Medical Material Quality Control Message

MMQC-23-1255

Message Number: MMQC-23-1255
Released On: 20 September 2023
Message Class: Informational
Material Type: Vaccine
MMQC/MMI Reference:
FDA Recall Reference:
ECRI Reference:
DLA Reference:
MFG Release Date:

Subject:
Ordering Guidance for 2023-2024 mRNA COVID-19 vaccines Moderna and Pfizer

Reason / Information:
The US Army Medical Materiel Agency Distribution Operations Center (USAMMA DOC) in
conjunction with Defense Health Agency (DHA) are providing ordering guidance for 2023-
2024 mRNA Pfizer and Moderna COVID-19 fall vaccines. REASON: On 11 September
2023, the U.S. Food and Drug Administration (FDA) took action approving two mRNA
vaccines for 12 years and older and authorizing for emergency use (EUA) three vaccines for
children under the age of 12 years.

Disposition / Instructions:
BACKGROUND: On 11 September 2023, the FDA approved and authorized for EUA updated
mRNA COVID-19 vaccines (2023-2024 formula) that include a monovalent (single) component that
 corresponds to the omicron variant XBB.1.5 of SARS-CoV-2.

ACTIONS NEEDED:
1) Medical Treatment Facilities (MTFs) will no longer order COVID-19 vaccines via the USAMMA
DOC ordering portal/SharePoint site.
   a. Defense Logistics Agency (DLA) along with DHA and other stakeholders are working
diligently on quickly enabling the new routine ordering of COVID-19 vaccines using the
Defense Logistics Agency (DLA) Pharmacy Prime Vendor (PPV) program with Cencora,
(formerly known as AmerisourceBergen).
   b. There is a temporary gap in availability of product as Cencora awaits arrival of product and
fills current backorders that were received from other customers.
   c. Tentatively shipments will begin the week of 25 September 2023 for the 2023 – 2024
mRNA COVID-19 vaccines.

2) Effective immediately, MTFs may begin submitting “HOLDING ORDERS” with the PVP to be
placed in the queue for when vaccine becomes available for distributions. (See attached document
for instructions).
   a. Holding Orders shall be placed electronically, as an off-line (SUBMIT).
   b. During product non-availability the Holding Orders will prevent transactions from being
cancelled due to a “Fill or Kill” requirement.

c. Credit balances cannot be used to place Holding Orders.

d. MTFs submitting Holding orders before Oct 1 23, shall use existing Pharmacy Operational funding.

3) Once the non-availability period has passed MTFs will continue submitting orders through the PVP (Cencora) for the 2023 – 2024 mRNA COVID-19 vaccines using their normal Defense Logistics Medical Standard Support (DMLSS)/Theater Enterprise-Wide Logistics System (TEWLS) ordering process for PV ordering by setting the source of supply (SOS) to PVP for any of the national drug codes (NDC) listed below. Below are some ordering changes:

a. COVID-19 Vaccines will no longer be a free issue item. Please work with your financial team to ensure funding is available for the purchasing of the vaccines.

b. MTFs submitting COVID orders within FY24 should tag all 2023-2024 COVID-19 vaccine purchases with FCA Code 4873.

c. COVID-19 vaccines will not be tracked within the DMLSS Assemblage Management module.

4) CONUS PVP Customers will notice the following changes when ordering/receiving COVID-19 vaccines.

a. MODERNA VACCINES:
   i. PVP will ship Moderna vaccines frozen at -20C.
   ii. PVP will not have temperature monitoring devices in their shippers, they will be using a pre-qualified frozen (-20C) shipper.
   iii. Store vaccine at -20C to obtain full shelf-life or store at 2C to 8C for 30 days.
   iv. Redistributions are only recommended in a frozen/solid (-20C).
   v. Minimum ordering quantity: 60 doses.

b. PFIZER VACCINES:
   i. PVP will ship Pfizer vaccines at refrigerated temp of 2C-8C.
   ii. When ordering note the reduced shelf-life of 10 weeks from the initial 2C-8C packaging which will be indicated by a By Use Date (BUD) Label that the PVP will adhere to the material.
   iii. No re-freezing is authorized by the customer post-receipt.
   iv. Minimum ordering quantity: Adult -10 doses / Pediatric – 30 doses presentations.

