**Purpose:** To reduce morbidity and mortality from COVID-19 by administering the Pfizer-BioNTech COMIRNATY® (COVID-19 Vaccine, mRNA) 2024-2025 Formula or, the Moderna SPIKEVAX® (COVID-19, Vaccine, mRNA) 2024-2025 Formul to individuals in accordance with the Center for Disease Control and Prevention’s (CDC) Vaccination Program and recommendations issued by the Advisory Committee on Immunization Practices (ACIP).

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| **COVID-19 Vaccination for Employees and Residents** | |
| **Policy** | 1. Under this non-patient specific standing order, Registered Nurses (RN), Advanced Practice Providers (APP), or Physicians, who are employees, and/or contractors of the Insert Facility Name may administer the Pfizer-BioNTech COMIRNATY® (COVID-19 Vaccine, mRNA) 2024-2025 Formula or, the Moderna SPIKEVAX® (COVID-19 Vaccine, mRNA) 2024-2025 Formula to facility employees and residents that have consented to receive the vaccine in accordance with the CDC’s Vaccination Program and recommendations issued by ACIP. |
| **Non-Patient Specific Standing Order- NYSED Nursing Guideline Overview** | 1. A non-patient specific order authorizes named RN’s or RN’s who are not individually named but employed or under contract with a legally authorized entity, to administer specified immunization agents or anaphylaxis treatment agents for a specified period of time to an entire group of persons such as school children, employees, patients of a nursing home, etc.  * The non-patient specific standing order and protocol must be authorized by a physician or certified nurse practitioner. * RN’s must maintain or ensure that a copy of the standing order(s) and protocol(s) authorizing them to administer immunizations is maintained. * An LPN can assist in administering immunizations (give the injection, assist in recordkeeping, and when appropriate, administer anaphylactic agents) as long as the RN assesses the recipient, and is responsible for the on-site direction of the LPN in administering the immunizations. It is expected that, in this setting a ratio is maintained of no more than three LPN’s to one RN. * An RN may assign the actual injection of the immunizing agent to an LPN. |
| **Vaccine Administration Procedure** | |
| **Consent to Vaccinate** | 1. Collect and review the Vaccine Consent. 2. Ensure all information is reviewed and completed appropriately. 3. **Confirm the Consent has been Signed.** |
| **Vaccine Information Statements/Patient Information** | 1. Provide all individuals receiving the 2024-2025 COVID-19 mRNA vaccine with the most current Vaccine Information Statement (VIS) in their preferred language available at:  * **VIS available at:** * <https://www.cdc.gov/vaccines/hcp/vis/vis-statements/covid-19.html> * **Patient Info sheets available at:** * COMIRNATY® (COVID-19 Vaccine, mRNA) by Pfizer: [COVID-19 vaccines by Pfizer-BioNTech | Official Site (covidvaxoption.com)](https://www.covidvaxoption.com/) * SPIKEVAX® (COVID-19 Vaccine, mRNA) by Moderna: [COVID-19 Vaccine Info for Consumer and Healthcare Providers (spikevax.com)](https://spikevax.com/) * Residents/healthcare decision makers may have previously received information sheets at time consent was signed, if not previously received, then provide. |
| **Assess Need for COVID-19 Vaccination** | 1. Asses all employees and residents for vaccination with either the SPIKEVAX® or COMIRNATY® 2024-2025 COVID-19 mRNA Vaccine based on the following criteria:  * Any immunocompetent (not moderately or severely immunocompromised) individual ≥12 years old who has received at least 1 dose of updated 2024-2025 COVID-19 mRNA vaccine is currently up to date – No further doses indicted. * Any immunocompetent (not moderately or severely immunocompromised) individual   ≥12 years old that has received any number of previous doses of COVID-19 vaccine, **Not Including** at least one dose of the 2024-2025 COVID-19 vaccine, may be brought up to date with a single dose of updated 2024-2025 COVID-19 mRNA vaccine (give at least 8 weeks after the last dose received).   * For individuals that are moderately or severely immunocompromised, see vaccination schedule recommendations section.  