

Medical Directive # 2108002  
FOR IMMEDIATE DISTRIBUTION  
Date 08/18/2021



Medical Oversight for the MedStar System

Effective: 08/18/2021  
Replaces Medical Directive #: 2012002  
Subject: COVID-19 Pandemic – Vaccination Procedure

Expiration:

**Purpose:** To outline the procedure for the administration of COVID-19 vaccines. These medicinal products have been given Emergency Use Authorization by the FDA for active immunization in individuals to prevent COVID-19 caused by SARS-CoV-2 virus. This directive may be used by System providers who have completed OMD-approved training for administration.

**Procedure:**

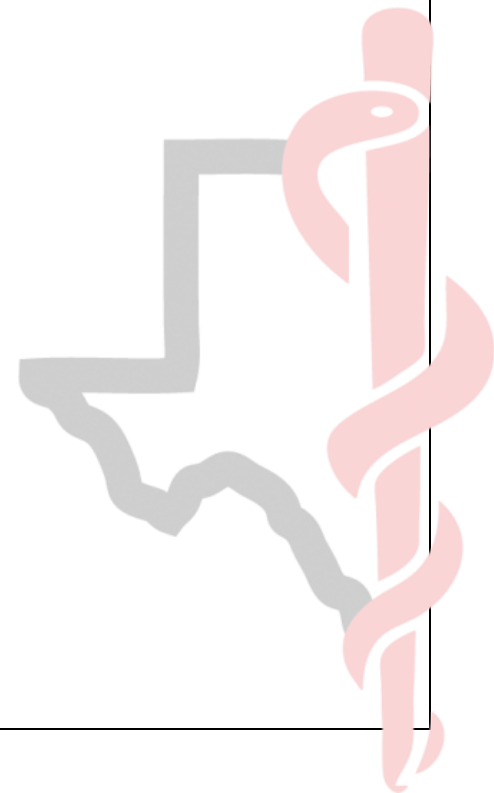
- Provide vaccinee appropriate CDC Vaccination Information Statement (VIS)
- Vaccinee to complete the top section of the Vaccine Administration Record (VAR)
- Review completed VAR
- VAR serves as written consent for the vaccination
- Follow vaccination specific protocol (see Appendices) to assess for appropriate indications, contraindications, preparation, and dose selection
  - Pfizer BNT162b2
  - Moderna cx-024414
  - Janssen (Johnson & Johnson) COVID-19 Vaccine
- Identify the injection site (L or R deltoid) and follow the **Intramuscular Injection Procedure**
- Deliver the appropriate dose of vaccine in the muscle in a quick, steady manner
- Monitor patient for 15-minutes for signs and symptoms of adverse reaction
  - If signs and symptoms of adverse reaction, follow **Allergic Reaction / Anaphylaxis protocol**

**Cautions:**

- History of severe allergies or reactions to any medications, foods, vaccines, or latex
- Bleeding disorder or taking blood thinners
- Has received a first dose of another COVID-19 Vaccine
  - Ensure same manufacturer as previous dose

Please feel free to reach out with any questions or concerns

Veer D. Vithalani MD, FACEP, FAEMS  
System Medical Director  
Metropolitan Area EMS Authority



## Appendix: Pfizer BNT162b2 Vaccine

### Indications:

- For active immunization in individuals 12-years of age and older

### Contraindications:

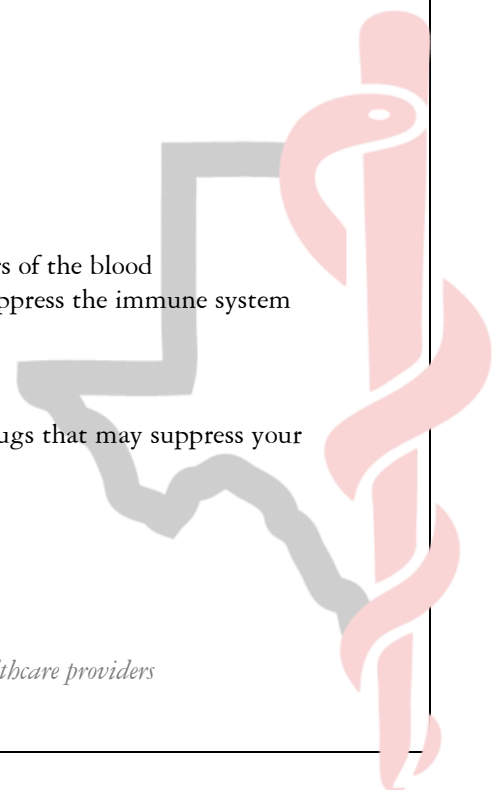
- Age < 12-years
- Current Illness (Current Infection)
- Hx of severe allergic reaction to a previous dose of this vaccine or any vaccine ingredients
- Active COVID-19 infection
- Treatment with monoclonal antibodies against COVID-19 in the past 90-days
- Any of the following symptoms in the last 10 days, fever (> 100.4F), chills, cough, shortness of breath, difficulty breathing, fatigue, muscle or body aches, headache, new altered sense of taste or smell, sore throat, congestion or runny nose, nausea, vomiting, or diarrhea
- History of myocarditis or pericarditis after receiving the first dose of an mRNA COVID-19 vaccine

### Preparation:

- For frozen, UNDILUTED vials:
  - Allow the thawed vial to come to room temperature (up to 25 °C)
  - Gently invert 10 times prior to dilution, DO NOT shake
  - Dilute in original vial with 1.8 mL 0.9% sodium chloride for injection, using aseptic techniques
  - Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe
  - Gently invert diluted solution 10 times, DO NOT shake
  - Use immediately, and within 6-hours after dilution.
- For DILUTED vials:
  - Gently invert diluted solution 10 times, DO NOT shake
  - Use immediately, and within 6-hours after dilution.