5) OCONUS PVP Customers will notice the following changes when ordering/receiving COVID-19 vaccines.

a. MODERNA VACCINES:
   i. PVP will be using their standard FedEx Priority Alert contract, shipping schedules, and transit times: Germany will ship on Mondays, South Korea will ship on Fridays, and all other locations will ship on Mondays and Fridays.
   ii. Material will continue to distribute out of the same two current OCONUS supporting distribution centers (DCs) (AB Sacramento – PACOM/AB Bethlehem – EUCOM).
   iii. Product will ship in DLA’s (PVP) “new” frozen (-20C) packaging, utilizing their standard shipper, with modified Utek coolant materials, and will include a Purple-labeled Sensitech TempTale (at full shelf life).
   iv. Customers will follow the same standard receiving process as all other Pharm PV Cold Chain Management (CCM) shipments.
   v. DLA Troop Support CCM will continue to send pre-alerts emails for the first year; after that, customers will receive the PV’s standard automated shipping alerts.
   vi. Minimum ordering quantity: 60 doses.

b. PFIZER VACCINES:
   i. PVP will be using their standard FedEx Priority Alert contract and transit times.
ii. Product will initially be staged at a centralized PVP DC, and then moved to the standard AB Sacramento (PACOM) and AB Bethlehem (EUCOM) DCs, with a By Use Date (BUD) label affixed to the material reflecting the new 10-week shelf life (initiated at 2-8C repackaging).

iii. PACOM will be shipping on Fridays only and EUCOM will be shipping on Mondays only.

iv. Material will ship in DLA’s (PVP’s) standard refrigerated (2-8C) shipper, to include an Orange-labeled Sensitech TempTale (at full shelf life).

v. Customers will follow the same standard receiving process as all other Pharm PV CCM shipments.

vi. DLA Troop Support – CCM will continue to send pre-alerts emails for the first year; after that, customers will receive the PV’s standard automated shipping alerts.

vii. Minimum ordering quantity: Adult -10 doses / Pediatric – 30 doses presentations.

6) Navy Fleet assets will order by placing MilStrip orders directly with DLA to utilize the Direct Vendor Delivery (DVD) program, as currently done for all other non-DLA depot stocked vaccines. The Fleet Prime Vendor program will not support COVID vaccine requirements.

7) Non-Pharm PV customers will be expected to order through their Theater Lead Agent for Medical Materiel (TLAMM), which is the standard SOS for most vaccines, or they may also utilize the DLA DVD program.

8) MTF’s with questions or concerns related to the PVP Cold Chain program and/or product quality should continue to contact DLA Troop Support Cold Chain Management (CCM) program office, per the terms of the PVP contract.

**Item Information:**

**NSN (FSC-NIIN):** 6505 – NS1  
**NDC:** 80777-0102-95  
**Nomenclature:** COVID-19 VACCINE MRNA (MODERNA) (PF) 50MCG/0.5ML INJ, VIAL  
**UI:** CA  
**Manufacturer:** MODERNA  
**LOT / SN:** ALL LOTS  
**NOTE:** SPIKEVAX / CARTON, 10 SINGLE-DOSE VIALS

**NSN (FSC-NIIN):** 6505 – NS2  
**NDC:** 80777-0102-96  
**Nomenclature:** COVID-19 VACCINE MRNA (MODERNA) (PF) 50MCG/0.5ML INJ, SYR  
**UI:** CA  
**Manufacturer:** MODERNA  
**LOT / SN:** ALL LOTS  
**NOTE:** SPIKEVAX / CARTON, 10 PRE-FILLED SYRINGES

**NSN (FSC-NIIN):** 6505 – NS3  
**NDC:** 80777-0102-93  
**Nomenclature:** COVID-19 VACCINE MRNA (MODERNA) (PF) 50MCG/0.5ML INJ, SYR  
**UI:** CA  
**Manufacturer:** MODERNA  
**LOT / SN:** ALL LOTS  
**NOTE:** SPIKEVAX / CARTON, 10 BLISTER-SEALED PRE-FILLED SYRINGES
NSN (FSC-NIIN): 6505 – NS4
NDC: 80777-0287-92
Nomenclature: COVID-19 VACCINE MRNA (MODERNA) (PF) 25MCG/0.25ML INJ,VI
UI: CA
Manufacturer: MODERNA
LOT / SN: ALL LOTS
NOTE: CARTON, 10 SINGLE-DOSE VIALS

NSN (FSC-NIIN): 6505 – NS5
NDC: 00069-2362-10
Nomenclature: COVID-19 VACCINE MRNA (PFIZER) (PF) 30MCG/0.3ML INJ,VIL
UI: CA
Manufacturer: PFIZER-BIONTECH
LOT / SN: ALL LOTS
NOTE 1: COMIRNATY (COVID-19 Vaccine, mRNA, 2023-2024 Formula)
NOTE 2: CARTON, 10 SINGLE-DOSE VIALS

NSN (FSC-NIIN): 6505 – NS6
NDC: 00069-2392-10
Nomenclature: COVID-19 VACCINE MRNA (PFIZER) (PF) 30MCG/0.3ML INJ,VIL
UI: CA
Manufacturer: PFIZER-BIONTECH
LOT / SN: ALL LOTS
NOTE 1: COMIRNATY (COVID-19 Vaccine, mRNA, 2023-2024 Formula)
NOTE 2: CARTON, 10 PRE-FILLED SYRINGES
NOTE 3: Pending pricing

