**Purpose**: To reduce morbidity and mortality from Orthopoxvirus (Monkeypox, Smallpox) by vaccinating individuals with JYNNEOS (SMALLPOX AND MONKEYPOX VACCINE, LIVE, NON-REPLICATING) vaccine who are at high risk for exposure or as part of pre and post-exposure prophylaxis.

Policy: In addition to the approved standard subcutaneous regimen, on August 9, 2022, the FDA granted Emergency Use Authorization of JYNNEOS intradermal administration as an alternative to the subcutaneous route, as well as subcutaneous administration in those under 18 years of age.

Under these standing orders, eligible nurses and other health care professionals working within their scope of practice may vaccinate patients who meet the criteria below.

Note: There is no change in product formulation. Dosage differs based on age of individual and vaccine administration route. Vials are preservative free. Unused vaccine will still need to be discarded 8 hours after the vial is first accessed. A 2nd dose is still required to be completely immunized. Please review (**alternative regimen**): [Fact Sheet For Healthcare Providers Administering Vaccine: Emergency Use Authorization Of Jynneos (Smallpox And Monkeypox Vaccine, Live, Non-Replicating) For Prevention Of Monkeypox Disease In Individuals Determined To Be At High Risk For Monkeypox Infection](https://www.fda.gov/media/160774/download) and the package insert for [JYNNEOS (Smallpox and Monkeypox Vaccine, Live, Non-replicating) suspension for subcutaneous injection](https://www.fda.gov/media/131078/download) (**standard regimen**) prior to implementing this standing order.

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| Condition or Situation | |
| Condition or Situation in Which the SO Will Be Used | JYNNEOS is a vaccine indicated for prevention of smallpox and monkeypox disease in high-risk individuals.  Patients who present requesting vaccination with JYNNEOS will receive:  **Primary Series STANDARD REGIMEN 18 years and older of age**   * **2 subcutaneous injections (SQ)** separated by 28 days. People who receive JYNNEOS are considered to reach maximum immunity 14 days after their second dose (~ 6 weeks from first dose). They should continue to take precautions against monkeypox during this time.   **NOTE**: Two doses are required to be considered completely immunized.  **Primary Series LESS THAN 18 YEARS OF AGE**   * **2 subcutaneous injections (SQ)** separated by 28 days. People who receive JYNNEOS are considered to reach maximum immunity 14 days after their second dose (~ 6 weeks from first dose). They should continue to take precautions against monkeypox during this time.   **NOTE**: Two doses are required to be considered completely immunized.  **Primary Series - ALTERNATE REGIMEN 18 years of age and older:**   * **2 intradermal injections (ID)** separated by 28 days. People who receive JYNNEOS are considered to reach maximum immunity 14 days after their second dose (~ 6 weeks from first dose). They should continue to take precautions against monkeypox during this time.   **Recommended 2nd dose minimum and maximum intervals**  See [CDC interim clinical considerations](https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html#:~:text=Vaccination%20Schedule,injection%20volume%20of%200.5mL) for more information   * Minimum interval: The vaccine manufacturer advises against giving the second dose before the minimum interval of 28 days. However, based on ACIP’s general best practices, a dose may be administered up to 4 days before the minimum interval of 28 days (known as the “grace period,” which would be a minimum of 24 days after the first dose). * The second dose of JYNNEOS vaccine should be given 28 days after the first dose but may be given up to 7 days later than the minimum interval (i.e., up to 35 days after the first dose). * If the second dose is inadvertently administered before the minimum interval, the dose may not need to be repeated. Please refer to [Table 7. Vaccine Administration Errors and Deviations.](https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/errors-deviations.html" \l ":~:text=Table%207.%20Interim%20recommendations%20for%20JYNNEOS%20vaccine%20administration%20errors%20and%20deviations)   **NOTE**:  Persons with a history of keloid scarring **should not** receive this vaccine intradermally. Vaccinate subcutaneously following the instructions for subcutaneous vaccination below.  Two doses are required to be considered completely immunized. If 1st dose was administered subcutaneously, provide ID injection as 2nd dose.  **NOTE**: Two doses are required to be considered completely immunized.   |  |  |  |  | | --- | --- | --- | --- | | **Standard and Alternative Dosing Regimens** | | | | | **Age** | **Route** | **Dose** | **Dosing Interval\*** | | ≥ 18   Standard Regimen | Subcutaneous | 0.5 mL | 28 days | | <18  Alternatie Regimen | Subcutaneous | 0.5 mL | 28 days | | People of any age who have a history of developing keloid scars | Subcutaneous | 0.5 mL | 28 days | | **≥ 18** **Alternative Regimen** | **Intradermal\*\*** | **0.1 mL** | **28 days** |   \*Recommended minimum interval to 2nd dose is 28 days and a maximum interval 7 days later than the minimum interval (i.e., up to 35 days). There is no need to restart or add doses to the series if there is an extended interval between doses.  \*\* Requires use of a tuberculin syringe of 1/4 to 1/2 in in length and a 26 or 27 gauge needle. |