### Dose Selection & Regimen:

- Each dose is 0.3 mL
- First Dose
  - No previous doses of a COVID-19 Vaccine
- Second Dose
  - 21-days ( $\pm$ 4-days) after previous dose of Pfizer BNT162b2
- Third Dose
  - 28-days after 2<sup>nd</sup> dose of Pfizer BNT162b2, for patients who have:
    - been receiving active cancer treatment for tumors or cancers of the blood
    - received an organ transplant and are taking medicine to suppress the immune system
    - received a stem cell transplant within the last 2 years
    - moderate or severe primary immunodeficiency
    - advanced or untreated HIV infection
    - active treatment with high-dose corticosteroids or other drugs that may suppress your immune response



## Appendix: Moderna cx-024414 Vaccine

### Indications:

- For active immunization in individuals 18-years of age and older

### Contraindications:

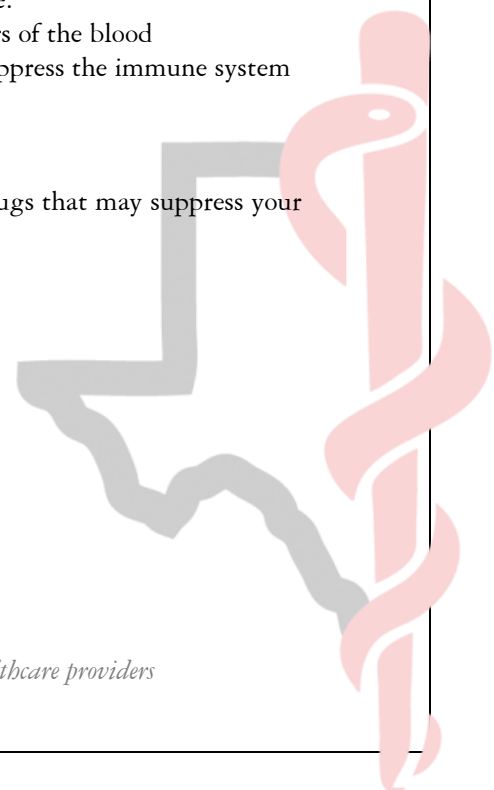
- Age < 18-years
- Current Illness (Current Infection)
- Hx of severe allergic reaction to a previous dose of this vaccine or any vaccine ingredients
- Active COVID-19 infection
- Treatment with monoclonal antibodies against COVID-19 in the past 90-days
- Any of the following symptoms in the last 10-days, fever (>100.4F), chills, cough, shortness of breath, difficulty breathing, fatigue, muscle or body aches, headache, new altered sense of taste or smell, sore throat, congestion or runny nose, nausea, vomiting, or diarrhea
- History of myocarditis or pericarditis after receiving the first dose of an mRNA COVID-19 vaccine

### Preparation:

- For frozen vials:
  - Transfer vial to thaw to room temperature (up to 25 °C)
  - Gently swirl vial after thawing, DO NOT shake; DO NOT dilute
  - Use immediately, and within 6-hours after thawing.

### Dose Selection & Regimen:

- Each dose is 0.5 mL
- First Dose
  - No previous doses of a COVID-19 Vaccine
- Second Dose
  - 21-days ( $\pm$ 4-days) after previous dose of Moderna cx-024414
- Third Dose
  - 28-days after 2<sup>nd</sup> dose of Moderna cx-024414, for patients who have:
    - been receiving active cancer treatment for tumors or cancers of the blood
    - received an organ transplant and are taking medicine to suppress the immune system
    - received a stem cell transplant within the last 2 years
    - moderate or severe primary immunodeficiency
    - advanced or untreated HIV infection
    - active treatment with high-dose corticosteroids or other drugs that may suppress your immune response



## Appendix: Janssen COVID-19 Vaccine

### Indications:

- For active immunization in individuals 18-years of age and older

### Contraindications:

- Age < 18-years
- Current Illness (Current Infection)
- Hx of severe allergic reaction to any vaccine ingredients
- Active COVID-19 infection
- Treatment with monoclonal antibodies against COVID-19 in the past 90-days
- Any of the following symptoms in the last 10 days, fever (> 100.4F), chills, cough, shortness of breath, difficulty breathing, fatigue, muscle or body aches, headache, new altered sense of taste or smell, sore throat, congestion or runny nose, nausea, vomiting, or diarrhea

### Preparation:

- Visually inspect multi-dose vial for particulate matter and discoloration
- Mix contents of multi-dose vial by gently swirling in upright position for 10-seconds, DO NOT shake
- After first dose is withdrawn, use contents of vial within 2-hours if kept at room temperature or within 6 hours if refrigerated (36° to 46°F).

### Dose selection:

- Single dose is 0.5 mL