1. Co-administration of vaccines (influenza, COVID-19) for eligible adults is acceptable and recommended (provide education and information as needed) **-If co-administering vaccines simultaneously, they should be given at separate sites, (preferably different extremities) but no less than 1 inch apart on same extremity**.  * Ensure to review and respect persons preference with vaccine administration schedule (this reduces vaccination fear and hesitancy). * If preference is to not receive co-administration of vaccines, then consider: * What priority vaccines should be administered. * Recommendations for current vaccines. * If individual is up to date with the recommended vaccines. * Ability to administer vaccinations on return visit (likelihood of compliance for return vaccination, or acceptance of vaccination upon return visit (i.e., is resident difficult to vaccinate due to behaviors). |
| **Screen for Contraindications and Precautions** | 1. **Contraindications for vaccination:**  * Do not administer vaccines to individuals who has had an allergic reaction or a serious systemic or anaphylactic reaction to a previous COVID-19 vaccine or to any of the components contained in the vaccine. If there is any concern or question to previous reaction do not vaccinate and refer to healthcare provider for further guidance. * History of severe allergic reaction (e.g., anaphylaxis) to any other vaccine or injectable therapy (e.g., intravenous, intramuscular, or subcutaneous)-refer to healthcare provider for further guidance.  1. **Precautions for use of vaccine:**  * Moderate or severe acute illness, with or without fever. * A diagnosed non-severe allergy to a component of the COVID-19 vaccine. * Non-severe, immediate (onset less than 4 hours) allergic reaction after administration to a previous dose of COVID-19 vaccine (if receiving the same vaccine type that caused the reaction). * Multisystem inflammatory syndrome in adults (MIS-A). * Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine. |
| **Special Considerations** | 1. If individual is COVID-19 positive; vaccination should be delayed until their symptoms have resolved and criteria to discontinue isolation has been met. 2. If individuals COVID-19 status is considered resolved, or they have a recent history of being COVID-19 positive (within the last 90 days) they should be vaccinated. Though if they desire, they may choose to delay vaccination up to 90 days after COVID-19 infection. 3. COVID-19 vaccine doses for individuals ≥12 years old may be any authorized product. 4. Immunocompromised individuals may obtain additional doses of the vaccine at the direction of the healthcare provider, based on the individual’s circumstances. The immunocompromised individual may self-attest to need for additional doses. They do not need to present any documentation or proof of being immunocompromised to receive additional vaccine doses. 5. When administering vaccines ensure you are prepared to respond to, and manage medical emergencies related to vaccination administration. Be familiar with, and have, written emergency medical protocol available in addition to, emergency medications and equipment. |
| **Moderate to Severe Immunocompromise** | 1. Conditions causing moderate to severe immunodeficiency 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 cell transplant (HCT) within 2 years of transplantation or taking immunosuppression therapy. * Moderate or severe primary immunodeficiency (e.g., Common variable immunodeficiency (CVID), X-linked agammaglobulinemia (XLA). * Advanced or untreated HIV infection (people with HIV and CD4 cell counts <22/mm³, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV). * Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day). * Active treatment with alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, TNF blockers, and other biologic agents that are immunosuppressive or immunomodulatory. |
