



September 26, 2021

HEALTH ADVISORY

Booster dosing of Pfizer mRNA COVID-19 vaccines after an initial 2-dose Pfizer COVID-19 mRNA vaccine series

Please distribute to the Chief Medical Officer, Internal Medicine, Family Medicine and Pediatric Departments, Director of Nursing, Pharmacy Director, and all primary care clinics

To: Healthcare Providers, Healthcare Facilities, Pharmacies, and Local Health Departments

From: New York State Department of Health (NYSDOH), Bureau of Immunization

SUMMARY

- On September 24, 2021, the Centers for Disease Control and Prevention (CDC) released a statement on the Advisory Committee on Immunization Practices' (ACIP) COVID-19 vaccine booster recommendations endorsing the following ACIP recommendations for a booster dose of the Pfizer-BioNTech COVID-19 vaccine in certain populations and additionally recommended a booster dose for those in high risk occupational and institutional settings.
- CDC recommends:
 - People 65 years and older and residents of long-term care settings **should** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series,
 - People aged 50-64 years with underlying medical conditions **should** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series.
 - People aged 18-49 years with underlying medical conditions **may** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks, and

- People aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting **may** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks.

A patient's clinical team is best able to assess booster eligibility and timing, clinical status of underlying medical conditions, risk of complications, comorbidities, and transmission/exposure/infection risk.

BACKGROUND

- The COVID-19 vaccines continue to exhibit high vaccine efficacy in reducing the risk of severe disease, hospitalization, and death, including against the Delta variant. We continue to see highly effective protection against hospitalizations and severe outcomes for people who are fully vaccinated.
- Booster doses of the Pfizer COVID-19 vaccines have been recommended for groups of people with specific risk factors and for which data has shown that these individuals are more likely to become severely ill from COVID-19 infection.
- The Pfizer-BioNTech COVID-19 vaccine (COMIRNATY) is FDA-approved as a 2-dose series for the prevention of COVID-19 disease in individuals 16 years of age and older. In addition, it is available under an emergency use authorization for individuals 12 through 15 years of age and for an additional third dose for a three-dose primary series in certain immunocompromised individuals 12 years of age and older.
- The Vaccines and Related Biological Products Advisory Committee (VRBPAC) met on September 17 to solicit input from independent scientific and public health experts on the data submitted in the supplement from Pfizer to the biologics license application.
- On September 22nd, 2021, the Food and Drug Administration (FDA) authorized booster dosing of the Pfizer mRNA COVID-19 vaccine for specific individuals, to be administered 6 months or more after their primary series. This is distinct from the additional dosing recommended for immunocompromised people.
- ACIP on September 23, 2021 made an interim recommendation for the use of a booster dose of Pfizer-BioNTech COVID-19 vaccine.
- Another population was added when the CDC aligned with the FDA on September 24th endorsing offering boosters to people aged 18-64 who are at an increased risk of COVID-19 because they live or work in high-risk occupational and institutional settings.

- Currently, there is insufficient data to support the use of a booster COVID-19 vaccine dose after an initial 2-dose series of Moderna vaccine series or a single-dose Janssen COVID-19 vaccination.
- Booster doses or third doses of the Pfizer-BioNTech SARS-CoV-2 vaccine are now recommended for certain individuals at least 6 months after their primary 2-dose Pfizer mRNA COVID-19 series: people aged 65 years and older, residents age 18 years or over in long-term care facilities, people aged 50-64 years with underlying medical conditions, and individuals aged 18-49 with underlying medical conditions.
- As always, New York State continues to strive toward social equity and fair distribution of vaccine among the priority groups that are eligible to receive booster and/or additional doses to ensure fair treatment and proportionate allocations both by population and by region.

Clinical Considerations for Pfizer booster mRNA COVID-19 Vaccine Administration

The following individuals who have received a 2-dose primary series of the Pfizer-BioNTech COVID-19 vaccine, with the second dose received at least six (6) months prior are eligible for a Pfizer booster vaccine dose, if they ALSO are:

- i. Age 65 years or older, **OR**
- ii. A resident of a long-term care facility age 18 years or older **OR**
- iii. Age 50 through 64 years with one or more of the following conditions due to increased risk of moderate or severe illness or death from the virus that causes COVID-19:
 1. Cancer (current or in remission, including 9/11-related cancers)
 2. Chronic kidney disease
 3. Pulmonary disease, including but not limited to, COPD (chronic obstructive pulmonary disease), asthma (moderate-to-severe), pulmonary fibrosis, cystic fibrosis, and 9/11 related pulmonary diseases
 4. Intellectual and developmental disabilities including Down syndrome
 5. Heart conditions, including but not limited to heart failure, coronary artery disease, cardiomyopathies, or hypertension (high blood pressure)

6. Immunocompromised state (weakened immune system) including but not limited to solid organ transplant or from blood or bone marrow transplant, immune deficiencies, HIV, use of corticosteroids, use of other immune weakening medicines, or other causes
 7. Severe obesity (BMI 40 kg/m²), obesity (body mass index [BMI] of 30 kg/m² or higher but < 40 kg/m²)
 8. Pregnancy
 9. Sickle cell disease or thalassemia
 10. Type 1 or 2 diabetes mellitus
 11. Cerebrovascular disease (affects blood vessels and blood supply to the brain)
 12. Neurologic conditions including but not limited to Alzheimer's disease or dementia
 13. Liver disease; **OR**
- iv. Ages 18 through 49 years with one or more of the underlying medical conditions listed above, based on individual benefits and risks; **OR**
 - v. Ages 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting based on individual benefits and risks.
- The reactogenicity profile of a booster dose was similar to prior doses of mRNA COVID-19 vaccines.
 - Clinical considerations including proposed eligibility, timing, and mitigation strategies are discussed.
 - FDA-authorized Pfizer-BioNTech COVID-19 Vaccine is the same formulation as the FDA-approved Comirnaty and the vaccines may be used interchangeably.

