

Medical Material Quality Control Message

MMQC-22-1268

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Subject:

Comirnaty-labeled (Tris-Sucrose/Gray Cap) Storage, Handling and Ordering Guidance

Reason / Information:

Defense Health Agency in conjunction with the US Army Medical Materiel Agency Distribution Operations Center (USAMMA DOC) are providing ordering guidance and implementation guidance for the Pfizer BioNTech, Comirnaty-labeled, Tris-Sucrose/Gray Cap, vaccine for 12 years and older. REASON: Department of Defense will be introducing Pfizer BioNTech, Comirnaty-labeled, Tris-Sucrose/Gray Cap vaccine into the distribution process.

Disposition / Instructions:

BACKGROUND:

1) On 16 December 2021, the FDA approved Pfizer-BioNTech supplement to the FDA approved mRNA COMIRNATY vaccine to include the new 30mcg dose formulation (Tris-Sucrose) of COMIRNATY. This formulation will have a gray cap to distinguish the product from other formulations of Pfizer-BioNTech vaccine currently available. The COMIRNATY package

insert is available at <https://go.usa.gov/xzff4> (See image under Additional Documentation / Attachments)

2) All gray cap Pfizer-BioNTech vaccine released to the Department of Defense (DoD) will be the COMIRNATY labeling on the vials. COMIRNATY labeled vaccine may be used for the Service member COVID-19 vaccine mandate. Service members will continue to have the option to receive the Moderna vaccine, or any other EUA approved or WHO EUL products to meet the requirement.

----- COMIRNATY labeled gray cap or Pfizer-BioNTech purple cap may be mandated to meet the DoD requirement. DoD will NOT receive EUA gray cap Pfizer-BioNTech. All Pfizer-BioNTech products at DoD facilities can be used for the Service member mandate.

3) Comirnaty-labeled (Tris-Sucrose) vaccine differs from the purple cap Pfizer-BioNTech vaccine in several distinct areas. Carefully review the attached FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS) for clinical information and Product Information Below. (See image under Additional Documentation / Attachments)

PRODUCT INFORMATION:

----- COMIRNATY multiple dose vial with a gray cap and a label with a gray border contains a volume of 2.25 mL, supplied as a frozen suspension that does not contain preservative.

----- Each vial must be thawed prior to administration.

----- Vials may be thawed in the refrigerator 2C to 8C (35F to 46F) or at room temperature up to 25C (77F)

----- One vial contains 6 doses of 0.3 mL. (10 vials per box)

----- The vial is for people 12 years of age and older that DOES NOT require diluent has a gray cap and gray border on the label. The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older when prepared according to their respective instructions for use can be used interchangeably

----- Discard 12 hours after first punctured when stored at 2C to 25C (35F to 77F)

----- Comirnaty package insert may be found at <https://www.fda.gov/media/151707/download>

*It is IMPERATIVE that sites maintaining both the Pfizer-BioNTech PBS/purple cap vials and Comirnaty-labeled Tris-Sucrose/gray cap vials store, prepare, and administer the vaccine according to their respective instructions for use.

Individuals who will be administering the Pfizer-BioNTech Grey Cap product will need to complete the CDC COVID-19 Pfizer Vaccine training module if previous training was taken before 7 Mar 22. CDC COVID-19 Vaccine Training Modules for Pfizer-BioNTech: <https://go.usa.gov/xzffR>

4) Resources for healthcare personnel to safely implement the use of the grey cap vaccine:

----- CDC COVID-19 Quick Reference Guide for HCP, updated 26 APR 22: <https://go.usa.gov/xzfff>

----- CDC Pfizer-BioNTech Gray Cap website which includes a storage and handling summary, storage and handling and Beyond Use Dating labels, and the preparation and administration guide: <https://go.usa.gov/xzfm3>

5) The current Pfizer-BioNTech Standing Orders and COVID-19 Vaccine Screening Form can be used for the admiration of

this vaccine.