| **Recommended COVID-19 Vaccination Administration Schedule** | |  |  | | --- | --- | | COVID-19 Vaccination History for  Individuals that are Not Moderately or Severely Immunocompromised | Recommended Dosing Schedule | | Unvaccinated | Give 1 dose 2024-2025 mRNA COVID-19 vaccine formula now | | Any number of previous mRNA COVID-19 vaccinations, but has NOT received a dose of 2024-2025 mRNA COVID-19 vaccine formula | Give 1 dose 2024-2025 mRNA COVID-19 vaccine formula at least 8 weeks after the last dose received | | Any number of previous mRNA COVID-19 vaccinations, AND received a dose of 2024-2025 mRNA COVID-19 vaccine formula | No further doses indicated | | 1 or more doses of any Novavax COVID-19 vaccine, but has NOT received a dose of 2024-2025 mRNA COVID-19 vaccine formula | Give 1 dose 2024-2025 mRNA COVID-19 vaccine formula at least 8 weeks after the last dose received | |
|  | |  |  | | --- | --- | | COVID-19 Vaccination History for Moderately to Severely Immunocompromised Individuals | Recommended Dosing Schedule (use same manufacturer for all vaccinations unless unavailable) | | Unvaccinated | Give full 3 dose series with 2024-2025 mRNA COVID-19 vaccine as follows:   1. Dose 1 now 2. Dose 2 at least 4 weeks after dose 1 3. Dose 3 at least 4 weeks after dose 2 | | 1 previous mRNA COVID-19 vaccination dose of any formula received | Give 2 doses 2024-2025 mRNA COVID-19 vaccine to complete series as follows:   1. Dose 2 at least 4 weeks after dose 1 2. Dose 3 at least 4 weeks after dose 2 | | 2 previous mRNA COVID-19 vaccination doses of any formula received | Give 1 dose 2024-2025 mRNA COVID-19 vaccine to complete series as follows:   1. Dose 3 at least 4 weeks after dose 2 | | 3 or more previous mRNA COVID-19 vaccination doses of any formula received, but has NOT received a dose of 2024-2025 mRNA COVID-19 vaccine formula | Give 1 dose 2024-2025 mRNA COVID-19 vaccine at least 8 weeks after the last dose received | | 3 or more previous mRNA COVID-19 vaccination doses of any formula received AND received at least 1 dose of 2024-2025 mRNA COVID-19 vaccine formula | May administer 1 additional dose of either mRNA vaccine (regardless of manufacturer for the initial series) at least 8 weeks after the last dose received   * Further doses may be administered under the direction of a physician or other applicable medical provider- further doses administered are to be given at least 8 weeks after the last dose received | | 1 or more doses of any Novavax COVID-19 vaccine, but has NOT received a dose of 2024-2025 mRNA COVID-19 vaccine formula | Give 1 dose 2024-2025 mRNA COVID-19 vaccine formula at least 8 weeks after the last dose received | |
| **COVID-19 Vaccination Orders Individuals ≥12 Years Old** | |  |  |  | | --- | --- | --- | | Vaccination Brand/Name | Administration Order | Minimum Time Between Doses | | COMIRNATY® (COVID-19 Vaccine, mRNA) 2024-2025 Formula | Give 0.3mL by intramuscular route x1  Dx. Z23: Encounter for immunization | At least 8 weeks after the last dose received | | SPIKEVAX® (COVID-19 Vaccine, mRNA) 2024-2025 Formula | Give 0.5mL by intramuscular route x1  Dx. Z23: Encounter for immunization | At least 8 weeks after the last dose received | |
| **Vaccine Preparation Prior to Administration** | |  |  |  | | --- | --- | --- | | Package | Storage of COMIRNATY Vaccine | Thawing COMIRNATY Vaccine | | 0.3mL Single Dose Vial | 1. Single dose vials may arrive frozen at ultra-cold conditions in thermal containers with dry ice. Once received, frozen vials may be immediately transferred to the refrigerator at 2°C to 8°C (36°F to 46°F), thawed and stored for up to **10 weeks**. The 10-week refrigerated expiry date should be recorded on the carton at the time of transfer. Cartons of 10 single dose vials may take up to **2 hours** to thaw at this temperature. Once thawed, **Do Not Refreeze.** 2. Cartons of single dose vials may be received at 2°C to 8°C (36°F to 46°F), and they should be stored at 2°C to 8°C (36°F to 46°F). Check that the carton has been previously updated to reflect the **10-week** refrigerated expiry date. | 1. If vial is frozen, thaw vial in the refrigerator [2°C to 8°C (36°F to 46°F) for up to **2 hours**] or at room temperature [up to 8°C (77°F)  for **30** **minutes**].   1. The total time out of refrigeration [at temperatures between 8°C to 25°C (46°F to 77°F)] must not exceed **12 hours.** Therefore, vial must be used or discarded within **12 hours** of being removed from refrigeration. | | 0.3mL Single Dose Pre-Filled Syringe | 1. Store glass prefilled syringes refrigerated at 2°C to 8°C (36°F to 46°F). 