

COVID-19 Update: Grand Rounds

Sherrill Brown, MD
Medical Director, Infection Prevention

8/23/2021

Main Points of Discussion

- **Updates on ordering the Monoclonal Antibody**
- **Medical Exemptions for COVID-19 Vaccine**
- **Reminder about Vaccine Storage and Handling**
- **Safe Environment During Gatherings**
- **Frequently Asked Questions**
- **Additional Questions**

Monoclonal Antibody Treatment for COVID-19 High Risk Patients

July 6th, 2021

Ursula Baffigo MD MPH Medical Director, Medical Management



Inclusion Criteria

- Inclusion criteria:
 - 12 or older age group
 - Weigh at least 40 kg
 - Positive COVID-19
 - Within 10 days of symptom onset
 - Meets **high risk criteria**

High Risk Conditions

- Obesity or being overweight (BMI >25 or if age 12-17, have BMI ≥85th percentile for their age and gender)
- Pregnancy
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension)
- Sickle cell disease
- Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)
- Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID 19))

Documentation

- .MONOCLONALABTX

MONOCLONAL ANTIBODY INFUSION ORDER FOR COVID-19 POSITIVE PATIENTS

INSTRUCTIONS: REQUIRED STEPS

* Print & fill out manually OR download & fill out electronically:

* Use Adobe Acrobat  and select  Fill & Sign

** Instructions for changing default program for PDFs to Acrobat*

☐ **PROVIDER:** Place Epic order "Referral to Home Health > IV Infusion" + mark order as **Urgent**

☐ Under order comments enter "MONOCLONAL ANTIBODY THERAPY"

☐ Fill out the attached **Infusion Order Form**

** Team member may complete form based on documentation in Epic, but PROVIDER must sign*

☐ **Completed AND signed form** must be RETURNED to AltaMed Centralized Referral Team for urgent processing:

Provider or Clinic CGC's can return form via

Email: **DL_Referral_Coordinators@altamed.org**

or Fax: **(323) 596-2166**

☐ **Send message** to Justin Maldonado on WebEx Teams to confirm that ORDER is placed & form emailed/faxed

Testing Undervaccinated Staff

- Starting August 18th, those that are unvaccinated or not fully vaccinated will need to be tested twice per week
- We will be using COVID antigen testing,
- Testing will be done at worksite
- EUA authorized test so need to provide EUA for staff that are being tested.
- Expiration date may show they are already expired, FDA extended the expiration date so they are still good, Supply Chain is monitoring this closely
- Vaccines will be made available onsite where vaccines are being stored for employee COVID-19 vaccine

Vaccine Requirements for Staff

- All AltaMed Staff will need to be fully vaccinated by Sept 30th 2021
- Policy getting approved by the board but we are following Governor Newsom's Health Officer Order from July 26th, 2021 and August 5th, 2021.
- Need to have 2 doses of mRNA or 1 dose of Janssen vaccine before Sept 30th, 2021.
- Exemption Attestation sent out to all undervaccinated staff
- Medical Exemption will be considered for absolute contraindications for the vaccine
- Those with Anaphylactic or allergic reaction to mRNA vaccine, should be considered for Janssen vaccine
- Other medical reasons for exemption will be reviewed by Committee.

Teammate Section: Complete the following information

Name (last, first) _____ Employee ID: _____

Work Email Address: _____ Best Phone Number: _____

After you and your provider complete this form, scan it and email to Employee Health (employeehealth@altamed.org)

The form will be kept as part of your confidential employee health record.

Clinician Section: A licensed physician, P.A., CNM or NP must complete and sign this section. (Forms completed by the employee will not be accepted)

Clinician Instructions: By completing this form, you certify that different methods of vaccinating against COVID-19 have been considered are that the following medical contraindication precludes any/all vaccinations for COVID-19. Guidance for medical exemption for COVID-19 vaccinations can be obtained from the Advisory Committee on Immunization Practices (ACIP) available at: <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html>

If a pregnancy exception is requested, this signed form from the provider is not necessarily an endorsement of exemption. The provider just needs to confirm pregnancy and provide Estimated Date of Confinement (return to work date) below.

