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AAP News

Pfizer's COVID-19 vaccine for kids would require different doses, dilution, storage

by Melissa Jenco, News Content Editor



Editor's note: For the latest news on COVID-19, visit <http://bit.ly/AAPNewsCOVID19>.

COVID-19 vaccines awaiting authorization for children ages 5-11 years will have different doses, dilution requirements and storage conditions than the vaccines currently available for adolescents and adults, according to Pfizer.

The **AAP has updated its materials** to help pediatricians prepare, and the American Medical Association (AMA) has released new Current Procedural Terminology (CPT) codes.

The COVID-19 vaccine manufactured by Pfizer and BioNTech is proposed to be given in two 10-microgram (mcg) doses administered 21 days apart. The dosage is one-third of the adolescent and adult dose.

The currently available vaccine product with a purple cap has not been studied in children under 12 and therefore should not be used for this age group. The vaccine vials for ages 5-11 years will have orange caps and borders to differentiate them.

Each vial will have 10 doses and will need 1.3 milliliters (mL) of diluent under Pfizer's preliminary plan. The vaccines would be stored for six months in an ultra-cold freezer or 10 weeks in a refrigerator, under Pfizer's proposal.

Investigators tested the lower-dose Pfizer-BioNTech vaccine in 2,268 children and **announced in late September** that their data demonstrate it is safe and produces a significant immune response.

The Food and Drug Administration's (FDA's) Vaccines and Related Biological Products Committee will meet Oct. 26 to discuss use of the Pfizer-BioNTech vaccine for this age group. The Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices is expected to meet shortly after.



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"We know from our vast experience with other pediatric vaccines that children are not small adults, and we will conduct a comprehensive evaluation of clinical trial data submitted in support of the safety and effectiveness of the vaccine used in a younger pediatric population, which may need a different dosage or formulation from that used in an older pediatric population or adults," Acting FDA Commissioner Janet Woodcock, M.D., said in a [news release](#).

Nearly 5.9 million children have tested positive for COVID-19, according to [data from the AAP and the Children's Hospital Association](#). There have been nearly 850,000 new pediatric cases over the past four weeks.

About 45% of 12- to 17-year-olds in the U.S. are fully vaccinated, [according to an AAP report](#). Pediatricians can get more information on signing up to be a vaccinator at <https://bit.ly/2YwgcRN>. The AAP also has guidance for pediatricians on [preparing for authorization](#), [practice implementation](#) and [getting paid](#) and has posted a list of [frequently asked questions](#).

The AMA released [new CPT codes](#) related to COVID-19 vaccines for 5- to 11-year-olds.

Vaccine product code:

91307 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, for intramuscular use

Vaccine administration codes:

0071A Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; first dose

0072A Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation; second dose

In addition to the new vials for children ages 5-11 years, Pfizer hopes to roll out a new formulation for adolescents and adults that would not require dilution and would have the same storage requirements as vials for children. The formulation would need approval from the FDA.