| Pre and Post-Exposure Prophylaxis | Administer JYNNEOS to persons who present requesting vaccination and self-attest to being in a high-risk category:  **JYNNEOS Eligibility Criteria**   1. Known contacts who are identified by public health via case investigation, contact tracing, and risk exposure assessments 2. Know that a sexual partner in the past 14 days was diagnosed with monkeypox 3. People who have been in close physical contact with someone diagnosed with monkeypox in the last 14 days (PEP) (see CDC [Exposure risk assessment](https://www.cdc.gov/poxvirus/monkeypox/clinicians/monitoring.html#:~:text=Exposure%20risk%20assessment%20and%20public%20health%20recommendations%20for%20individuals%20exposed%20to%20a%20patient%20with%20monkeypox)) 4. Men who have sex with men, or transgender individuals, who report any of the following in the last 90 days:    1. Having multiple or anonymous sex partners    2. Being diagnosed with a sexually transmitted infection    3. Receiving HIV pre-exposure prophylaxis (PrEP) 5. People who have been exposed to monkeypox who are at risk for severe adverse events with ACAM2000 or severe disease from monkeypox (such as people with HIV or other immunocompromising conditions). 6. Health care workers who were in the same room with or within 6 feet of a patient suspected or confirmed to have monkeypox during any procedures that may create aerosols from oral secretions, skin lesions, or resuspension of dried exudates (e.g., shaking of soiled linens), without wearing an N95 or equivalent respirator (or higher) and eye protection. 7. Persons exposed to monkeypox virus who have not received the smallpox vaccine within the last 3 years should consider getting vaccinated.   \*At this time, most clinicians in the United States and laboratorians not performing the orthopox virus generic test to diagnose orthopox viruses, including monkeypox virus, are not advised to receive monkeypox vaccine as Pre Exposure Prophylaxis (PrEP).   1. Clinical laboratory personnel who perform testing to diagnose orthopox viruses, including those who use polymerase chain reaction (PCR) assays for diagnosis of orthopox viruses, including Monkeypox virus 2. Research laboratory workers who directly handle cultures or animals contaminated or infected with orthopox viruses that infect humans, including Monkeypox virus, replication-competent Vaccinia virus, or recombinant Vaccinia viruses derived from replication-competent Vaccinia virus strains 3. Certain healthcare and public health response team members designated by public health authorities to be vaccinated for preparedness purposes 4. People who can get PrEP if they want to receive it include healthcare personnel who administer ACAM2000 or anticipate caring for many patients with monkeypox. |
| Assessment | |
| Assessment Criteria | Patients determined to be at high risk for exposure shall be vaccinated with JYNNEOS.  Patients who have experienced a high-risk exposure should ideally be vaccinated with JYNNEOS within 14 days of the date of exposure. Vaccination is most effective when given within 4 days of the date of the exposure. Vaccine given between 4–14 days after the date of exposure may reduce symptoms of disease but may not prevent the disease. |
|  | Subjective |
|  | 1. Client presents requesting smallpox vaccine (JYNNEOS) and meets criteria above. 2. Client presents requesting 2nd dose of JYNNEOS 3. People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting any dose of JYNNEOS™. 4. Persons recommended to receive JYNNEOS™ due to an exposure to monkeypox virus should be vaccinated regardless of concurrent illnesses, pregnancy, breastfeeding, or weakened immune system. |
|  | Objective |
|  | 1. Immunization record reveals client has not previously completed a smallpox vaccine series with either ACAM2000 (smallpox) or JYNNEOS vaccine within the last two years for pre-exposure prophylaxis or within the last three years for post-exposure prophylaxis. 2. Immunization record indicates receipt of 1 dose of JYNNEOS at least 4 weeks ago, and patient is presenting for second dose of the primary series. |
| Nursing Plan of Care | |