The following are **NOT** considered contraindications COVID-19 vaccination:

- * Local injection site reactions after (days to weeks) previous COVID-19 vaccines (erythema, induration, pruritus, lymphadenopathy, vomiting, diarrhea, myalgia, arthralgia)
- * Previous COVID-19 infection
- * Vasovagal reaction after receiving a dose of any vaccine
- * Being an immunocompromised individual or receiving immunosuppressive medications
- * Autoimmune conditions, including Guillian-Barre Syndrome
- * Allergic reactions to anything not contained in the COVID-19 vaccines, including injectable therapies, food, pets, venom, environmental allergens, oral medication, latex, etc. Please note the COVID vaccines do not contain egg or gelatin.
- * Immunosuppressed person in the healthcare worker's household
- * Alpha-gal Syndrome
- * Family member or household member who falls into a medically exempt category
- * Breastfeeding intention to become pregnant or undergoing infertility treatment

Please indicate medically indicated contraindication below:

- ☐ Severe allergic reaction (anaphylaxis) after previous dose of or to a component of the COVID-19 Vaccine. Including Polyethylene Glycol (PEG) (Please describe response in detail below and contraindication to alternatives, such as the Johnson & Johnson vaccine, which does not contain PEG)
- ☐ Immediate allergic reaction to a previous doses or known (diagnosed) allergy to a component of the vaccine (Please describe response in detail below and contraindication to alternative vaccines)
- ☐ Other medical circumstances preventing vaccination with any available COVID-19 vaccine (Be specific and describe in detail below) Please note that this will be reviewed by the medical exemption committee. Submission of a signed form does not guarantee and exemption will be granted.
- ☐ Pregnancy (Note: [The American College of Obstetrician and Gynecologists](#), [the Society for Maternal-Fetal Medicine](#) and the [American Society for Reproductive Medicine](#) all strongly support COVID-19 vaccine before and during pregnancy and while breastfeeding.) Pregnancy is not a medical contraindication. However, a time deferment to the COVID-19 vaccine policy will be granted during pregnancy. Employees will need to receive vaccination when they return back to work. Return to work date: _____

Vaccine Storage and Handling

Sherrill Brown, MD
Director, Infection Prevention



General Vaccine Info

- COVID vaccines have special storage requirements
- All vaccine vials should be labeled with use by date
- Once vials are removed from fridge, they should be labeled with a use by time.
- Only take a vial out of the fridge when you are about to use it.
- Vaccine doses should not be drawn up into a syringe until they are ready to be used.
- Syringes need to be labeled once drawn up with a use by time and date
- Any vaccine that is punctured or drawn up should be disposed of in medication waste when use by time comes up.
- If vaccine still not expired per used by time but at end of day, dispose of all punctured vials or drawn up syringes.
- Vaccine doses administered and wasted need to be reported to pharmacy every evening.
- Don't store vaccines in the side door.
- All clinics need a COVID-19 Vaccine Binder and Management Plan

PFIZER COVID-19 VACCINE
Lot **EW0198** Exp 09/30/21
Opened _____ Use By _____

Labels

PFIZER COVID-19 VACCINE

Lot **EW0198**

Exp 09/30/21

Opened _____ **Use By** _____

Pfizer Vaccine Vial Management

Today's Date: _____

Lot# _____

Use By Date: _____

Time taken out of refrigerator: _____

Time reconstituted: _____

Use by time (6 hours following reconstitution): _____

Dose Time Wasted Administered

Dose	Time Drawn	Drawn Up By: Name of Employee (first last)	Administered to Patient? Check	Wasted? Check
1				
2				
3				
4				
5				
6				

Reminders:

Ages 12 and Up

Clean vial with alcohol wipe prior to reconstituting AND when drawing up each dose.

Vial must be at room temperature prior to reconstituting with 1.8 ml supplied diluent.

Equalize pressure in vaccine vial when reconstituting by drawing out 1.8ml of air after injecting 1.8ml of diluent.

Label vial with time when taking out to room temperature.

Label vial with use by time 6 hours following reconstitution.

Must use low dead volume syringes to draw up vaccine doses.

Draw up 0.3ml per dose immediately prior to each administration.

Label each dose after drawing up vaccine with

Store vial in dark bag or opaque container to reduce exposure to ambient light.

Pfizer-BioNTech COVID-19 Vaccine Vaccine Preparation and Administration Summary



General Information

Vaccine: Pfizer-BioNTech COVID-19 Vaccine

Diluent: 0.9% sodium chloride (normal saline, preservative-free) Use a new vial every time.

Multidose vial: 6 doses per vial

Dosage: 0.3 mL

Vaccine MUST be mixed with diluent before administration.

Age Indications

12 years of age and older

Schedule

2-dose series separated by 21 days

A series started with Pfizer-BioNTech COVID-19 Vaccine should be completed with this product.

Administration

Intramuscular (IM) injection in the deltoid muscle



Thawing Frozen Vaccine

■ Frozen vaccine must be thawed before using.

