**Purpose**

To reduce morbidity and mortality from Orthopoxvirus (Monkeypox) by vaccinating with the JYNNEOS vaccine persons at high risk of exposure to the virus, or as a post-exposure prophylaxis of persons who meet the criteria established by the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices (ACIP).

**Policy**

This standing order establishes administration parameters for any individual authorized to administer a JYNNEOS vaccine for vaccination of persons at risk of infection with Orthopoxvirus based on ACIP recommendations and eligibility criteria for [Monkeypox vaccine](https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html#vaccine-information). Under this standing order, eligible nurses and other healthcare professionals working within their scope of practice may vaccinate patients who meet the criteria below.

**Procedure**

1. Assess adults in need of vaccination against orthopoxvirus (Monkeypox).
	1. Must be 18 years of age and older.
	2. Post Exposure Prophylaxis (PEP) administer within 4 days from the date of exposure to prevent symptom onset. If administered between 4-14 days after the date of exposure symptoms may be reduced but disease may not be prevented.
	3. Pre-Exposure Prophylaxis (PrEP) for persons at occupational risk for exposure to orthopox viruses [MMWR 2022 JYNNEOS.](https://www.cdc.gov/mmwr/volumes/71/wr/mm7122e1.htm)
	4. Patient previous vaccination status regarding JYNNEOS and ACAM2000 (Smallpox vaccination status).
		1. Individuals with occupational exposure to more virulent forms of orthopox should be boosted with JYNNEOS every 2 years following completion of the primary series.
		2. Individuals with occupational exposure to less virulent forms of orthopox should be boosted with JYNNEOS every 10 years following completion of the primary series.
		3. Individuals who have previously received ACAM2000 (Small Pox vaccine) may receive the JYNNEOS vaccine for subsequent booster doses.
2. Screen all adults for contraindications and precautions for the Monkeypox vaccine.
	1. Contraindications
		1. Under 18 years of age.
		2. Do not give the vaccine to anyone who has had a severe allergic reaction to the JYNNEOS vaccine or any ingredient of the vaccine <https://www.fda.gov/media/131078/download>.
		3. Allergy to gentamicin, ciprofloxacin or egg protein.
		4. Patient is currently taking Deflazacort (Calcort).
	2. Precautions
		1. Moderate to severe acute illness with or without fever.
		2. Allergic reaction of any severity to polysorbate (due to potential cross-reactivity hypersensitivity with the vaccine ingredient PEG\*\*).
			1. Action
				1. Assess the risk of vaccination.
				2. Observe patient for 30 minutes following vaccination.
		3. Severe allergic reaction (e.g. Anaphylaxis) to a medication\*\* that is injectable.
			1. Action
				1. Assess the risk of vaccination.
				2. Observe patient for 30 minutes following vaccination.
		4. Separate JYNNEOS and an mRNA COVID-19 vaccine by 4 weeks due to theoretical concerns regarding myocarditis. If JYNNEOS is recommended for PEP in an outbreak setting do not delay.
		5. If taking any of the following medications consult with a physician before vaccination.

▪ SAPHNELO™ (Anifrolumab-fnia) ▪ ILARIS® (Canakinumab) ▪ DUPIXENT® (Dupilumab) ▪ GILENYA® (Fingolimod) ▪ TALTZ® (Ixekizumab) ▪ ZEPOSIA® (Ozanimod) ▪ PONVORY™ (Ponesimod) ▪ COSENTYX® (Secukinumab) ▪ MAYZENT® (Siponimod) ▪ ADBRY™ (Tralokinumab-ldrm) ▪ LUPKYNIS™ (Voclosporin)

