

**CHINLE SERVICE UNIT**

**Pharmacy Department  
POLICY & PROCEDURES**

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**SUBJECT** Pharmacy JYNNEOS Vaccine Clinic

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<b>ORIGINAL EFFECTIVE DATE CODE</b>	<b>LATEST REVISION</b>	<b>MANUAL</b>
	09.2022	03.205

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**DISTRIBUTION** Pharmacy Staff, Medical Staff, Nursing Staff Administration

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**POLICY**

To briefly outline the procedure for JYNNEOS Vaccine Administration to insure that patients are fully and appropriately immunized. **Please reference approved CSU Policy and Procedure Statement about JYNNEOS Clinical Use, Administration, Monitoring, and Reporting Policy**

**PURPOSE**

To ensure that policies related to JYNNEOS Vaccine Administration is outlined according to current guidelines and administration and to serve as an alternative site for delivery of JYNNEOS vaccination services.

**BACKGROUND**

On August 4, 2022 the United States Government declared a Public Health Emergency for the continuous uncontrolled spread of the Monkeypox Virus. The Monkeypox virus is part of the same family as the variola virus which is the same class of virus that also causes Smallpox infection. Monkeypox virus is not related to the varicella virus or chicken pox. Monkeypox virus can spread between people when an individual has contact with a person who is infected with Monkeypox or touches materials that are contaminated with the virus. Monkeypox and smallpox virus are closely related, the medications and vaccines developed to protect against small pox may be used to prevent and treat Monkeypox virus infections. The FDA has two smallpox vaccines licensed and available to prevent Monkeypox. The preferred vaccine is a live, non-replicating vaccine, Jynneos vaccine.

**PROCEDURE**

**1. CSU Monkeypox OPD Guidance**

**2. Patient Eligibility Criteria**

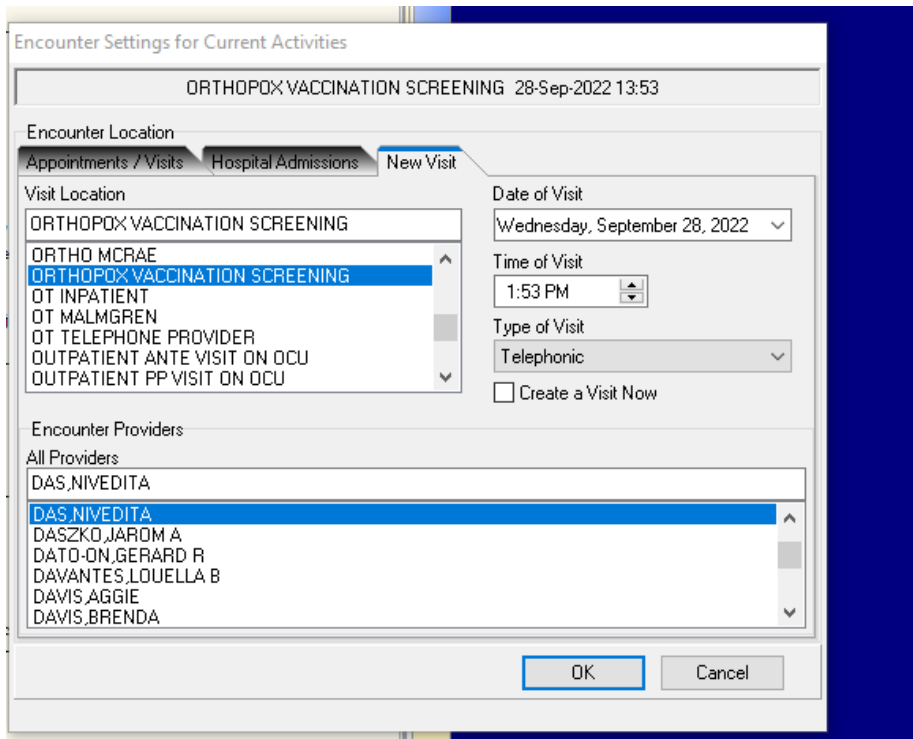
- a. Patients 18 years of age and older.
- b. Based on guidance from CSU Public Health Department and Clinical SME
- c. **Generally:** patients are divided in the following categories listed below

