



State of New Jersey
DEPARTMENT OF HEALTH
PO BOX 360
TRENTON, N.J. 08625-0360

PHILIP D. MURPHY
Governor

www.nj.gov/health

SHEILA Y. OLIVER
Lt. Governor

JUDITH M. PERSICILLI, RN, BSN, MA
Commissioner

November 3, 2021

TO: Points of Dispensing participating in the COVID-19 Vaccination Program
FROM: Judith M. Persichilli, B.S.N., M.A. Commissioner
SUBJECT: Expansion of Pfizer Pediatric COVID-19 Vaccine to Ages 5 to 11

Effective November 2, 2021, Points of Dispensing (PODs) can immediately begin administration of the Pfizer-BioNTech pediatric COVID-19 vaccine to persons 5 years of age through 11 years of age.

On Friday, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) and, yesterday, the the Centers for Disease Control and Prevention (CDC) adopted the Advisory Committee on Immunization Practices' (ACIP) recommendations for the expanded age group.

This memo serves to alert you to use of the new pediatric formulation of the Pfizer-BioNTech COVID-19 vaccine in New Jersey's COVID-19 vaccination effort. **Please share this information with appropriate staff in your program.**

Thank you for your partnership in this initiative. This memo supplements the other materials circulated by the New Jersey Department of Health (NJDOH) regarding the provision, delivery, and administration of COVID-19 vaccines. https://www.state.nj.us/health/cd/topics/covid2019_vaccination.shtml. Points of Dispensing may contact the New Jersey Department of Health Vaccine Operations Center at Vax.Operations@doh.nj.gov with any further questions.

Eligible population

COVID-19 vaccination sites in New Jersey may offer the two-dose Pfizer-BioNTech pediatric formulation COVID-19 vaccine series to persons aged 5 through 11 immediately.

Meanwhile, the following remain eligible:

- All persons ages 12 through 17 are eligible for the Pfizer-BioNTech adult formulation COVID-19 two-dose series.
- All persons 18 and older are eligible for the Pfizer-BioNTech and Moderna two-dose series, and for the Johnson & Johnson/Janssen one-dose vaccine.
- Persons who are moderately to severely immune compromised are eligible for an additional dose of the Pfizer-BioNTech or Moderna vaccines.

- Certain adults are eligible for a booster dose if they received a primary series with Pfizer-BioNTech adult formulation and/or Moderna COVID-19 vaccine at least six months ago:
 - People aged 65 years or older,
 - People aged 18 and older who live in long-term care settings,
 - People aged 18 and older with [underlying medical conditions](#), and
 - People aged 18 and older who [work or live in high-risk settings](#).
- All adults (aged 18 years or older) who received one Johnson & Johnson/Janssen vaccine at least two months ago are eligible for a booster dose.

Vaccine types

The Pfizer-BioNTech COVID-19 Vaccine for individuals 5 through 11 years of age is a lower dose (10 micrograms) than that used for individuals 12 years of age and older (30 micrograms).

There is a new product configuration for this age cohort with new packaging (orange cap for pediatric formulation versus purple cap for current adult/adolescent formulation), new preparation, and a new national drug code (NDC). The current product for adults and adolescents should not be used in children. Please review the new Pfizer-BioNTech Fact Sheet for Healthcare Providers for this age group: <https://www.fda.gov/media/153714/download>. Reference guide is available here: <https://www.cdc.gov/vaccines/covid-19/downloads/Pfizer-Pediatric-Reference-Planning.pdf>.

Each vial of the pediatric formulation (orange cap/packaging) will be filled to 1.3mL before dilution. The pediatric formulation will require the addition of 1.3mL of diluent and will contain 10 doses per vial. Orders of Pfizer-BioNTech pediatric vaccine include ancillary kits that contain 10mL diluent vials. Diluent vials are a one-time-use item and should be discarded with the remaining content after each use. For each vial of vaccine, extract 1.3mL of diluent from a single-use vial to reconstitute 1.3mL of vaccine.

Pfizer-BioNTech pediatric vaccines will be shipped on dry ice in smaller disposable shippers. Unlike the adult shippers, these smaller shippers cannot be used for temporary storage. The contents must be removed and placed in a refrigerator (2°C to 8°C for up to 10 weeks) or ultra-cold freezer (90°C to -60°C for up to six months) as soon as the order is received.

Administration timeline

The two-dose primary series is administered with a three week interval between first and second dose.

Co-administration

COVID-19 and other vaccines (e.g., influenza vaccines, childhood vaccines) may be administered without regard to timing. This includes administration of COVID-19 and other vaccines on the same day, as well as co-administration within 14 days.

