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TO: Points of Dispensing participating in the COVID-19 Vaccination Program

FROM: Judith M. Persichilli, R.N., B.S.N., M.A. Commissioner

SUBJECT: Provision of Additional mRNA Vaccine Dose for Certain Immunocompromised Individuals

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On Saturday, August 14, Points of Dispensing (PODs) could begin administration of an additional (third) Pfizer BioNTech COVID-19 vaccine or Moderna COVID-19 vaccine to certain immunocompromised persons as defined by the Centers for Disease Control and Prevention (CDC).

On Thursday, the Food and Drug Administration (FDA) issued a revised Emergency Use Authorization (EUA) and, on Friday, the CDC adopted the Advisory Committee on Immunization Practices' (ACIP) recommendations for certain immunocompromised individuals to receive an additional dose of the Pfizer-BioNTech COVID-19 Vaccine or of the Moderna COVID-19 Vaccine.

This memo serves to alert you to the amended use of the Pfizer and Moderna vaccines 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

The additional vaccine is available to people with 'moderate to severe' immune compromise due to a medical condition, or receipt of immunosuppressive medications or treatments. With emerging evidence showing some people who are immunocompromised experienced a reduced immune response to the initial COVID-19 vaccine series, this update aims to prevent serious and possibly life-threatening COVID-19 within this population.

'Moderate to severe' immune compromised is defined as people who have:

- Active treatment for solid tumor and hematologic malignancies,
- Receipt of a 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 (such as DiGeorge syndrome, Wiskott-Aldrich syndrome),
- Advanced or untreated HIV infection, and/or
- Active treatment with high-dose corticosteroids (≥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.

All PODs are advised to make the mRNA vaccines available to those who present as immunocompromised. No documentation nor doctor's notes are needed. Providers must accept self-reported eligibility from the vaccine recipient as sufficient. Do not add barriers to access for this vulnerable population receiving a needed additional dose (e.g. serologic testing or cellular immune testing outside of the context of research studies is not recommended at this time).

Vaccine types

The additional mRNA COVID-19 vaccine dose should be the same vaccine product as the initial two-dose mRNA COVID-19 primary vaccine series (Pfizer-BioNTech or Moderna).

Providers should seek to ensure completion with the same vaccine type as the original two-dose mRNA series. If a person does not present with a vaccination record or the Docket app, providers should query the New Jersey Immunization Information System (NJIIS).

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.

COVID-19 vaccination sites in New Jersey may offer Pfizer vaccine to those aged 12 and older and the Moderna vaccine to those aged 18 and older.

Note: Guidance is forthcoming from CDC and FDA for Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 Vaccine recipients. Per the CDC, there is not enough data at this time to determine whether immunocompromised people who received the J&J vaccine also have an improved antibody response following an additional dose of the same vaccine.

Administration timeline

The third dose of the mRNA vaccine should be administered no sooner than 28 days (four weeks) following the second dose of the Pfizer vaccine or of the Moderna vaccine.

Note: Series completion for the mRNA vaccines remains defined as two doses plus two weeks.

Site readiness

In the near-term, demand is uncertain. People who have a weakened immune system comprise about 3 percent of U.S. adults, and are more at risk of serious, prolonged COVID-19 illness.

To accommodate as many eligible vaccine recipients as soon as possible, all sites should have additional mRNA vaccines on hand at all vaccine sites, provide night and weekend hours, accommodate walk-ins,

and update appointment availability reflected on the New Jersey Vaccine Appointment Finder (https://covid19.nj.gov/finder). Sites are also encouraged to actively promote the availability of additional doses for immunocompromised persons. If additional vaccine supply is needed at a site, please be in touch with New Jersey Department of Health to arrange for allocation and/or transfer.

Reporting

The NJIIS has been upgraded to accept third doses in vaccine recipients' records.

However, the New Jersey Vaccine Scheduling System (NJVSS) is still undergoing upgrades to be completed this week. Until resolved, NJVSS providers should:

- Accommodate vaccine recipients as walk-ins, and
- Document additional dose recipients through either (a) manual Excel upload to NJIIS or (b) direct entry by provider into NJIIS.

Co-administration

ACIP now recommends that COVID-19 and other vaccines (e.g., influenza vaccines, childhood vaccines) may now 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.

Federal recommendation

On Thursday, August 12, the FDA issued revised EUA for the two mRNA vaccines with updated fact sheets.

- FDA statement: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-vaccine-dose-certain-immunocompromised
- For Pfizer-BioNTech vaccine:
    - Updated EUA: https://www.fda.gov/media/150386/download
    - Updated EUA Fact Sheet for Healthcare Providers: https://www.fda.gov/media/144413/download
    - Updated EUA Fact Sheet for Recipients and Caregivers: https://www.fda.gov/media/144414/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
- For Moderna vaccine:
    - Updated EUA: https://www.fda.gov/media/144636/download
    - Updated EUA Fact Sheet for Healthcare Providers: https://www.fda.gov/media/144637/download
    - Updated EUA Fact Sheet for Recipients and Caregivers: https://www.fda.gov/media/144638/download
    - Translations of the Fact Sheet for Recipients and Caregivers: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine

On Friday, August 13, the CDC adopted the ACIP recommendations for the additional dose.

- CDC statement: https://www.cdc.gov/media/releases/2021/s0813-additional-mRNA-mrna-dose.html

Provider education

Please ensure vaccination providers are 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 additional dose. Key resources:

- 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#considerations-additional-vaccine-dose
- CDC advice for talking with immunocompromised patients: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/immunocompromised-patients.html
- ACIP meeting presentations: https://www.cdc.gov/vaccines/acip/meetings/slides-2021-08-13.html
- General best practices for serving immunocompromised:
    - ACIP's General Best Practice Guidance: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html
    - CDC's Yellow Book: https://wwwnc.cdc.gov/travel/page/yellowbook-home-2020
    - IDSA's Clinical Practice Guidance: https://academic.oup.com/cid/article-pdf/58/3/e44/13142100/cit684.pdf

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 Vaccines for Moderately to Severely Immunocompromised People: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html