Strategy	Definition	Criteria
<b>Post-Exposure Prophylaxis (PEP)</b>	Vaccination <b>after known exposure</b> to monkeypox	<ul style="list-style-type: none"> <li>• People who are known contacts to someone with monkeypox who are identified by public health authorities, for example via case investigation, contact tracing, or risk exposure assessment</li> </ul>
<b>Expanded Post-Exposure Prophylaxis (PEP++)</b>	Vaccination <b>after known or presumed</b> exposure to monkeypox	Any of the following: <ul style="list-style-type: none"> <li>• People who are known contacts to someone with monkeypox who are identified by public health authorities, for example via case investigation, contact tracing, or risk exposure assessment</li> <li>• People who are aware that a recent sex partner within the past 14 days was diagnosed with monkeypox</li> <li>• Certain gay, bisexual, or other men who have sex with men, or transgender people, who have had any of the following <b>within the past 14 days</b>: sex with multiple partners (or group sex); sex at a commercial sex venue; or sex in association with an event, venue, or defined geographic area where monkeypox transmission is occurring</li> </ul>
<b>Pre-Exposure Prophylaxis (PrEP)</b>	Vaccination <b>before exposure</b> to monkeypox	<ul style="list-style-type: none"> <li>• People in certain occupational risk groups* (PrEP is not generally recommended for HCPs)</li> </ul>

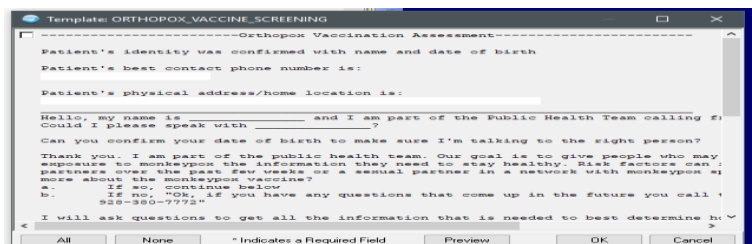
\*People at risk for occupational exposure to orthopoxviruses include research laboratory workers performing diagnostic testing for *Monkeypox virus*, and members of health care worker response teams designated by appropriate public health and anterior authorities (see [ACIP recommendations](#)).

- d. **Expanded MPX Vaccine guidance for PrEP** per Navajo Area IHS
  - i. Anyone (any sexual orientation or gender identity) who has had close physical contact with someone who has monkeypox in the last 14 days.
  - ii. Anyone (any sexual orientation or gender identity) who:
    - 1. Has had multiple sexual partners in the last 14 days, or
    - 2. Has had sexual partners they did not previously know in the last 14 days, or

3. Has had close physical contact with other people in a venue where anonymous or group sex may occur in the last 14 days, or
  4. Was diagnosed with gonorrhea, chlamydia\*or syphilis in the past three months, or
  5. Already uses or is eligible for HIV PrEP (medication to prevent HIV, e.g. Truvada or Descovy or Apretude) or has HIV infection\*, or
  6. Engages in commercial and/or transactional sex (e.g. sex in exchange for money, shelter, food, and other goods or needs).
- e. Anyone (any sexual orientation or gender identity) identified by public health as a known high-risk contact of someone who has monkeypox.
- 3. Special Populations:**
- a. JYNNEOS vaccine can be offered to people who are pregnant or breastfeeding who are otherwise eligible
    - i. Risk and benefits should be discussed with the patient using shared decision making
  - b. Vaccination if patient is diagnosed with monkeypox
    - i. A person who is diagnosed with monkeypox after their first dose of JYNNEOS is not recommended to receive the second dose at this time, because monkeypox infection likely confers additional immune protection.
    - ii. A person who would be eligible for vaccination but has been diagnosed with monkeypox during this outbreak, which started in the United States on May 17, 2022, is not recommended to be vaccinated at this time, because monkeypox infection likely confers immune protection.
    - iii. An immunocompromised person who is diagnosed with monkeypox after their first dose of JYNNEOS may be eligible to receive the second dose of JYNNEOS on a case-by-case shared decision-making basis based on the clinical judgment of the healthcare provider.
- 4. Patients referred to Pharmacy JYNNEOS Vaccine Clinic:**
- a. MPX PrEP Initiative:
    - i. Public Health identifies and calls patients using Orthropox Vaccination Screening template: APPENDIX A