■ Thaw vaccine in the refrigerator or at room temperature:

- **Refrigerator:** Between 2°C and 8°C (36°F and 46°F)
Unpunctured vials may be stored in the refrigerator for up to 1 month (31 days).
- **Room temperature (for immediate use):** Up to 25°C (77°F)
Unpunctured vials cannot be kept at room temperature for more than 2 hours (including thaw time).

■ Amount of time needed to thaw vaccine varies based on temperature and number of vials.

■ **Do NOT** refreeze thawed vaccine.

■ Use vials in the refrigerator before removing vials from ultra-cold temperature or freezer storage.

■ Use CDC's beyond-use date labels for this vaccine to track storage time at refrigerated and frozen temperatures.

Prepare the Vaccine

Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.*



Remove vaccine from the freezer or refrigerator. Allow vaccine to come to room temperature. Vials can be held at room temperature for up to 2 hours before mixing.



Before mixing, check the expiration dates of the vaccine and diluent. NEVER use expired vaccine or diluent. The expiration dates for the diluent and the vaccine are located on the respective vials.



With the vaccine at room temperature, gently invert vial 10 times. **Do not shake the vial.** If the vial is shaken, contact the manufacturer. The vaccine is white to off-white in color and may contain opaque particles. Do not use if liquid is discolored.



Using a new, sterile alcohol prep pad for each vial, wipe off the stoppers of the diluent and vaccine vials. Using a 21-gauge (or narrower) needle, **withdraw 1.8 mL** of 0.9% sodium chloride (normal saline, preservative-free) into a mixing syringe. Discard diluent vial and any remaining diluent every time. **Do NOT** use bacteriostatic normal saline or other diluents to mix the vaccine.



Inject 1.8 mL 0.9% sodium chloride (normal saline, preservative-free) diluent into the vaccine vial.



Using the mixing syringe, remove 1.8 mL of air from the vaccine vial to equalize the pressure in the vaccine vial.



Gently invert the vial containing vaccine and diluent 10 times. The vaccine will be off-white in color. Do not use if discolored or contains particulate matter. **Do not shake.** If the vial is shaken, contact the manufacturer.



Note the date and time the vaccine was mixed on the vial.



Keep mixed vaccine between 2°C and 25°C (36°F to 77°F), minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Administer within 6 hours. **Discard any unused vaccine after 6 hours.** Do not return to freezer storage.



*Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand hygiene and change gloves between patients.

Moderna

Moderna Vaccine Vial Management

Today's Date: _____

Lot# _____

Use By Date: _____

Time taken out of refrigerator: _____

Use by time (12 hours after 1st puncture): _____

Dose Time Wasted Administered

Dose	Time Drawn	Drawn Up By: Name of Employee (first last)	Administered to Patient? Check	Wasted? Check
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				

Reminders:

Ages 18 and Up

Swirl vaccine to mix gently, do not shake.

Clean vial with alcohol wipe prior to drawing up each dose.

Vial must be at room temperature prior to drawing up dose.

Label vial with time when taking out to room temperature.

Label vial with use by time 12 hours following 1st puncture.

Draw up 0.5ml per dose immediately prior to each administration.

Label each dose after drawing up vaccine with patients name, vaccine type, lot number and use by time/date.

Store vial in dark bag or opaque container to reduce exposure to ambient light.

Moderna COVID-19 Vaccine

Vaccine Preparation and Administration Summary



» General Information

Vaccine: Moderna COVID-19 Vaccine

Two multidose vial presentations:

- Maximum of 11 doses per vial
- Maximum of 15 doses per vial

Dosage: 0.5 mL

Do NOT mix with a diluent.

» Age Indications

18 years of age and older

» Schedule

2-dose series separated by 1 month (28 days). A series started with Moderna COVID-19 Vaccine should be completed with this product.

» Administration

Intramuscular (IM) injection in the deltoid muscle



» Thawing Frozen Vaccine

- Frozen vaccine must be thawed before using.
- Thaw vaccine in the refrigerator or at room temperature:
 - Refrigerator:** Between 2°C and 8°C (36°F and 46°F). Unpunctured vials may be stored in the refrigerator for up to 30 days.
 - Room temperature:** Between 8°C and 25°C (46°F and 77°F). Unpunctured vials may be held at room temperature for up to 24 hours.

- Amount of time needed to thaw vaccine varies based on temperature and number of vials.
 - In the refrigerator: Up to 3 hours
 - Room temperature: Up to 1 hour and 30 minutes
- Do NOT** refreeze thawed vaccine.
- Use vials in the refrigerator before removing vials from the freezer.
- Use CDC's beyond-use date labels for this vaccine to track storage time at refrigerated temperatures.

