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ANDREW M. CUOMO
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HOWARD A. ZUCKER, M.D., J.D.
Commissioner

LISA J. PINO, M.A., J.D.
Executive Deputy Commissioner

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

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

HEALTH ADVISORY: Additional mRNA COVID-19 vaccine dose after an initial 2-dose COVID-19 mRNA vaccine series for immunocompromised people.

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

SUMMARY

- The U.S. *Food and Drug Administration* (FDA) amended the Emergency Use Authorization (EUA) for the available mRNA vaccines to include the option of administering an additional dose of an mRNA vaccine to immunocompromised individuals.
- The Advisory Committee on Immunization Practices (ACIP) made an interim recommendation for the use of an additional dose of Pfizer-BioNTech COVID-19 vaccine or Moderna COVID-19 vaccine at least 28 days after the completion of an initial 2-dose primary mRNA COVID-19 vaccine series for moderately to severely immunocompromised people.
- Currently, there are insufficient data to support the use of an additional mRNA COVID-19 vaccine dose after a single-dose Janssen COVID-19 vaccination series in immunocompromised people.
- The age groups authorized for an additional dose remain the same as those for the primary mRNA COVID-19 dose series (Pfizer: aged ≥12 years or Moderna: aged ≥18 years).
- The reactogenicity profile of the additional dose was similar to prior doses of mRNA COVID-19 vaccines.
- Clinical considerations including proposed eligibility, timing, testing, and mitigation strategies are discussed.

Background

According to the Centers for Disease Control and Prevention (CDC), an estimated 2.7 percent or more than 7 million adults in the United States are considered immunocompromised. Additional doses of Pfizer and Moderna COVID-19 vaccines have been recommended for individuals with immunocompromising conditions as data have shown that these individuals are more likely to become severely ill from COVID-19 infection; are at a higher risk for prolonged SARS-CoV-2 infection and viral

shedding; have increased viral evolution during infection and treatment (noted in hospitalized patients); have documented lower antibody/neutralization titers to SARS-CoV-2 variants; are more likely to transmit SARS-CoV-2 to household contacts; and are more likely to have breakthrough infections.

On August 12, 2021, the U.S. Food and Drug Administration (FDA) authorized an additional dose of either mRNA COVID-19 vaccines (Pfizer: aged ≥12 years or Moderna: aged ≥18 years) for immunocompromised individuals, to be administered after their primary series. On August 13, 2021 the Advisory Committee on Immunization Practices recommended an additional dose of mRNA vaccine at least 28 days after the completion of an initial 2-dose primary mRNA COVID-19 vaccine series in immunocompromised people.

New York State continues to strive toward social equity and fair distribution of vaccine among the priority groups that are eligible to receive an additional dose to ensure fair treatment and proportionate allocations both by population and by region.

Terminology

An additional dose after an initial primary vaccine series can be administered when the immune response following a primary vaccine series is likely to be insufficient for moderately to severely immunocompromised people after an initial 2-dose primary mRNA vaccine series.

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 and timing of a COVID-19 booster dose have not been established. No booster doses are recommended at this time.

Clinical Considerations for Additional mRNA COVID-19 Vaccine Doses

For the purposes of this FDA additional dose authorization, persons with the following conditions would be eligible to receive an additional mRNA COVID-19 vaccine dose:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

Different medical conditions can result in widely varying degrees of immunosuppression. A patient's clinical team is best able to assess the level of immune competence, disease severity duration, clinical stability, complications, comorbidities, and any potential immune-suppressing therapy. Information to assist in discussions with patients about an additional dose can be found at CDC's talking with patients page. Please encourage eligible patients to receive an additional dose.

Vaccine Timing

Until additional data are available, the additional dose of an mRNA COVID-19 vaccine should be administered at least 28 days after completion of the initial 2-dose mRNA COVID-19 vaccine series.

Whenever possible, mRNA COVID-19 vaccination doses (including the primary series and an additional dose) should be completed at least two weeks before initiation or resumption of immunosuppressive therapies. The timing of COVID-19 vaccination should take into consideration current or planned immunosuppressive therapies and optimization of both the patient's medical condition and response to vaccine. A patient's clinical team is best able to determine the degree of immune compromise and preferred timing of vaccination.

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 are not recommended. Additional doses of the same or different COVID-19 vaccines are not recommended based on antibody test results at this time.

Additional Considerations

Additional doses of the mRNA COVID-19 vaccine should be the same vaccine product as the initial 2-dose mRNA COVID-19 primary vaccine series. If the mRNA COVID-19 vaccine product given for the first two doses is not available, the other mRNA COVID-19 vaccine product may be administered. A person should not receive more than three mRNA COVID-19 vaccine doses.

Currently there are insufficient data to support the use of an additional mRNA COVID-19 vaccine dose after a single-dose Janssen COVID-19 vaccination series in immunocompromised people. FDA and CDC are actively working to provide guidance on this issue.

Reinforcement of the need for prevention measures among immunocompromised people

People who 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 to COVID-19 vaccines and should continue to follow prevention and mitigation strategies such as:

- continuing to wear a well-fitted mask
- maintaining social distancing of six feet apart
- avoiding crowds and poorly ventilated indoor spaces
- handwashing and health monitoring
- strongly encouraging the close contacts of immunocompromised people to be vaccinated against COVID-19 to protect these people

Fully Vaccinated Status

Immunocompromised people who have completed a primary vaccine series (i.e., 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 the receipt of the additional dose of an mRNA COVID-19 vaccine.

Resources

- NYSDOH COVID-19 Guidance for Healthcare Providers: https://coronavirus.health.ny.gov/information-healthcare-providers
- FDA EUA Amendment for Boosters https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-vaccine-dose-certain-immunocompromised
- The CDC's General Best Practice Guidelines for Immunization https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html
- The CDC Yellow Book https://wwwnc.cdc.gov/travel/yellowbook/2020/travelers-with-additional-considerations/immunocompromised-travelers
- The Infectious Diseases Society of America policy statement, 2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host https://academic.oup.com/cid/article/58/3/e44/336537
- CDC's Clinical Considerations for COVID-19 Vaccine https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-additional-vaccine-dose
- CDC mitigation strategies https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html
- CDC: Talking with Patients who are Immunocompromised https://www.cdc.gov/vaccines/covid-19/clinical-considerations/immunocompromised-patients.html
- CDC: COVID-19 Vaccines for Moderately to Severely Immunocompromised People https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.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.