| Contraindications and Precautions | Screen all individuals for contraindications and precautions to JYNNEOS vaccine. Note that **pregnancy and breastfeeding are not contraindications.** Because JYNNEOS is non-replicating, it can be administered regardless of timing to previous live virus vaccine administration (e.g., MMR, Varicella). JYNNEOS is also safe for administration to people with HIV and atopic dermatitis.  Consult with medical staff if the following contraindications or precautions are present. These contraindications apply to use of STANDARD OR ALTERNATIVE REGIMEN.  **Contraindications:**   * Severe allergic reaction (e.g., anaphylaxis) after a previous dose of JYNNEOS vaccine. * People with a severe allergy to any component of the vaccine (gentamicin, ciprofloxacin, egg protein) should not receive this vaccine. (Note: JYNNEOS is formulated without preservatives. The vial stoppers are not made with natural rubber latex). More information on JYNNEOS cell line [here](https://www.precisionvaccinations.com/vaccines/jynneos-smallpox-monkeypox-vaccine#:~:text=109%2C090%20doses%20procured.-,JYNNEOS%20Cell%20Line,-JYNNEOS%C2%A0(MVA%2DBN). * Patient is currently taking Deflazacort (Calcort) * ALTERNATIVE REGIMEN ONLY: People of any age who have a history of developing keloid scars   **Precautions:**   * Moderate to severe acute illness with or without fever. * Patient is currently taking one of the following medications:   + - SAPHNELO™ (Anifrolumab-fnia)     - ILARIS® (Canakinumab)     - DUPIXENT® (Dupilumab)     - GILENYA® (Fingolimod)     - TALTZ® (Ixekizumab)     - ZEPOSIA® (Ozanimod)     - PONVORY™ (Ponesimod)     - COSENTYX® (Secukinumab)     - MAYZENT® (Siponimod)     - ADBRY™ (Tralokinumab-ldrm)     - LUPKYNIS™ (Voclosporin) * History of severe allergic reaction (e.g., anaphylaxis) to gentamicin or ciprofloxacin **or** * History of severe allergic reaction (e.g., anaphylaxis) to chicken or egg protein AND currently avoiding all chicken and egg products **or** * Persons who experienced anaphylaxis after any injectable. * After discussing risks and benefits with the patient, persons falling within these 3 categories of allergies may be vaccinated with a 30-minute observation period or referred for allergist-immunologist consultation prior to vaccination * Specific Groups: * Pregnancy and breast feeding are not contraindications to vaccination. * Pediatric and Geriatric populations: there have not been adequate studies to determine safety and efficacy in those under 18\* or over the age of 65. (\*JYNNEOS is not licensed for administration to individuals under the age of 18; however, it has been authorized under EUA for use in individuals less than 18.). Due to an unknown risk for myocarditis after JYNNEOS, persons might consider waiting 4 weeks after receipt of vaccination before receiving an mRNA COVID-19 vaccine. If post-exposure prophylaxis is recommended, vaccination with JYNNEOS should not be delayed because of recent receipt of an mRNA COVID-19 vaccine. |
| Nursing Actions | Implement the following vaccine regimen if above eligibility and assessment criteria are met and no precautions or contraindications are identified:   * Prior to vaccination provide patient with a copy of [Fact Sheet For Recipients And Caregivers About Jynneos (Smallpox And Monkeypox Vaccine, Live, Non-Replicating) To Prevent Monkeypox Disease In Individuals Determined To Be At High Risk For Monkeypox Infection](https://www.fda.gov/media/160773/download) . [Smallpox/Monkeypox Vaccine (JYNNEOS™)- English](https://www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.pdf) and [Smallpox/Monkeypox Vaccine (JYNNEOS™)-Spanish](https://www.immunize.org/vis/pdf/spanish_smallpox_monkeypox.pdf)  may be provided to augment EUA. * Per [NC Statute **90-21.5**](https://www.ncleg.net/enactedlegislation/statutes/html/bysection/chapter_90/gs_90-21.5.html)**,** written consent is required for JYNNEOS administration of JYNNEOS in persons less than 18 years old. * Inform patient/caregiver of possible side effects and reactions. Injection site redness is common. Persons with a history of immunocompromising conditions should be counseled on the possibility of a reduced response to the vaccine. * Counsel patients that it is not known if JYNNEOS will fully protect against monkeypox virus infection in this outbreak. Individuals wanting to minimize their risk of infection should take additional [preventive measures](https://www.cdc.gov/poxvirus/monkeypox/prevention/protect-yourself.html#:~:text=Monkeypox%20Prevention%20Steps) and immediately self-isolate should symptoms occur, such as a rash. * Health care personnel should follow routine infection control procedures when administering vaccines. Follow strict aseptic medication preparation practices. Perform hand hygiene before preparing vaccines. Use a designated, clean medication area that is not adjacent to areas where potentially contaminated items are placed. Avoid distractions. Some facilities have a no-interruption zone, where health care