- ii. Click on New Note and type in: ORTHOPOX\_VACCINE\_SCREENING and complete template:



- iii. After patients are screened, PH makes appointment using Practice Management Suite under Orthropox Vaccination Screening
- b. PEP and PEP++
  - i. Trained Pharmacists are scheduled as needed
  - ii. MPX SME providers reach out to pharmacy management to set up vaccination appointments
- c. Referral System:
  - i. Patients may also be referred to Pharmacy by clinicians using Orthropox Vaccination Referral
    1. COVID-19 Pharmacy Provider receives these consults, calls patients and screens using Orthropox Vaccination Screening template
    2. Order set for the consult includes referral to the vaccine clinic, order for the 1<sup>st</sup> dose, and the order for the 2<sup>nd</sup> dose 28 days later
  - ii. COVID-19 Pharmacy Provider makes appointment using Practice

Management Suite under Orthropox Vaccination Screening

5. JYNNEOS Pharmacy Vaccine Clinic
  - a. Thursday: 8AM to 12PM
    - i. 2 vaccinators
    - ii. Appointment length: 15 minutes
6. JYNNEOS Vaccine Storage and Handling Summary
  - a. Receiving Frozen Vaccines:
    - i. Storage between -25°C and -15°C (between -13°F and +5°F)
    - ii. Expiration date: printed expiration date on the carton
  - b. Receiving Refrigerated Vaccines:
    - i. Refrigerator storage between 2°C and 8°C (between 36°F and 46°F).
    - ii. As specified in the note above, refrigerated vaccine is thawed vaccine and must be used within 8 weeks from thawing.
    - iii. DO NOT refreeze.
  - c. **JYNNEOS may be stored refrigerated between 2°C and 8°C (between 36°F and 46°F) for up to 8 weeks from thawing.**
7. JYNNEOS Vaccination Step-by-Step Guide
  - a. Please see Appendix B
8. JYNNEOS Vaccine Regimen

JYNNEOS Vaccine Regimen	Route of Administration	Injection Volume	Recommended Number of Doses	Dosing Interval between 1 <sup>st</sup> and 2 <sup>nd</sup> Dose
<b>Alternate Regimen -</b>				
People ≥18 years of age	Intradermal (ID)	0.1 ml	2	28 days
<b>Standard Regimen -</b>				
People <18 years of age	Subcutaneously (SQ)	0.5 ml	2	28 days
People of any age who have a history of developing keloid scars	Subcutaneously (SQ)	0.5 ml	2	28 days

9. Patient Monitoring:
  - a. The pharmacy immunizer will instruct the patient to wait 15 minutes in the waiting area after the vaccine administration.
  - b. If patient has had a history of anaphylactic reaction to Gentamicin, Ciprofloxacin, chicken, or egg protein allergy, they will be instructed to wait 30 minutes after vaccine administration.
  - c. If an allergic reaction or serious vaccine reaction occurs, EPI pen will administered and depending on the severity of the reaction, CODE Blue may be called.
10. Vaccine Adverse Reactions and Errors (VAERS)
  - a. Documentation of Adverse Reactions and Errors
  - b. The adverse event will be noted in the EHR and reported within I-STAR.

- c. Under the EUE reporting is required to the Vaccine Adverse Events Reporting Systems (VAERS) by calling 1-800-822-7967 or by reporting it on the VAERS website: [www.vaers.hhs.gov](http://www.vaers.hhs.gov)

**11. Training Requirements:**

- a. Intradermal Vaccine Administration Training
- b. IHS JYNNEOS Vaccine Competency
- c. Monkeypox Vaccine Administration Vaccinator Training Completion Attestation

**12. References:**

- a. <https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/special-populations.html>
- b. [https://www.lah.gov/assets/oph/monkeypox/333240-B\\_Monkeypox\\_JYNNEOS\\_Storage\\_and\\_Handling.pdf](https://www.lah.gov/assets/oph/monkeypox/333240-B_Monkeypox_JYNNEOS_Storage_and_Handling.pdf)