Booster versus Additional Dose Terminology

Booster dosing consists of an additional dose of vaccine administered when the initial sufficient immune response to a primary vaccine series is likely to have waned over time. The need for a COVID-19 booster dose is based on age, underlying co-morbidities and risk of infection/exposure. Previously, additional dosing after an initial primary vaccine series administered when the immune response following a primary vaccine series is likely to be insufficient for moderately to severely immunocompromised people was authorized. This is different from booster dosing.

COVID-19 Vaccine Timing with other Immunizations

The booster dose is authorized for administration to these individuals at least six months following completion of their primary series and may be given at any point after that time. A patient's clinical team is best able to determine the preferred timing of booster vaccination. COVID-19 vaccines may be administered without regard to timing of other vaccines including simultaneous administration on the same day. This includes the seasonal influenza vaccines.

If administering COVID-19 vaccine at the same time as other vaccines that are likely to cause local reactions, administer them in separate limbs, if possible. Label each syringe with the name and the dosage (amount) of the vaccine, lot number, the initials of the preparer, and the exact beyond-use time, if applicable. Separate injection sites by 1 inch or more, if possible.

Testing Considerations

Currently, the utility of serologic or cellular immune testing to assess immune response to vaccination or infection and guide clinical care has not been established and is not recommended. Additional or booster doses of the same or different COVID-19 vaccines are not recommended based on antibody test results at this time.

Additional Considerations regarding Mixed Series Vaccines

Booster dosing of the Pfizer mRNA COVID-19 vaccine should only be given after an initial Pfizer 2-dose mRNA COVID-19 primary vaccine series. At this time, COVID-19 vaccine products are not considered interchangeable, and data on the safety and efficacy of a mixed-product series are limited.

Currently, there are insufficient data to support the use of an additional or booster mRNA COVID-19 vaccine dose after a single-dose Janssen COVID-19 vaccination series or after a second dose of the Moderna mRNA vaccination series. Recommendations for the Moderna and Janssen booster and additional dose vaccines should be on the horizon.

Continued Reinforcement of the Need for Prevention Measures and Mitigation Strategies

People who are older, have underlying medical conditions, or are immunocompromised (including people who receive an additional mRNA COVID-19 vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series) should be counseled about the potential for a reduced immune response or waning of response to COVID-19 vaccines and should continue to follow prevention and mitigation strategies such as:

- Continuing to wear a well-fitted mask

- Maintaining physical distancing of six feet apart
- Avoiding crowds and poorly ventilated indoor spaces
- Awareness of levels of community transmission and risk mitigation with activities
- Handwashing and health monitoring/screening
- Strongly encouraging close contacts to be vaccinated against COVID-19 to protect these high-risk people

Fully Vaccinated Status

People who have completed a primary vaccine series (e.g., 2-dose mRNA vaccine series (Pfizer-BioNTech and Moderna) or single dose of the Janssen vaccine) are considered fully vaccinated ≥ 2 weeks after completion of the series, without consideration of receipt of the additional dose or booster dose of an mRNA COVID-19 vaccine, even if they are eligible for an additional dose or booster dose.

RESOURCES:

- Guidance for The New York State COVID-19 Vaccination Program:
https://coronavirus.health.ny.gov/system/files/documents/2021/09/guidance_for_covid_vaccine_providers_9.24.21_1.pdf
- Information About Screening Checklist for COVID-19 Vaccine:
https://coronavirus.health.ny.gov/system/files/documents/2021/09/information_for_health_care_providers_covid19_screening_checklist_9.24.21.pdf
- COVID-19 Immunization Screening and Consent Form
https://coronavirus.health.ny.gov/system/files/documents/2021/09/covid-19-immunization-screening-and-consent-form_092421.pdf
- FDA Authorization for Boosters:
<https://www.fda.gov/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations>
- CDC Information on Vaccine Boosters and Eligibility
<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html>
- CDC list of Underlying Medical Conditions
<https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>
- CDC Recommendations for Coadministration of the COVID-19 vaccine and other immunizations
<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Coadministration>
- ACIP Best Practices for Timing and Spacing of Vaccines
<https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html>
- ACIP Booster Recommendations

<https://www.cdc.gov/media/releases/2021/p0924-booster-recommendations-.html>

- FDA EUA Amendment for Boosters
<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-vaccine-dose-certain-immunocompromised>
- Public Health Collaborative Booster Dosing Messaging and Outreach Tools
<https://publichealthcollaborative.org/resources/resource-covid-19-booster-dose-messaging-and-outreach-tools/>
- CDC's Clinical Considerations for COVID-19 Vaccine
<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>
- CDC mitigation strategies
<https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html>

For additional questions about vaccines or immunization recommendations, contact the NYSDOH Bureau of Immunization via email at immunize@health.ny.gov or by phone at (518) 473-4437.