» Expiration Date

To determine the expiration date, scan the QR code located on the vial or carton. The QR code will bring up a website; then choose the lookup option, enter the lot number, and the expiration date will be displayed. Another option is to access the website directly: <http://www.modernatx.com/covid19vaccine-eua>. CDC's expiration date tracking tool (<https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/expiration-tracker.pdf>) can facilitate documenting expiration dates.

» Prepare and Administer the Vaccine

Assess recipient status:

- Screen for contraindications and precautions.
- Review vaccination history.
- Review medical considerations.



Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.*



Vaccine must be thawed before using. If removing the vial from the refrigerator, let it stand at room temperature for 15 minutes.



Unpunctured vials: Check the expiration date. Never use expired vaccine.
Punctured vials: Check the beyond-use time. Never use vaccine after the beyond-use time.



With the vial upright, gently swirl the vaccine. **Do NOT shake.** If the vial is shaken, contact the manufacturer. Note: Gently swirl the vaccine before withdrawing subsequent doses.



Examine the vaccine. It should be white to off-white in color and may contain white or translucent particles. Do not use if liquid contains other particulate matter or is discolored.



Using a new, sterile alcohol prep pad, cleanse the stopper of the multidose vaccine vial.



Choose the correct equipment, including the correct needle size. Use a new, sterile needle and syringe for each injection.



*Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand hygiene and change gloves between patients.

Johnson and Johnson Vaccine Vial Management

Today's Date: _____

Lot# _____

Use By Date: _____

Time taken out of refrigerator: _____

Use by time (2 hours after 1st puncture room temp, see below): _____

Dose Time Wasted Administered

Dose	Time Drawn	Drawn Up By: Name of Employee (first last)	Administered to Patient? Check	Wasted? Check
1				
2				
3				
4				
5				

Reminders:

Ages 18 and Up

Swirl vaccine to mix gently, do not shake.

Clean vial with alcohol wipe prior to drawing up each dose.

Vial must be at room temperature prior to drawing up dose.

Label vial with time when taking out to room temperature.

Label vial with use by time 2 hours following 1st puncture if kept at room temp, 6 hours if kept in the fridge after 1st puncture.

Draw up 0.5ml per dose immediately prior to each administration.

Label each dose after drawing up vaccine with patients name, vaccine type, lot number and use by time/date.

Store vial in dark bag or opaque container to reduce exposure to ambient light.

Janssen COVID-19 Vaccine (Ad26.COV2.S)

Janssen COVID-19 Vaccine - Dosing/Administration & Storage/Handling (Vials - Shipped Refrigerated)

Date Last Updated: 07/13/2021

SUMMARY

- The Janssen COVID-19 Vaccine has been granted an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA). The Janssen COVID-19 Vaccine has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA for active immunization to prevent Coronavirus Disease 2019 (COVID-19) in individuals 18 years of age and older. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the medical product under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act unless the declaration is terminated or authorization revoked sooner.^{1,2}
- **Refrigerate vaccine upon receipt. Do not store in the freezer.**
- The Janssen COVID-19 Vaccine (Ad26.COV2.S; JNJ-78436735) is supplied in a carton of 10 multi-dose vials (NDC 59676-580-15). A maximum of 5 doses can be withdrawn from the multi-dose vial.²

Safe Environment Update: Gathering at Work

Sherrill Brown, MD
Director, Infection Prevention



Indoor Meetings/Gatherings

1. All participants must be screened for COVID exposure risk or symptoms prior to meeting.
2. All participants wear masks unless actively taking a sip or bite of food.
3. All participants sit 6 feet apart.
4. All food or beverages being served must be in single serve and individually packaged servings or be served by an attendant who is masked.
5. Hand hygiene station should be made available near beverage/food area and easily accessible by all meeting participants.
6. Disinfect Tables Before and After Use.

Outdoor Meetings/Gatherings

1. All participants must be screened for COVID exposure risk or symptoms prior to meeting.
2. All participants wear masks unless actively eating or drinking.
3. All participants should sit a minimum 3 feet apart.
4. All food or beverages being served must be in single serve and individually packaged servings or be served by an attendant who is masked.
5. Hand hygiene station should be made available near beverage/food area and easily accessible by all meeting participants.
6. Disinfect Tables Before and After Use.

Questions?

- CDC COCA Calls
- IDSA/Clinician Calls Every Other Week
- SHEA Weekly TownHall



AltaMed

QUALITY CARE WITHOUT EXCEPTION™