professionals can prepare medications without interruptions. Prepare medications for one patient at a time. Always follow the vaccine manufacturer’s directions, located in the package inserts. * Allow the vaccine to thaw and reach room temperature before use. * Swirl the vial gently before use for at least 30 seconds. * For individuals 18 years of age and older utilizing the **ALTERNATE REGIMEN** administer vaccine intradermally. Withdraw a dose of 0.1 mL into a sterile syringe. I**nject** using an area on the inner surface of the forearm that is free of lesions, moles or scars. Use a low dead volume syringe with a 26g or 27 g needle. Pull skin taut, insert needle bevel up at a 5-15 -degree angle until bevel is just under the epidermis. Administer medication slowly. A wheal or bubble-like area will appear under the skin. Do not rub area after administration of medication. Pat dry if weeping. Provide band-aid if needed. * For individuals 18 years of age and older utilizing the **STANDARD REGIMEN** administer the vaccine subcutaneously. Administer 0.5ml JYNNEOS via subcutaneous injection in the fatty tissue over triceps in adults. Use a 23-25g, 5/8" needle. Inject at a 45° angle. * For individuals **LESS THAN 18 YEARS** of age the vaccine must be administered subcutaneously. Administer 0.5ml JYNNEOS via **subcutaneous injection.** Withdraw a dose of 0.5 mL into a sterile syringe for injection. Administer JYNNEOS by subcutaneous injection, preferably into the anterolateral thigh for infants less than 1 year of age, or into the upper arm(deltoid) for individuals 1 through 17 years of age. Use a 23-25g, 5/8" needle. Inject at a 45° angle. * Once the vial is punctured and a dose is withdrawn, if it is not used in its entirety, it should be stored at +2°C to +8°C (+36°F to +46°F) and discarded within 8 hours of the first puncture. After thawing, the total time stored at +2°C to +8°C (+36°F to +46°F) should not exceed 8 weeks. * Document each patient’s vaccine administration information and follow up in the following locations: Electronic medical record/North Carolina Immunization Registry (NCIR)- record the date the vaccine was administered, manufacturer and lot number, the vaccination site and route, the name and title of the person administering the vaccine. Race, ethnicity, and gender and are now required fields in NCIR and should be reviewed and updated to ensure accurate documentation for the JYNNEOS recipient. For tracking purposes, ensure doses are documented from live inventory in NCIR (do not enter historically). * If the vaccine was not administered, record reason (s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). * Inform patient/caregiver to go to the Emergency Department of the nearest hospital if an adverse reaction occurs. * Advise vaccine recipient to report any adverse events to their healthcare provider or to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 and [www.vaers.hhs.gov](http://www.vaers.hhs.gov). * Instruct patient to call clinic, or their health care provider with any questions and/or problems. * Inform vaccine recipient of the importance of completing the two dose vaccination series (at least 28 days apart) for first time vaccine recipients. |
| Follow-up | **VAERS Reporting**: Healthcare providers are required to report to VAERS adverse events found in the Reportable Events Table (RET) at <https://vaers.hhs.gov/resources/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf>. For events not included in the RET, healthcare providers are encouraged to report any additional clinically significant adverse events after vaccination to VAERS even if it is uncertain whether the vaccine caused the event.  **Anaphylaxis Management**: Be prepared to manage medical emergencies by following your emergency response policies, procedures, and standing orders for any vaccine reaction, which must include appropriate equipment and medications (e.g., epinephrine, diphenhydramine) where vaccines are provided to respond to [severe allergic reactions and anaphylaxis](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).  **Syncope:** Be prepared to manage syncope as it may occur in association with administration of injectable vaccines, particularly in adolescents. Procedures should be in place to avoid injury from fainting. |
|  | Criteria for Notifying the physician/APP |
| Criteria for Notifying the physician/APP | 1. Allergic reaction: Call 911, implement medical protocols and immediately notify the medical provider providing clinical supervision of the vaccination site/service. 2. Consult with physician/ advanced practice provider if the patient reports any contraindications or precautions to the vaccine prior to administration. |

Approved by: \_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date approved (or last reviewed): \_\_\_\_\_\_\_\_\_\_\_\_

(Signature of physician/APP)