DATE: August 17, 2021
TO: Health Alert Network
FROM: Alison Beam, JD, Acting Secretary of Health
SUBJECT: COVID-19 Vaccines for Moderately to Severely Immunocompromised People

DISTRIBUTION: Statewide
LOCATION: Statewide
STREET ADDRESS: n/a
COUNTY: n/a
MUNICIPALITY: n/a
ZIP CODE: n/a

This transmission is a “Health Advisory” conveys the highest level of importance; warrants immediate action or attention.

HOSPITALS: PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, INFECTION CONTROL, NURSING AND LABORATORY STAFF IN YOUR HOSPITAL; EMS COUNCILS: PLEASE DISTRIBUTE AS APPROPRIATE; FQHCs: PLEASE DISTRIBUTE AS APPROPRIATE; LOCAL HEALTH JURISDICTIONS: PLEASE DISTRIBUTE AS APPROPRIATE; PROFESSIONAL ORGANIZATIONS: PLEASE DISTRIBUTE TO YOUR MEMBERSHIP

Summary
- The Pennsylvania Department of Health (DOH) is alerting healthcare facilities, and providers caring for/providing services to people whose immune systems are moderately to severely compromised about the CDC’s recommendation that they may benefit from an additional dose of mRNA COVID-19 vaccine to ensure they have enough protection against COVID-19.
- Widespread vaccination is a critical tool to help stop the COVID-19 pandemic.
- COVID-19 vaccination is widely available and is recommended for all people aged 12 years and older for the prevention of COVID-19 in the United States.
- People who are moderately to severely immunocompromised are especially vulnerable to COVID-19 because they are more at risk of serious, prolonged illness.
- Studies indicate that some immunocompromised people don’t always build adequate immunity after vaccination and in some small studies, fully vaccinated immunocompromised people have accounted for a large proportion of hospitalized breakthrough cases.
- Following the U.S. Food and Drug Administration (FDA) decision to amend Pfizer-BioNTech and Moderna’s COVID-19 vaccine Emergency Use Authorizations on August 12, 2021 and the CDC’s Advisory Committee on Immunization Practices (ACIP) recommendation on August 13, 2021, CDC recommends that people who are moderately to severely immunocompromised receive an additional dose of mRNA COVID-19 vaccine at least four weeks after the initial two-dose mRNA series.
- An additional dose is only recommended for individuals who are moderately or severely immunocompromised. CDC does not recommend additional doses or booster shots for any other population at this time.
- Healthcare facilities, providers and laboratories should ensure all persons diagnosed with COVID-19 are reported via PA-NEDSS
- Please call DOH at 1-877-PA-HEALTH or your local health department if you have any questions about this condition or if you have any cases to report.
The Department of Health (DOH) is releasing the following information from the CDC about COVID-19 vaccines for moderately to severely immunocompromised people.

**Background**

People who are moderately to severely immunocompromised make up about 2.7% of the adult population and are especially vulnerable to COVID-19 because they are more at risk of serious, prolonged illness.

Studies indicate some immunocompromised people don’t always build the same level of immunity after vaccination the way non-immunocompromised people do and may benefit from an additional dose to ensure adequate protection against COVID-19. In small studies, fully vaccinated immunocompromised people have accounted for a large proportion of hospitalized “breakthrough cases,” and that suggests immunocompromised people are more likely to transmit the virus to household contacts.

Currently, CDC is recommending that moderately to severely immunocompromised people receive an additional dose of mRNA COVID-19 vaccine at least 28 days after the completion of the initial mRNA COVID-19 vaccine series. The additional dose should be considered for people with moderate-to-severe immunocompromised status due to a medical condition, or receipt of immunosuppressive medications or treatments. This includes 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 two years of transplantation or taking immunosuppression therapy).
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome).
- Advanced or untreated HIV infection.
- 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.

An “additional dose” refers to people who are moderately to severely immunocompromised receiving an additional dose of an mRNA COVID-19 Vaccine (Pfizer-BioNTech or Moderna) at least 28 days after the completion of the initial mRNA COVID-19 vaccine series. This is because they may not have received adequate protection from their initial two-dose vaccine series. A “booster dose” is a supplemental vaccine dose given to people when the 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 has not been established, and no booster doses are recommended at this time. CDC and FDA continue to review evidence and data as it is available about whether or when booster doses for the broader U.S. public may be needed and will update guidance as more information becomes available.

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

There is not enough data at this time to determine whether immunocompromised people who received Johnson & Johnson’s Janssen (J&J/Janssen) COVID-19 Vaccine also have an improved antibody response following an additional dose of the same vaccine. One small study showing immunocompromised people have a more robust immune response to two doses of an mRNA COVID-19 vaccine (Pfizer-BioNTech and Moderna) than to a single dose of Janssen COVID-19 vaccine support use
of mRNA COVID-19 vaccines as the primary vaccination series for this population. FDA and CDC are actively working to provide guidance on this issue.

It is recommended that people talk to their healthcare provider about their medical condition, and whether getting an additional dose is appropriate for them.

Recommendations for Health Care Providers

1. CDC recommends that people who are moderately to severely immunocompromised receive an additional dose of mRNA COVID-19 vaccine at least 28 days after the 2nd dose of the original two-dose mRNA series. Ideally, the additional dose would be the same vaccine product as the initial mRNA vaccine series.
2. As a clinician, your answers to patient questions matter. Your strong recommendation can help your moderately to severely immunocompromised patients make an informed decision and feel confident about getting an additional dose of an mRNA COVID-19 vaccine.
3. Ensure all persons diagnosed with COVID-19 are reported to the PADOH web-based electronic disease surveillance system, PA-NEDSS: https://www.nedss.state.pa.us/nedss/default.aspx Additional information on reporting into PA-NEDSS can be found in HAN 534.

If you have questions about this guidance, please call your local health department or 1-877-PA-HEALTH (1-877-724-3258).

Individuals interested in receiving further PA-HANs are encouraged to register at https://han.pa.gov/.

Categories of Health Alert messages:

- **Health Alert**: conveys the highest level of importance; warrants immediate action or attention.
- **Health Advisory**: provides important information for a specific incident or situation; may not require immediate action.
- **Health Update**: provides updated information regarding an incident or situation; unlikely to require immediate action.

This information is current as of August 17, 2021 but may be modified in the future.