Vaccine Provider Weekly Update

August 18, 2021

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

NC DHHS COVID-19 Response

AGENDA

Slide #	Topic
3, 4	FDA/CDC/ACIP 3rd dose authorization
5	Reminder: Monoclonal Antibodies for COVID-19
6	Pfizer and Janssen (Johnson & Johnson) Updates
7	Long-Dated Pfizer COVID-19 Vaccine Ordering Process
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FDA/CDC/ACIP 3RD DOSE AUTHORIZATION

Last week, the ACIP and CDC backed the **FDA modification of the Emergency Use Authorizations (EUAs) for Pfizer-BioNTech COVID-19 vaccine and Moderna COVID-19 vaccine to allow for administration of an additional dose (i.e., a third dose) of an mRNA COVID-19 vaccine after an initial 2-dose primary mRNA COVID-19 vaccine series for moderate to severely immunocompromised people**. The age groups authorized to receive the additional dose are unchanged.

The additional dose should be the same vaccine product as the initial 2 dose mRNA vaccine

If the vaccine product given for the first two doses is not available, the other vaccine product may be administered. A person should not receive more than three mRNA COVID-19 doses. The additional dose should be administered at least 28 days after the completion of the initial vaccine series.

Patients should **self-attest** to their medical condition and documentation should occur in the **CVMS notes**

The clinical considerations for use of an additional dose of an mRNA COVID-19 vaccine **apply only to people who are moderately or severely immunocompromised**

If you and your patient have jointly made a decision related to an additional dose outside the EUA…

No matter the reason, administration details must always be captured in CVMS per your provider agreement. **Currently there are insufficient data to support the use of an additional mRNA COVID-19 vaccine dose after a single-dose Janssen COVID-19 vaccination series in immunocompromised people.** FDA and CDC are actively working to provide guidance on this issue.

Other resources and links:

Statewide Standing Order for FDA Authorized
Pfizer and Moderna COVID-19 Vaccine Administration
Pfizer EUA
Pfizer Health Care Provider Fact Sheet
Pfizer Fact Sheet for Recipients
Moderna EUA
Moderna Health Care Provider Fact Sheet
Moderna Fact Sheet for Recipients

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ADDITIONAL DOSES FOR IMMUNOCOMPROMISED CONDITIONS

Currently, CDC is recommending that moderately to severely immunocompromised people receive an additional dose.

Conditions and treatments associated with moderate and severe immunocompromise include but are not limited to:

- 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 syndrome, Wiskott-Aldrich syndrome)
- 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, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

Patients should self-attest to their medical condition.

Conditions that would be considered to result in a moderate or severe compromise are **further described on the CDC website and the State Standing Order**

Additional Doses for Other Populations Not Authorized

Additional doses for those patients who are not immunocompromised remains outside of the FDA's EUAs and are not recommended at this time.

- The CDC COVID-19 Vaccination Program Provider Agreement currently directs providers to follow the U.S. Food and Drug Administration, EUA and CDCs Advisory Committee on Immunization Practices (ACIP) recommendations for any COVID-19 vaccine administration.
- Coverage under the Public Readiness and Emergency Preparedness (PREP ACT) extends to organizations if they comply with the EUA and ACIP recommendations, however, it may not cover a provider if there is an adverse event when vaccine given outside of current EUA.
- Under the CDC Provider agreement, providers are not allowed to offer additional doses outside of EUA authorization. The FDA is looking into expanding the regulatory guidance to allow "off-label use" and changes may occur soon.

mAb Antibody Treatment for Immunocompromised Individuals with Active Infection

In the case that infection is already active, FDA recommends the following:

- Immunocompromised individuals should discuss monoclonal antibody treatment options with their health care provider should they contract or be exposed to COVID-19. The FDA has authorized monoclonal antibody treatments for emergency use during this public health emergency for adults and pediatric patients (ages 12 and older weighing at least 40 kilograms or about 88 pounds) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

REMINDER: MONOCLONAL ANTIBODY THERAPY

REGEN-COV (Casirivimab + Imdevimab) is authorized for emergency use as treatment or post-exposure prophylaxis (prevention) in some individuals 12 years of age and older who are considered high-risk for severe COVID-19.

Monoclonal antibodies are not a substitute for vaccination against COVID-19

How are mAbs administered?
Under the EUA, mAbs can be administered via **intravenous infusion (IV)** or **subcutaneous injection**. All individuals must be observed for 1 hour following administration.

How can providers order mAbs?
REGEN-COV is currently available at **no cost** from a federal stockpile. Providers capable of meeting EUA requirements can order product through AmerisourceBergen using this mAb order form.

Interested in mAbs? Start here:
1. Read REGEN-COV Health Care Provider EUA Fact Sheet
2. Review Federal Monoclonal Antibody Playbook
3. Email Tim Davis (tim.davis@dhhs.nc.gov) for additional support

PFIZER AND JANSSEN (JOHNSON & JOHNSON) UPDATES

Pfizer

1. **Shelf life extension:**
   - The FDA is in the process of assessing an extension for the Pfizer COVID-19 vaccine shelf-life and is expected to make an announcement before the end of the month.
   - Monitor your emails for additional updates
2. **Pfizer ordering process:**
   - The State will begin to resupply Hubs and providers with long-dated Pfizer vaccine over the next two weeks
   - See slide 6 for the updated provider ordering process

Janssen

1. **Upcoming expiration:**
   - There is a large quantity of Janssen (Johnson & Johnson) vaccine expiring in mid-September
2. **Janssen ordering process:**
   - The CDC has made an exception in the Janssen ordering freeze to allow limited ordering starting early September
   - The State will begin resupplying Hubs with long-dated Janssen in early September. Please monitor your email for more details on receiving long-dated Janssen Vaccine

Please continue using Vaccine Marketplace and Updating Inventory

1. **Continue to use Vaccine Marketplace:**
   - We'd like to thank you for using Vaccine Marketplace for transfers and encourage you to continue utilizing Vaccine Marketplace to identify vaccine available near them for use throughout this month. Posts on the Vaccine Marketplace can be viewed in the CVMS Provider Portal.
2. **Update inventory on CVMS:**
   - Please practice diligence in updating your inventory in CVMS. Please follow this user guide to update your vaccine inventory, and **if you have expired vaccine on-hand**, make sure to accurately log vaccine wastage events in CVMS.
   - If there is another reason why the vaccine is labeled as available, when in fact it is not, please submit a ticket in the CVMS Help Desk Portal.

