Additional Dose Recommended for Certain Immunocompromised Individuals

The Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) recommends the use of an additional dose of Pfizer-BioNTech or Moderna COVID-19 vaccine following a primary series in moderately and severely immunocompromised people. This recommendation follows amendments to the emergency use authorizations (EUAs) for the Pfizer-BioNTech and Moderna COVID-19 vaccines by the Food and Drug Administration (FDA). Reference CDC's Interim Clinical Considerations for COVID-19 Vaccines for more information.

Who is considered moderately or severely immunocompromised?

- 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, Wiskott-Aldrich syndromes)
- 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, TNF blockers, and other biologic agents that are immunosuppressive or immunomodulatory)

What steps should pharmacists take to verify that a person is severely or moderately immunocompromised?

Pharmacists should **obtain an attestation from the patient** that they are severely or moderately immunocompromised. Pharmacists can also utilize screening questions, review the patient's medication profile, or refer to available patient medical history to verify patient eligibility. A prescription or recommendation from the patient's physician is not required.

What steps can pharmacists take to assess and document the patient's COVID-19 vaccine history?

Before administering an additional dose, pharmacists should assess the patient's COVID-19 vaccine history by:

- Asking for the patient's COVID-19 vaccination card **and/or**
- Checking the immunization information system (IIS) to determine which vaccine(s) the patient has received. Pharmacists should look to their state IIS for guidance on documenting additional doses.

Should the additional dose be the same as the primary mRNA vaccine series?

Yes. The same mRNA product administered in the primary series should be used for the additional dose. If the product is not available, an alternate mRNA COVID-19 vaccine could be used. Further information on this will be provided in CDC's clinical guidance.

Additional Dose Recommended for Certain Immunocompromised Individuals (continued)

Is the additional dose at a different dose from the previous 2 doses?

No, the dose administered for the additional vaccine administered is the same as the previous doses administered (0.3 mL for Pfizer-BioNTech or 0.5 mL for Moderna).

When should an additional dose be administered?

An additional dose of mRNA COVID-19 vaccine should be **administered at least 28 days after the second dose in the primary series.**

If the patient received the Janssen (J&J) COVID-19 vaccine as a primary series, can they receive a dose of mRNA COVID-19 vaccine?

No. The EUA amendments only authorize an additional dose of mRNA COVID-19 vaccine for patients who received two-doses of mRNA COVID-19 vaccine as their primary series. More data is needed to evaluate the level of protection afforded to immunocompromised patients who received the Janssen COVID-19 vaccine as their primary series. FDA and CDC are working to provide more guidance on this important consideration.

How should an additional dose be billed and how will this dose be reimbursed?

When billing a COVID-19 vaccine using the pharmacy dispensing system to submit a claim to a pharmacy benefit manager (PBM), pharmacies should use a submission clarification code value of 7 when an additional third dose of the same COVID-19 vaccine product is administered. If a different vaccine product is used for the additional dose because the product used for the primary series is not available, the new NDC will identify the product administered as a distinct product.

When billing a COVID-19 vaccine through a medical billing pathway, pharmacies can reference AMA's COVID-19 CPT coding and guidance for appropriate CPT codes, as needed.

Refer to "Reimbursement for Administration of COVID-19 Vaccine(s)—What We Know" in APhA's COVID-19 Resources: Know the Facts library for an in-depth overview of the medical and pharmacy billing pathways for COVID-19 vaccines.

How is an additional dose different from a booster dose?

An additional dose is the administration of an additional dose when the initial immune response following a primary vaccine series is likely to be **insufficient**. A booster dose is a dose of vaccine administered when the initial **sufficient** immune response to a primary vaccine series is likely to have waned over time.