1. Special Populations
	1. Pregnancy- Data are insufficient to determine vaccine-associated risks in pregnancy. In animals who received JYNNEOS, there has been no evidence of harm to the developing fetus.
	2. Breastfeeding and lactating females- It is not known whether JYNNEOS is excreted in human milk or is safe in breastfed infants. However, per CDC it is unlikely to present a risk of transmission to breastfed infants and can be administered to women who are breastfeeding if vaccination is critical.
	3. Immune compromised individuals may have a diminished immune response to JYNNEOS.
	4. Individuals with underlying heart disease or 3 or more cardiac risk factors (hypertension, diabetes, hypercholesterolemia, heart disease at age 50 or younger in a first degree relative (parent, sibling or child) and smoking should be counseled about theoretical risk of myopericarditis following vaccination with JYNNEOS.
2. Provide the Vaccine information Statement
	1. Provide all patients (or in the case of minors or incapacitated adults their legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language if one is available and desired; these can be found at [Vaccine Information Statement for JYNNEOS](https://www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.pdf).
3. Prepare the Vaccine
	1. Choose the correct needle length and gauge for an intramuscular injection.

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| **Age of Patient**  | **Needle Gauge**  | **Needle Length** | **Injection Site** |
| 18 years and older  | 23-25 | 5/8”  | Fatty tissue over the triceps  |

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* 1. Prepare the JYNNEOS Vaccine
1. Remove the single dose vial from the storage unit.
2. If preparing from a frozen state allow 10 minutes for vaccine to thaw.
3. Gently swirl the vial for 30 seconds (vaccine should be milky, light yellow to pale white).
	1. If any particulates or discoloration are noted – do not use.
4. Remove the cap.
5. Clean off the top of the vial with an alcohol wipe.
6. Using a 1 or 3 cc syringe with a 5/8” 23-25 gauge needle.
7. Withdraw 0.5mL the vaccine.
8. Discard the remaining vaccine in the vial in a sharps container.
9. Administer the Vaccine

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| **Age Group** | **Dose** | **Route** | **Instructions**  |
| 18 years and older | 0.5mL | Subcutaneous injection  | Administer dose 1 and 2 at least 28 days apart  |

1. Document
	1. Consent Form: Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, the vaccine dosage, and the name and title of the person administering the vaccine. Document the VIS given, and VIS publication date.
	2. Immunization Record Card: Record the date of vaccination and the name/location of the administering clinic and supply to recipient at time of vaccination.
	3. Documentation of the vaccination in Missouri’s immunization information system, ShowMeVax, within 24-48 hours following vaccination.
2. Emergency Protocols
	1. If a patient experiences itching and swelling confined to the injection site where the vaccination was given, apply a cold compress to the injection site. Observe patient closely for the development of generalized symptoms until symptoms subside.
	2. If symptoms are generalized (generalized itching, redness, urticaria (hives); or include angioedema (swelling of the lips, face, or throat); shortness of breath; shock; or abdominal cramping; call 911 and notify the patient’s physician. Notifications should be done by a second person while the primary healthcare professional assesses the airway, breathing, circulation and level of consciousness of the patient. Vital signs (heart rate, respirations and Blood Pressure, pulse ox) should be taken every 5 minutes.
		1. First-line treatment of an anaphylactic reaction is to administer Epinephrine 1:1000 dilution intramuscularly adult dose 0.3ml to 0.5ml with maximum dose of 0.5ml; or
		2. To administer Epinephrine auto-injector (0.3ml).
		3. For hives or itching, you may also administer diphenhydramine (orally or intramuscular with a standard dose of 25-50mg.) or hydroxyzine (standard oral dose is 25mg -100mg or 0.5-1.0 mg/kg.
		4. Monitor the patient closely until EMS arrives. Monitor blood pressure and pulse every 5 minutes.
		5. If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 5-15 minutes for up to 3 doses depending on patient’s response.
		6. Record the patient’s reaction to the vaccine (e.g., hives, anaphylaxis), all vital signs, and medications administered to the patient, including time dosage, response, and the name of the medical personnel who administered the medication and other relevant clinical information.
		7. Notify the patient’s primary care physician.
		8. Report any adverse event or vaccine error to VAERS. Report the incident to the Vaccine Adverse Event Reporting System (VAERS) at <https://vaers.hhs.gov/reportevent.html> or call 1-800-822-7967.

Authorization

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