LONG-DATED PFIZER COVID-19 VACCINE ORDERING PROCESS

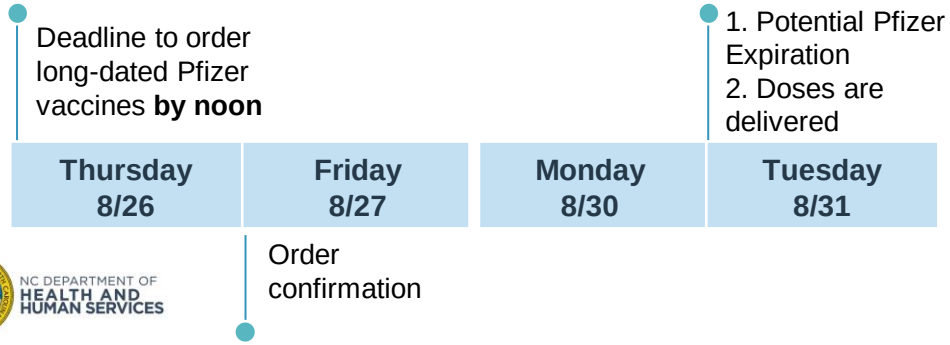
We will place orders for providers that can:

1. Store the Pfizer COVID-19 vaccine 450 dose minimum order quantity (MOQ) **AND**
2. Administer the requested vaccine in 3 months

We will restock Hubs to supply other providers with long-dated Pfizer vaccine prior to the August 31 shelf-life expiration

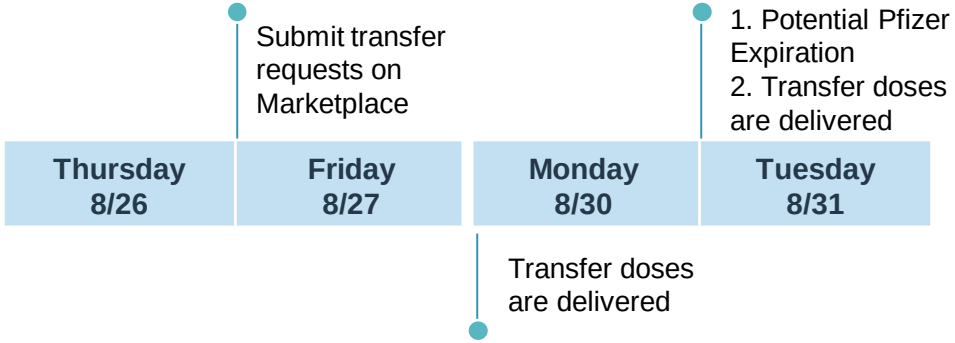
PROVIDERS THAT CAN STORE THE MOQ AND ADMINISTER IN 3 MONTHS:

1. Final date to order your long-dated Pfizer doses is **August 26 at 12:00 PM** through the NC DHHS Vaccination Allocation Request Form.
2. You will receive communications with your order confirmation or guidance on requesting long-dated Pfizer vaccine transfers
3. If you would like to adjust your current long-dated Pfizer COVID-19 vaccine request, submit a ticket to the CVMS Help Desk.
4. You will receive doses on **Tuesday, August 31**



PROVIDERS THAT CANNOT MEET THE ORDERING REQUIREMENTS:

1. Your provider location will need to submit a transfer request via Vaccine Marketplace in CVMS to receive vaccine from a local Hub starting **Friday, August 27**
2. You will receive these transfers on **Monday, August 30 through Tuesday, August 31**



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WEBSITE FOCUS GROUP: VOLUNTEERS NEEDED

We love hearing from our NC Providers and ensuring that we deliver the best tools and experience.

In that spirit, **we are looking for focus group volunteers** willing to share their feedback and ideas about our NCDHHS provider website.

If you are interested in helping shape the future covid19.ncdhhs.gov site please add email to the chat

Questions?

NEED HELP?

Contact CVMS Help Desk Support
Providers can submit support request through the CVMS Help Desk portal

Please reference the How to Submit a Ticket Through the CVMS Help Desk Portal--Provider User Guide to learn how to register for an account, log in and submit a ticket in the CVMS Help Desk Portal.

COVID-19 Vaccine Provider Help Center
(877)-873-6247 **Dial Option 1**
Hours of Operation
Monday - Friday: 7 AM - 7 PM ET
Saturday - Sunday: 8 AM - 4 PM ET

Please reference the COVID-19 Vaccine Provider Guidance for administrative guidance on vaccinating North Carolinians for COVID-19.

Access the COVID-19 Provider Toolkit for a quick reference guide for all current and prospective vaccine providers.

Explore the COVID-19 Vaccine Communications Toolkit for ready-made materials to help you communicate about safe and effective COVID-19 vaccines within your community.

Review the COVID-19 Vaccine Discussion Guide for Health Care Providers for tips on leading conversations with you patients about the COVID-19 vaccines.