2. **Do Not Freeze**, if glass prefilled syringe has been frozen, discard. 3. Minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. | 1. Once syringe removed from the refrigerator it should be used immediately. However, if unable to be used immediately, it must be used or discarded within **4 hours.** |  1. **COMIRNATY®** (COVID-19 Vaccine, mRNA) 2024-2025 Formula is supplied in single dose vials and glass single dose pre-filled syringes and do not contain a preservative. If single dose vials of COMIRNATY® are frozen, thaw before use following the instructions below.      1. **SPIKEVAX®** (COVID-19 Vaccine, mRNA) 2024-2025 Formula is supplied in single dose vials and single dose pre-filled syringes and do not contain a preservative. If pre-filled syringes or vials of SPIKEVAX® are frozen, thaw before use following the instructions below.  |  |  |  |  | | --- | --- | --- | --- | | Package | Storage | Thawing SPIKEVAX® in Refrigerator Between 2°C to 8°C (36°F to 46°F) | Thawing SPIKEVAX® at Room Temperature Between 15°C to 25°C (59°F to 77°F) | | 0.5mL Single Dose Vial | 1. Store frozen between ­50°C to ­15°C   (­58°F to 5°F).   1. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. 2. **Do not refreeze once thawed.** 3. Thawed syringes can be handled in room light conditions. | One vial: Thaw for 45 minutes.  \* After thawing, may be stored refrigerated between 2°C to 8°C (36°F to 46°F) for up to **60 days** or up to the expiration date printed on the carton, whichever comes first. | One vial: Thaw for 15 minutes.  \*Must be used or discarded within **12 hours** of being thawed at room temperature [15°C to 25°C (59°F to 77°F)]. | | Carton of 10 vials: Thaw for 1 hour and 45 minutes.  \* After thawing, may be stored refrigerated between 2°C to 8°C (36°F to 46°F) for up to **60 days** or up to the expiration date printed on the carton, whichever comes first. | Carton of 10 vials: Thaw for 45 minutes.  \*Must be used or discarded within **12 hours** of being thawed at room temperature [15°C to 25°C (59°F to 77°F)]. | | 0.5mL Single Dose Pre-Filled Syringes | 1. Store frozen between ­50°C to ­15°C   (­58°F to 5°F).   1. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. 2. **Do not refreeze once thawed.** 3. Thawed syringes can be handled in room light conditions. | One syringe: Thaw for 1 hour.  \* After thawing, may be stored refrigerated between 2°C to 8°C (36°F to 46°F) for up to **60 days** or up to the expiration date printed on the carton, whichever comes first. | One syringe: Thaw for 45 minutes.  \*Must be used or discarded within **12 hours** of being thawed at room temperature [15°C to 25°C (59°F to 77°F)]. | | Carton of 10 syringes: Thaw for 2 hours and 30 minutes.  \* After thawing, may be stored refrigerated between 2°C to 8°C (36°F to 46°F) for up to **60 days** or up to the expiration date printed on the carton, whichever comes first. | Carton of 10 syringes: Thaw for 2 hours and 15 minutes.  \*Must be used or discarded within **12 hours** of being thawed at room temperature [15°C to 25°C (59°F to 77°F)]. | |
| **Equipment/**  **Supplies** | * Appropriate COVID-19 Vaccine to be administered (i.e., Pfizer or Moderna). * 23-25 gauge 1-inch safety needle (if using multidose vial you will need 3mL syringe with needle) * For larger individuals, 1.5-inch needle may be needed/more appropriate * Alcohol swabs * Nonsterile 2x2 woven gauze sponges * Adhesive Bandages * Exam gloves * Hand sanitizer- waterless, containing at least 60% alcohol * Sharps container * Garbage receptacle |
