Medical Material Quality Control Message MMQC-21-1549

Message Number: MMQC-21-1549

Released On: 27-Sep-21
Message Class: Informational
Material Type: Vaccine

MMQC\MMI Reference: FDA Recall Reference:

ECRI Reference: DLA Reference: MFG Release Date:

Subject:

Pfizer-BioNTech / COMIRNATY COVID-19 Vaccine Booster Dose Recommendations

Reason / Information:

On September 22, 2021, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for a single booster dose of Pfizer/ BioNTech / COMIRNATY COVID-19 vaccine in certain populations, who has previously received the two-dose Pfizer/ BioNTech / COMIRNATY COVID-19 primary series at least six months ago.

On September 24, 2021 the CDC provided an updated interim guidance for this booster dose.

Disposition / Instructions:

ACTIONS NEEDED:

- 1) Military Medical Treatment Facility (MTF) and Department of Defense (DoD) vaccination sites are authorized to begin administering a single Pfizer-BioNTech / COMIRNATY COVID-19 vaccine booster dose to eligible individuals who completed the two-dose Pfizer-BioNTech / COMIRNATY COVID-19 primary series at least six months ago and meet any of the criteria in paragraph 4. The CDC statement on the booster recommendation may be found at https://www.cdc.gov/media/releases/2021/p0924-booster-recommendations-.html
- 2) Individuals eligible to receive a single booster dose must have received a two-dose Pfizer-BioNTech / COMIRNATY COVID-19 primary series. Individuals who received two-doses of Moderna, a single dose of Janssen, or a mixed vaccine series are not recommended to receive a booster at this time.
- 3) Booster doses are not part of the DoD or Federal worker mandatory COVID-19 vaccine requirement at this time.
- 4) Subsequent to the Advisory Committee on Immunization Practices (ACIP) submitting its booster recommendations to the CDC Director, update's to (ACIP's) recommendations were made under her authority. Therefore, the following groups are eligible for a booster at least six months after their Pfizer/ BioNTech / COMIRNATY COVID-19 primary series as follow:
- People 65 years and older and residents in long term care facilities should receive a booster dose
- People 50-64 years with underlying medical conditions should receive a booster dose
- People 18-49 years with underlying medical conditions may receive a booster dose
- People 18-64 years who are increased risk for COVID-19 exposure and transmission because of occupational or institutional settings may receive a booster dose
- 5) Individuals not meeting criteria for the booster shot are not recommended to receive a booster dose at this time. Sites should continue to monitor CDC's Interim Clinical Considerations for the use of COVID-19 vaccines currently approved or authorized in the United States for additional or clarifying booster recommendations at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.htm
- 6) Proof of an underlying condition or an occupational risk are not required to receive a booster dose at MTF or DoD vaccination sites. Further, ACIP has prepared frequently asked questions to assist vaccination sites when engaging with vaccine booster questions (see attachments under additional documentation / attachment).
- 7) DoD sites are required to provide updated FDA fact sheets for the Pfizer/ BioNTech / COMIRNATY COVID-19 vaccine to vaccine recipients, revised on 22 September 2021 (see attachments under additional documentation / attachment).
- 8) Continue using DHA Form 207v13 for COVID-19 vaccine screening located on the DHA Forms Management site https://info.health.mil/cos/admin/DHA Forms Management/Pages/DHA-Forms-Management.aspx

Item Information:

NSN (FSC-NIIN): 6505 - 016924172 **NDC:** 59267-1000-02

Nomenclature: Coronavirus Vaccine -80C to -60C (VIAL, 195S)

UI: CT

Manufacturer: Pfizer-BioNTech

Distributor:

LOT / SN:

All

NSN (FSC-NIIN): 6505 - 016924173 NDC: 59267-1000-01

Nomenclature: Coronavirus Vaccine -80C to -60C (VIAL)

UI: VI

Manufacturer: Pfizer-BioNTech

Distributor:

LOT / SN:

All

NSN (FSC-NIIN): 6505 - 016924174 **NDC:** 59267-1000-03

Nomenclature: Coronavirus Vaccine -80C to -60C (VIAL, 25S)

UI: CT

Manufacturer: Pfizer-BioNTech

Distributor:

LOT / SN:

All

Service/Additional Instructions:

POC Contact Information:

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Additional Message Recipients:

Please ensure dissemination of this information to the following:

Command Channels
Immunization Clinics
Medical Log Officers
Medical Staff
Pharmacy Officers
Supply Officers
Supply Officers
Supported Activities/Centers
Vaccince Shot Teams

Message Dissemination Authorization

AF Activities will take action as prescribed in AFMAN41-209, Medical Logistics Support, Chapter 7. For MAJCOMS & NGB – This Msg has been transmitted to all designated subordinate medical activities

See Army Regulation (AR) 40-61, 28 January 2005, Chapter 4, and The Department Of The Army Supply Bulletin (SB 8-75-11) For Applicable Policies and Procedures.

DODD 5105.22 and DODD 6025.13

COMNAVSURFPAC/COMNAVSURFLANT INSTRUCTION 6000.1. SECTION 12. Procedures for Quality Control Surveillance of the Medical Material, g. The SMDR and Pharmacy technician shall subscribe to MMQC messages to ensure all drug recall, extensions and suspensions are addressed in an expeditious manner.

Additional Documentation / Attachments

MMQC-21-1549 1.p

MMQC-21-1549 2.EUA

MMQC-21-1549 3.EUA

*** END OF MESSAGE ***