia Department of Public Health has been collaborating with pediatricians to address a technical problem. Few of them have the ultra-cold freezers needed for long-term storage of the Pfizer-BioNTech vaccine. Doses can be kept in a standard freezer for only 14 days, plus five in a refrigerator, and the standard distribution trays hold 1,170 doses, putting enormous pressure on doctors to get shots in arms quickly or risk wasting vaccine.

Scornik said DPH may be able to help split up the trays and divide them between practices.

In Decatur, a local pediatrician will have no problem using at least one tray quickly. Parents of just over a thousand 12-15-year-old students there had signed up for vaccination clinics by last Tuesday afternoon, within hours of a school system announcement that it was partnering with the office. By Friday, that number had risen to more than 1,200.

“If these people all show up for their vaccine and our calculations of how many kids are in the school system are correct, it seems to me that there’s no way that middle and high school in Decatur next year cannot be full in-person,” said Dr. Jane Wilkov, the founder of the doctors’ office, DeKalb Pediatric Center.

Decatur has about 1,800 students in grades seven through 10, those most populated by 12-15-year-olds.

The center typically saw maybe 150 patients a day before the pandemic, and is planning to be vaccinate as many as 1,800 Wednesday, including children from outside Decatur and adults. Wilkov is urging people to carpool, given the limited parking at her office.

Wilkov said a lot of families want their kids to be immune in time for summer camps and family trips. Cooped-up teenagers have been pressuring their parents to let them get vaccinated, including a 17-year-old whose family had never had him vaccinated for any other disease, she said. “It’s been a long hard year so I think this is a sign of hope.”



Credit: Jenni Girtman

Credit: Jenni Girtman

DeKalb Pediatric Center administers Jude Hiley, 16, his first dose of the Pfizer vaccination Thursday. The office expects long lines for the first week when 15-year-olds and younger become eligible for covid vaccines. (Jenni Girtman for The Atlanta Journal-Constitution)

That enthusiasm is not universal, though.

In Early County along the Alabama state line, many of the older high school students apparently remain unvaccinated, said school Superintendent Bronwyn Ragan-Martin. She hasn't heard much interest among parents and thinks there will be similar disinterest in vaccinating 12-15-year-olds.

"Down here I just don't see a lot of people jumping on that," said Ragan-Martin, president of the Georgia School Superintendents Association.

Just over half (52%) of parents nationally say they are likely to have their child get the COVID-19 vaccine as soon as it is available to their age group, [according to an April Axios-Ipsos poll](#).

Fehrman, the interim Decatur superintendent, said schools likely will likely be more — but not completely — normal in the fall. She'll be awaiting CDC guidance but her mitigation committee is currently calling for an ongoing mask mandate.

“Because it’s an emergency approved vaccine at this point we can’t require students to get vaccinated to come to school,” she said. “So that means we have to operate under the understanding that not everyone is vaccinated.”

Still, she plans to remove the transparent cough shields surrounding most desks even with more students per classroom. Lunch will be a challenge since masks must come off. Students will eat outside as often as possible, but Fehrman is looking for more space indoors when the weather won't permit it, so they can spread out. Lunchtime will probably be extended, too, to group students into more shifts.

Ragan-Martin, the Early County superintendent, is still dealing with outbreaks. She recently had to quarantine more than three dozen high school students and the kids from three fifth-grade classrooms.

She thinks her secondary schools could return to normal in the fall if a majority of 12-18-year-olds get vaccinated. She would like to return without the mask mandate that she has in place in middle and high school but knows some teachers and parents may not be comfortable with that.

And it's unclear how many students there will be vaccinated. Ragan-Martin got a shot as soon as she was eligible but has not had her 17-year-old son vaccinated, though he has been eligible for more than a month. She thinks he's safe in his school with the protocols she has in place and said she will ensure he gets jabbed before he heads off to college. Also, none of the children infected in her school district has become seriously ill.

“I think it’s safe enough for adults, but I would like a little bit more information about the safety for 12-15-year-olds,” Ragan-Martin said. She said if the Georgia Department of Public Health would produce documents vouching for the vaccine’s safety, she would share them with parents.

What will it take to get everyone vaccinated?

“I think just seeing other people doing it,” she said.





Beth and Tom Warren of east Cobb with their children, left to right, Samuel, 12, Patrick, 16 and Ellie, 11. Both parents and Patrick are vaccinated. They look forward to Samuel being vaccinated and hope eligibility will be expanded soon for Ellie, too. Courtesy of Warren Family

Beth Warren, an east Cobb mother of three, is eager to get her 12-year-old son, Samuel, vaccinated. His 16-year-old brother, Patrick, is already vaccinated.

“He felt this sense of freedom. His social interaction had been so limited,” Warren said, adding that he’s planning now to go to a band camp this summer.

She hopes her youngest child, 11-year-old Ellie can get vaccinated soon, too.

*Database specialist John Perry contributed to this article.*

---





Siblings Samuel, Patrick, and Ellie Warren. Their mother, Beth Warren, said she knows her children were glad, even relieved, to see their parents get vaccinated, and authorization of a vaccine for ages 12 to 15 feels like a natural progression to help her family be protected and return to more normalcy. Courtesy of Warren family.

### **More on the Pfizer-BioNTech vaccine**

The Pfizer-BioNTech COVID-19 vaccine is the only vaccine with FDA authorization for use in adolescents and teenagers. It is logistically challenging to distribute since it must be stored in special ultracold freezers that are not widely available. To locate the nearest facility administering Pfizer, go to [vaccine.gov/search/](https://vaccine.gov/search/) then select Pfizer-BioNTech COVID Vaccine and input your zip code.

Pfizer-BioNTech is filing for full FDA approval of its vaccine for people age 16 and up, making it the first vaccine in the U.S. to be assessed for full regulatory approval.

Pfizer-BioNTech has also announced it plans to file in September for emergency use authorization for its COVID-19 vaccine in ages 2 to 11.