| **Vaccine Administration** | 1. Cleanse with alcohol-based hand sanitizer or wash hands (if visibly soiled). 2. Don gloves. 3. Check vaccine expiration date and visibly inspect the vial for any irregularities, such as discoloration, particulate matter, damage, or contamination- If problems noted, the vial should not be used (check with facility administration for need to return to pharmacy for replacement).  * SPIKEVAX is a white to off white suspension and may contain white or translucent product-related particles. * COMIRNATY is a white to off white suspension.  1. Prepare vaccination for administration.  * COMIRNATY Single Dose Vial- Prior to use, mix by inverting vial gently 10 times. **Do Not Shake**. Draw up 0.3mL dose using appropriate sterile needle and syringe. Discard vial and any excess volume. * COMIRNATY Single Dose Glass Prefilled Syringe- Ready to use. If frozen discard. **Do Not Shake**. Remove tip cap by slowly turning the cap counterclockwise while holding the Luer lock and attach appropriate sterile needle. * SPIKEVAX Single Dose Vial- Prior to use, gently swirl. **Do Not Shake**. Draw up 0.5mL dose. Discard after single use. * SPIKEVAX Single Dose Pre-Filled Syringe- Ready to use. **Do Not Shake**. With tip cap upright, remove tip cap in a slow, steady motion. Avoid pulling tip cap while twisting. Attach appropriate sterile needle by twisting in a clockwise direction until needle fits securely on the syringe.  1. Have individual sit in a chair or lie down for vaccination to prevent syncope. 2. Choose the deltoid site/arm for injection – deltoid muscle injection improves absorption of the vaccine. If this is not the first vaccination, choose the limb opposite the site of the previous injection.   A diagram of a person's knee  Description automatically generated   * Deltoid landmarks: 2-3 finger widths down from the acromion process; bottom edge is imaginary line drawn from axilla.      1. Firmly spread skin with the thumb and index finger, grasping the muscle deeply on each side. Cleanse the injection site with alcohol swab and allow area to air dry. 2. Insert the needle at a 90-degree angle. 3. Release the isolated tissue when the needle is safely inserted. 4. Inject entire dose of the vaccine at a rapid rate, using a smooth continuous motion (this decreases the pain of injection). 5. Withdraw the needle and engage built-in needle safety mechanism while simultaneously covering the injection site with clean gauze (hold gentle pressure). 6. Immediately dispose of the needle/syringe set in the sharp’s container. **Do not recap or remove the needle.** 7. Cover injection site with a band aid. 8. Remove and dispose of gloves and other waste in garbage receptacle and cleanse hands with alcohol-based hand sanitizer. Clean vaccination area and prepare for vaccination of next individual if applicable. 9. Monitor individual for **15** minutes (monitor for **30** minutes if individual has a history of non-severe allergic reaction to any previous vaccine or injectable therapy) post vaccination administration for any adverse reaction or side effect. 10. Document procedure, noting date of vaccination, name of vaccine, lot number, expiration date, site, route, and dose.  * Residents – place in eMAR Preventative Health section. * Employees – place on immunization screening and administration sheet keeping a copy for employee health records and giving original to employee. |

**References:**

1. [**https://www.immunize.org/**](https://www.immunize.org/)
2. [**https://assets.modernatx.com/m/7ce607d0bf1f0e20/original/FPI-0717\_Spikevax-2023-2024-Formula-Prescribing-Inform**](https://assets.modernatx.com/m/7ce607d0bf1f0e20/original/FPI-0717_Spikevax-2023-2024-Formula-Prescribing-Inform)
3. [**https://www.fda.gov/media/151707/download#:~:text=The%20vaccine%20will%20be%20a,dose%20intramuscularly%20immediately%20after%20preparation**](https://www.fda.gov/media/151707/download#:~:text=The%20vaccine%20will%20be%20a,dose%20intramuscularly%20immediately%20after%20preparation)**.**
4. [**https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/standing-orders-5yrs-older-508.pdf**](https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/standing-orders-5yrs-older-508.pdf)

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| **A map of the state with a coronavirus  Description automatically generated** | **Standing Orders Authorization** |
| This non-patient specific order and policy and procedure shall remain in effect for all residents and employees of Insert Facility Name from the order beginning date of \_\_\_\_\_\_\_\_\_\_\_\_ until \_\_\_\_\_\_\_\_\_\_\_\_ or until rescinded, whichever occurs first.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Medical Director Signature License Number Date |