Purpose: To reduce morbidity and mortality from Orthopoxvirus (Monkeypox, Smallpox) by vaccinating individuals with JYNNEOS vaccine who are at high risk for exposure or as part of pre and post-exposure prophylaxis who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Policy note published June 3, 2022. Use of JYNNEOS for Vaccination of Persons at Risk of infection with Orthopoxvirus based on ACIP Recommendations. 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.

<table>
<thead>
<tr>
<th>Condition or Situation</th>
<th>Condition or Situation in Which the SO Will Be Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>JYNNEOS is a vaccine indicated for prevention of smallpox and monkeypox disease in high-risk adults 18 years of age and older. JYNNEOS is recommended to be administered within 4 days from date of exposure to Monkeypox to prevent the onset of disease. If given between 4-14 days post exposure, symptoms may be reduced, but disease may not be prevented. JYNNEOS can be administered at the same time as other vaccines.</td>
<td>Patients who present requesting vaccination with Jynneos will receive:</td>
</tr>
</tbody>
</table>

**Primary Series**

2 subcutaneous injections separated by 4 weeks. 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.

Pre and Post-Exposure Prophylaxis

Administer Jynneos to persons 18 years of age and older who present requesting vaccination and self-attest to meeting current criteria for persons receiving vaccination in North Carolina described below and outlined in NCDHHS provider memo.

**Post-Exposure Prophylaxis (PEP)**

1. PEP is recommended for:
   a. People who have been in close physical contact with someone diagnosed with monkeypox
   b. Men who have sex with men, or transgender individuals, who have had multiple or anonymous sex partners in the last 14 days immunocompromising conditions).
   Health care workers who were in the same room with or within 6 feet of a patient with 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.
   2. Persons exposed to monkeypox virus who have not received the smallpox vaccine within the last 3 years should consider getting vaccinated.
   3. Vaccine should be given within 4 days from the date of exposure to prevent onset of the disease. If given between 4–14 days after the date of exposure, vaccination may reduce the symptoms of disease, but may not prevent the disease.

**Pre-Exposure Prophylaxis (PrEP)**

*At this time, most clinicians in the United States and laboratorians not performing the orthopox virus test to diagnose orthopox viruses, including monkeypox virus, are not advised to receive monkeypox vaccine PrEP. However, the Federal Department of Health and Human Services is considering a broader PrEP strategy as supply allows and based on evolving need.*
| Assessment | Criteria | 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**

Assess patient’s risk level using the **[CDC’s Exposure risk assessment guidance](https://www.cdc.gov/poxvirus/monkeypox/prevention/vaccine.html)**. Patients 18 years and older who self-attest to meeting criteria for vaccination as described above, shall be vaccinated with JYNNEOS. Patients reporting a high-risk exposure or meet eligibility guidelines for expanded PEP/PrEP shall 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 not prevent disease but could reduce symptoms.

**Subjective**

1. Client 18 years and older presents requesting smallpox vaccine (JYNNEOS) and self-attests to being at risk for Monkeypox disease (due to a high risk exposure or potential for high risk exposure to monkeypox within 14 days).
2. Client 18 years and older presents requesting 2nd dose of Jynneos
   a) 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™.
   b) Persons eligible to receive JYNNEOS™ due to an exposure, or potential exposure, to monkeypox virus should be vaccinated regardless of concurrent illnesses, pregnancy, breastfeeding, or weakened immune system.

**Objective**

JYNNEOS is licensed for persons over 18 years of age.
1. Laboratory diagnosis of Monkeypox or pending results of testing.
2. Clinical evaluation suspicious for Monkeypox.
3. 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.
4. 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.
5. Jynneos is safe for administration to people with HIV and atopic dermatitis

**Nursing Plan of Care**

**Contraindications and Precautions**

Screen all adults 18 years and older 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). Consult with medical staff if the following contraindications or precautions are present:
### Contraindications:
- 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](#).
- Patient is currently taking Deflazacort (Calcort)

### 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-ldrg)
  - LUPKYNIST™ (Voclosporin)

### Nursing Actions
Implement the following vaccine regimen if above criteria are met and no precautions or contraindications are identified:

1. Provide patient with a copy of the most current federal Vaccine Information Statement (VIS) for Smallpox/Monkeypox. The VIS can be found at [https://www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.html](https://www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.html). You must document in the patient's medical record or office log, the publication date of the VIS and date it was given to the patient (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred; these can be found at [https://www.immunize.org/vis/vis_smallpox_monkeypox.asp](https://www.immunize.org/vis/vis_smallpox_monkeypox.asp).
2. Written consent is not required under federal or state law for JYNNEOS administration. However, administering agencies may obtain consent following internal guidelines/policies.
3. Inform patient/caregiver of possible side effects and reactions. Persons with a history of immunocompromising conditions should be counseled on the possibility of a reduced response to the vaccine.
4. 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 and immediately self-isolate should symptoms occur, such as a rash.
5. Specific Groups:
   a. Pregnancy and breast feeding are not contraindications to vaccination.
   b. 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). 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.

6. 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.

7. Allow the vaccine to thaw and reach room temperature before use.

8. Swirl the vial gently before use for at least 30 seconds. Withdraw a dose of 0.5 mL into a sterile syringe for injection.

9. 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.

10. 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 and ethnicity 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).

11. If the vaccine was not administered, record reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).

12. Inform patient/caregiver to go to the Emergency Department of the nearest hospital if an adverse reaction occurs.

13. 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.

14. Instruct patient to call clinic, or their health care provider with any questions and/or problems.

15. 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.

**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)