Scheduling

During the initial ages rollout, in addition to appointments, walk-ins should still be accommodated. This is especially important to ensure timely access without barriers for those newly eligible. All appointment schedulers should be updated to account for the Pfizer-BioNTech pediatric COVID-19 vaccine.

Points of dispensing must continue to be listed on the [New Jersey COVID-19 Information Hub](#) and your POD must update NJDOH in a timely manner if any information on the state website is incomplete or out-of-date.

The New Jersey Vaccine Scheduling System (NJVSS) is ready to accept scheduling for the Pfizer-BioNTech pediatric vaccine for those ages five through 11. Parents and guardians may register and schedule their children for a pediatric Pfizer dose using the NJVSS portal at <https://covidvaccine.nj.gov> at PODs that list their availability of pediatric Pfizer vaccine.

Site Readiness

To accommodate as many eligible vaccine recipients as soon as possible, all active sites should prepare to have additional vaccines on hand at all vaccine events, provide night and weekend hours, accommodate walk-ins, update appointment availability reflected on the New Jersey Vaccine Appointment Finder (<https://covid19.nj.gov/finder>), and share information with NJDOH about pop-up vaccination clinics to be included in the COVID-19 Community Calendar (<https://covid19.nj.gov/pages/communitycalendar>). Sites are also encouraged to actively promote the availability of pediatric doses. If additional vaccine supply is needed at a site, please contact the New Jersey Department of Health to arrange for allocation and/or transfer.

To the extent possible while maintaining appropriate vaccine stewardship, all points of dispensing are expected to optimize use of all authorized COVID-19 vaccines. No vaccination opportunity should be missed, so sites should request and carry sufficient inventory to vaccinate at capacity.

Reporting

The New Jersey Immunization Information System (NJIS) is ready to accept the age expansion for Pfizer-BioNTech in vaccine recipients' records.

All doses of COVID-19 vaccine administered in New Jersey must be reported to NJIS. Doses reported to NJIS will then be available for display in the vaccine recipient's Docket app upon refreshing the "Immunization Records" page in the app.

Federal recommendation

On Friday, October 20, the FDA issued revised EUAs with fact sheets for the ages 5 through 11 cohort.

- FDA statement: <https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age>
- For Pfizer-BioNTech vaccine for ages 5 through 11 cohort:
 - Updated EUA: <https://www.fda.gov/media/150386/download>
 - New EUA Fact Sheet for Healthcare Providers: <https://www.fda.gov/media/153714/download>
 - New EUA Fact Sheet for Recipients and Caregivers: <https://www.fda.gov/media/153717/download>
 - Translations of the Fact Sheet for Recipients and Caregivers: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine>

On Tuesday, November 2, the CDC adopted recommendations for the booster dose.

- CDC statement: <https://www.cdc.gov/media/releases/2021/s1102-PediatricCOVID-19Vaccine.html>

Provider education

Please ensure vaccination providers are trained and well versed in the updated vaccine information, provider fact sheet, and clinical considerations. We expect providers to be prepared to address questions from their patients and their families about the recommended booster dose. Information about COVID-19 vaccines and training materials is available through the CDC website at <https://www.cdc.gov/vaccines/covid-19/index.html>. Please see CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>

Consumer education

Points of dispensing play a critical role in building trust in vaccination. Please note CDC's dedicated webpage with information on COVID-19 Vaccination for Children 5–11 Years Old: <https://www.cdc.gov/vaccines/covid-19/planning/children.html> and on COVID-19 Vaccines for Children and Teens: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/children-teens.html>.

Informed consent

Each patient must receive the updated Pfizer vaccine information, including the newly issued EUA patient fact sheet. For minors under age 18, the EUA fact sheet for caregivers must be provided to the parents/guardians in advance of administration. These are available in multiple languages here:

- <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine>

Informed consent must be obtained from a parent/guardian in order for the minor to be vaccinated. For example, informed consent can be obtained:

- a. By the parent/guardian verbally consenting on-site to the minor receiving the vaccine,
- b. By the parent/guardian verbally consenting in-advance or verbally consents from off-site to the minor receiving the vaccine,
- c. By a parent/guardian signing on-site an informed consent form, or
- d. By a parent/guardian signing in-advance an informed consent form.

Points of dispensing are encouraged to minimize barriers to entry and to honor all of the above formats for collecting informed consent. There is no federal- or state-mandated form.

Points of Dispensing should follow existing laws regarding consent for minors for medical procedures. Each POD should consult with their own legal counsel regarding the facility's specific policies and procedures for consent.