

Medical Material Quality Control Message

MMQC-23-1255

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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.navy.medlogcomftdmd.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):

Fax: 315-737-4490

USCG

Email: D05-DG-HSWLSC-USCG-Pharmacy-Logs@uscg.mil

Phone (COMM):

Phone (DSN):

Fax: 757-628-433

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
Supported Activities/Centers

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.

*** 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 material 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>.

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**.



[View Full Template Library](#)

4. You will then see the list below and can select **BACKORDERS** from the list.

Create a New Report



Blank Report | Select a report type to build from scratch.

Accounts

Products

Purchases

Report Templates | Quick-start your report with pre-filled columns and filters. You can always change these settings.

Search by Report Name or Description

Filter by

All Types

Account Listing

Account details

Accounts Report

Backorders

Provides status of items placed on Backorder

Purchases Report

Contract Changes

Contract changes by date range

Contracts Report

Contract Eligibility and Restrictions

Current contract eligibility and restrictions

Contracts Report

Close

5. Select your date range.

Order Date Range

Select a date range for your report

Select a date

Start Date (MM/DD/YY)

09/11/21

End Date (MM/DD/YY)

11/09/21

September 2021

S	M	T	W	T	F	S
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

October 2021

S	M	T	W	T	F	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

Today

Yesterday

Last 3 Days

Last 7 Days

Last 30 Days

Last 60 Days

Last 90 Days

Last Week

Last Month

Last Month + Current Month

Last 3 Months

Cancel

Apply

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


Backorder Status

Select at least one backorder status to include in this report

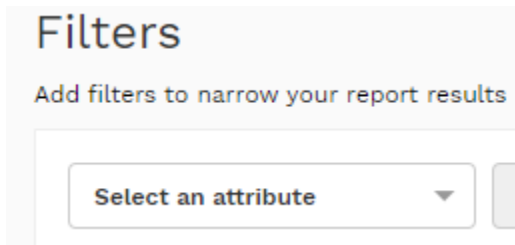
Filled Partially Filled Not Filled

7. The next step is to select the account(s) for which to run the report.

Add an Account

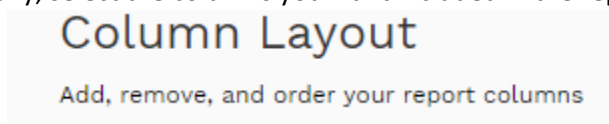
 Search your accounts

8. You can then set a filter if you wish, EX: material number or ndc.



The screenshot shows a section titled "Filters" with the subtitle "Add filters to narrow your report results". Below this is a dropdown menu with the text "Select an attribute" and a downward-pointing arrow. To the right of the dropdown is a vertical scrollbar.

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



The screenshot shows a section titled "Column Layout" with the subtitle "Add, remove, and order your report columns".

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.