NSN (FSC-NIIN): 6505 – NS7
NDC: 59267-4331-02
Nomenclature: PFIZER C19VACCINE 5YR-12YR 10X.48ML SDV
UI: CA
Manufacturer: PFIZER-BIONTECH
LOT / SN: ALL LOTS
NOTE: CARTON, 10 SINGLE-DOSE VIALS

NSN (FSC-NIIN): 6505 – NS8
NDC: 59267-4315-02
Nomenclature: PFIZER C19 VACCINE 6M-<5YR 10X.48ML MDV
UI: CA
Manufacturer: PFIZER-BIONTECH
LOT / SN: ALL LOTS
NOTE: CARTON, 10 MULTI-DOSE VIALS
Service/Additional Instructions:

Screening Forms and Standing Orders are being updated. Updated guidance for COVID-19 vaccination and myocarditis or pericarditis can be found at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#myocarditis-pericarditis

Reorganization and consolidation of sections on contraindications and precautions, including allergic reactions to COVID-19 vaccines can be found at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#contraindications

Interim Clinical Guidance can be found at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

POC Contact Information:

Air Force
Email: usaf.detrick.afmoa.mbx.sgmx-readiness-vaccines@mail.mil
Phone (COMM): 301-619-4183
Phone (DSN): 312-343-4183
Fax:

Army - USAMMA DOC Vaccines
Email: usarmy.detrick.usamma.mbx.vaccines@army.mil
Phone (COMM): 301 619-4128/4318
Phone (DSN): 343-4128/4318
Fax: 301-619-4468

DHA 24/7 Immunization Healthcare Support Center
Email: DoDvaccines@mail.mil
Phone (COMM): 877-438-8222
Phone (DSN): 312-761-4245
Fax:

NAVY OR MARINES
Email: usn.detrick.navmedlogcomftdmd.list.vialhelp@mail.mil
Phone (COMM): 301-619-8054
Phone (DSN): 343-8054
Fax: 301-619-2473

USAMMC-E
Email: usarmy.rheinland-pfalz.medcom-usammce.list.dtd-quality-assurance@mail.mil
Phone (COMM): 011-49-6331-86-7118/7181
Phone (DSN): 495-6265
Fax: 6218

USAMMC-K
Email: usarmy.carroll.usammc-k.list.usammc-k-customer-support@mail.mil
Phone (COMM): 05033374490/+821092328897
Phone (DSN): 315-737-4490
Fax:

USCG
Email: D05-DG-HSWLSC-USCG-Pharmacy-Logs@uscg.mil
Phone (COMM): 757-628-433
Phone (DSN): 757-628-433
Fax:

Additional Message Recipients:

Please ensure dissemination of this information to the following:
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.


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.

*** END OF MESSAGE ***
Standard Operating Procedure

Pharmaceutical Prime Vendor Holding Orders

(AmerisourceBergen Customers Only)

Overview

The holding order process has been established to enable eligible ordering facilities to place orders for items that are on prolonged manufacturer backorder or have a limited shipment status. Eligibility will be determined as mutually acceptable to DLA TS and the Primary Supplier. The holding order process is designed to allow ordering facilities to keep non-narcotic orders open for up to 180 days (60 days for narcotics) which would have otherwise been rejected by the Prime Vendor (PV) with a R4: Manufacturers or National Backorder rejection code. Holding orders may only be placed from ordering accounts (non-credit). It is not recommended for authorized ordering facilities to use the holding order process when a manufacturer has announced that a backorder item is within 30 days of becoming fully available.

Holding orders shall be placed electronically by all eligible ordering facilities. Manual holding orders can be placed in limited circumstances when electronic ordering capability is not available. For manual holding orders placed as an offline, non-submit, the ordering facility must agree to a flat fee of $25.00 per order to be deducted from their credit account to compensate the PPV for this additional service. The fee will not be deducted until the product (full or partial quantity) is delivered. There will be no fee for Holding Orders that result in no quantity delivered to the customer. NOTE: CII Narcotic orders must be submitted manually until notice from Primary Supplier that NORA/CSOS orders can be submitted electronically.

Placing a Holding Order

The following provides a step-by-step guide to the holding order process:

Customer

1. An eligible ordering facility identifies items which are on long term backorder or have a limited shipment status.

2. **Electronic Ordering**

   The ordering facility prepares a single line, (non-credit account) off-line (submit) order through DMLSS, TEWLS or through their assigned web ordering system for the holding orders to be sent electronically. **NOTE:** CII Narcotic orders must be submitted manually until notice from Primary Supplier that NORA/CSOS orders can be submitted electronically.
3. **Manual Ordering**

The ordering facility prepares a **single line, offline, (non-credit account) non-submit order** via a DD 1155 for each item. DMLSS customers can generate the 1155 in the system however, TEWLS customers will need to generate the 1155 via a pdf file. Multi-line orders **WILL NOT** be accepted. **Holding orders can only be placed via a customer ordering account (non-credit).** Customers who intend to submit a holding order for narcotics will also need to generate a DEA Form 222.

Once the DD 1155 is generated, the preapproved ordering facility will submit the single line, offline non-submit order to one of the PV’s following customer service email addresses:

CONUS: DoDCustomerCARE@amerisourcebergen.com  
OCONUS: DODOCONUS@amerisourcebergen.com

**Note:** It is **critical** that the subject line of the email is titled “Holding Order”. Customers must also include pertinent data such as ordering account and PIID numbers as well as confirm that they accept the $25 flat fee for each order submitted.

4. After the order is submitted, the preapproved ordering facility must keep the holding order(s) open for 180 days **(60 days for narcotics) or until the product ships. If product does not become available and ship within the allotted 180 day (60 day for narcotics) timeframe**, the ordering facility may cancel the holding order. The ordering facility may not cancel holding orders in DMLSS/TEWLS/EDI until they first notify the PV. The PV can be notified through the following customer service email addresses:

CONUS: DoDCustomerCARE@amerisourcebergen.com  
OCONUS: DODOCONUS@amerisourcebergen.com

**Note:** Please ensure that the subject line states **“holding order cancellation”**. Customers should also include pertinent data such as ordering account and PIID numbers. The PV may decline to cancel the line if the order is in process.

**Prime Vendor**

1. The PV will accept electronic holding orders from the eligible ordering facilities. If a manual holding order is placed, the PV may not accept the manual order without a copy of a generated DD 1155 from DMLSS customers and a pdf file of the order from TEWLS customers. **The PV will not accept holding orders for narcotics without receiving a DEA Form 222.**
2. Once the ordering facility submits a manual holding order, the PV will respond with an email confirming receipt of the order. The PV will then input the holding order into their order processing system as a backordered item until materiel becomes available or 180 days (60 days for narcotics) has passed, whichever comes first. If the holding order exceeds 180 days (60 days for narcotics) then the PV may cancel the order. The PV must communicate its intent to cancel the holding order with the customer prior to making a cancellation.

The price for a holding order item is determined at the time of the order confirmation (EDI 855). As means to ensure pricing accuracy, the PV will not generate the EDI 855 until the product is received from the manufacturer. The EDI 855 must be sent/received prior to the advanced shipment notice (EDI 856) which is prior to shipment to the customer.

3. If a **manual holding order** is placed and confirmed as delivered (full or partial), the PV may deduct the $25 flat fee per order from the customer’s credit account. If no product is delivered, the PV may not deduct this flat fee from the customer’s credit account.

**Electronic holding orders shall not be subject to a fee.**

---

**Customer Holding Order Management**

Customers are encouraged to utilize the “Backorder Report” located in AB Order to track all holding orders placed. This report is especially useful for comparing the unit price of when the order was placed versus the current unit price *(prices are subject to change throughout the 180 day period. Customers must keep track of the unit price at the time the order was placed. This report will only display the current unit price of the item).* Customers who wish to access this backorder report may do so by through the following steps:

Log into AB Order at [https://abcorderhs.amerisourcebergen.com](https://abcorderhs.amerisourcebergen.com).

1. If the user does not have an AB Order account, they can contact AB Customer Systems Support at CustomerSystemsSupport@amerisourcebergen.com to have one created.

2. Once logged in, select the ABC ORDER REPORTING tab located at the top of the screen

3. The first thing you do is to go ABC Order Reporting, and under the Report Templates, select **View Full Template Library**.

4. You will then see the list below and can select **BACKORDERS** from the list.
5. Select your date range.

Order Date Range
Select a date range for your report

Start Date (MM/DD/YY) 09/11/21 - 11/09/21

6. Select the Backorder Status (all are preselected as a default):

Backorder Status
Select at least one backorder status to include in this report

- Filled
- Partially Filled
- Not Filled

7. The next step is to select the account(s) for which to run the report.
8. You can then set a filter if you wish, EX: material number or ndc.

9. Finally, select the columns you want included in the report.

10. You can then save and generate the report.

11. Once the report is generated, users can choose to export it to an excel spreadsheet. Users can also schedule to have an updated report sent to their email. For any additional questions regarding the use of this or any report in Passport, please contact Customer Systems Support at CustomerSystemsSupport@amerisourcebergen.com.