ACTIONS NEEDED:

ORDERING GUIDANCE:

1) Medical Treatment Facilities and vaccination sites should submit Comirnaty-labeled (Tris-Sucrose/Gray Cap) vaccine, via the USAMMA DOC portal at <https://a01.usamma.amedd.army.mil/docvac/Account/Login>

2) MTF's shall continue order the Pfizer-BioNTech, Purple Cap, until inventory is exhausted or expired.

3) Vaccinations sites shall consider the following guidelines when submitting their order:

----- Review total requirement for the 12 years and older population still needing to meet vaccination requirements.

----- Minimum ordering quantity 300 doses (5 boxes)

----- MTFs and vaccination sites located OCONUS, will use the USAMMA DOC ordering portal.

----- All orders for OCONUS sites will be filled at 100 percent, to ensure maximum receipt of vaccine received for the service members within country/theater.

SHIPPING INFORMATION:

1) Vaccine directly from the Pfizer, the vaccine will arrive in a thermal shipping container at ultra-cold temperatures between -90°C and -60°C (-130°F and -76°F) with dry ice or between -25°C and -15°C (-13°F and 5°F).

2) Remove the temperature monitoring device from the shipping container and return using the included pre-labeled foldable return box.

3) Dispose of the single-use thermal shipping container. Do NOT use the thermal shipping container for storage.

4) An ancillary supply kit which have been reconfigured to support the number of doses ordered will be delivered separately from the vaccine and includes: Needles, syringes, sterile alcohol prep pads, vaccination record cards, and some PPE. Ancillary supply kits

5) OCONUS shipments will arrive from DLA will be packaged at 2C to 8C. Upon receipt immediately transfer to the refrigerator at 2C to 8C (35F to 46F), stored for up to 10 weeks.

STORAGE GUIDANCE:

1) Ultra-Cold Freezer: The vaccine may be stored in an ultra-cold freezer between -90C and -60C (-130F and -76F). If received frozen at -90C and -60C (-130F and -76F). If received frozen at

----- Store vaccine vials upright in the tray or box.

----- Minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light.

----- Vaccine may be stored until the expiration date.

2) Refrigerator: Once received, frozen vials may be immediately transferred to the refrigerator at 2C to 8C (35F to 46F), thawed and stored for up to 10 weeks.

*If cartons of COMIRNATY multiple dose vials with gray caps and labels with gray borders are received at 2C to 8C, they

should be stored at 2C to 8C.

----- Monitor how long the vaccine has been in the refrigerator using CDC's beyond-use date labels for Pfizer-BioNTech COVID-19 Vaccine.

----- Store the vaccine in the tray or box.

----- Minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light.

----- Ensure that the carton has been updated to reflect the 10-week refrigerated expiry date.

----- A carton of 10 vials may take up to 6 hours to thaw at this temperature.

----- DO NOT refreeze thawed vaccine

*COMIRNATY multiple dose vials with gray caps and labels with gray borders may be stored at room temperature 8C to 25C (46F to 77F) for a total of 12 hours prior to the first puncture.

NOTE: DO NOT store vials at -25C to -15C (-13F to 5F).

EXPIRATION INFORMATION: The manufacture date is printed on the vial (gray cap), count out 12 months, using the month printed on the vial as month one. (11 months from the printed date on the vial)

---- The vaccine expires on the last day of the 12th month

---- The 10-week refrigerated expiry date should be recorded on the carton at the time of transfer.

---- Regardless of storage condition, the vaccine should not be used after the expiration date printed on the vial and cartons.

3) DoD REDISTRIBUTION:

---- Redistribution of vaccine if local redistribution is needed, vials may be transported at 2C to 8C (35F to 46F). DO NOT REFREEZE upon completion of redistribution.

Item Information:

NSN (FSC-NIIN): 6505 - 016995814

NDC: 00069-2025-10

Nomenclature: COMIRNATY 30MCG/0.3ML VAC-GRAY 1.8ML (CA OF 10 VI OF 1.8ML)

UI: CA

Manufacturer: PFIZER

Distributor:

LOT / SN:

All

Service/Additional Instructions: