LOUISIANA DEPARTMENT OF HEALTH Public Health	**Health Alert Network Message 22-27: Interim Clinical Considerations for Use of JYNNEOS Vaccine during the 2022 U.S. Monkeypox Outbreak**
Origination Date: *August 10, 2022*	**Revision Dates (List All Revision Dates):**

Interim Clinical Considerations for Use of JYNNEOS Vaccine during the 2022 U.S. Monkeypox Outbreak

Summary

On August 9, 2002, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the emergency use of JYNNEOS for:

- Active immunization by intradermal injection for prevention of monkeypox disease in individuals 18 years of age and older determined to be at high risk for monkeypox infection.
- Active immunization by subcutaneous injection for prevention of monkeypox disease in individuals less than 18 years of age determined to be at high risk for monkeypox infection.

The Centers for Disease Control and Prevention (CDC) recommends that vaccination with JYNNEOS can be considered for people determined to be at high risk for infection to prevent monkeypox disease and has provided interim guidance regarding use of JYNNEOS vaccine during the monkeypox outbreak that began in the United States on May 17, 2022. This interim guidance is in addition to existing standard guidance and recommendations for use of these vaccines from CDC's Advisory Committee on Immunization Practices (ACIP).

Vaccination Schedule

JYNNEOS vaccine is licensed as a series of two doses administered 28 days (4 weeks) apart.
The **standard regimen** involves a subcutaneous (Subcut) route of administration with an injection volume of 0.5mL. The standard regimen is the FDA-approved dosing regimen and has now been authorized for people aged <18 years under an EUA.

In the context of the current national Public Health Emergency (PHE), an **alternative regimen** may be used for people age ≥18 years under an EUA. The authorized alternative regimen involves an intradermal (ID) route of administration with an injection volume of 0.1mL. This approach could increase the number of available JYNNEOS vaccine doses by up to five-fold. Results from a clinical study showed that the lower intradermal dose was immunologically non-inferior to the standard subcutaneous dose (Frey SE et al, Vaccine, 2015; 33(39):5225-5234).

Table 2. Vaccination Schedule and Dosing Regimens for JYNNEOS Vaccine

JYNNEOS vaccine regimen	Route of administration	Injection Volume	Recommended number of doses	Recommended interval between 1st and 2nd dose
Alternative regimen				
People age ≥18 years	ID	0.1 mL	2	28 days
Standard regimen				
People age <18 years	Subcut	0.5 mL	2	28 days
People of any age who have a history of developing keloid scars	Subcut	0.5 mL	2	28 days

Duration of Immunity

Peak immunity is expected to be reached 14 days after the second dose of JYNNEOS vaccine. The duration of immunity after two doses of JYNNEOS is unknown.

Dosing Intervals

Recommended interval: The second dose of JYNNEOS vaccine should be given 28 days after the first dose. Based on available clinical study data, the second dose may be given up to 7 days later than the minimum interval of 28 days (i.e., up to 35 days after the first dose).
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).

Please refer to "Table 7. Vaccine Administration Errors and Deviations" for guidance related to administration of second doses outside the recommended interval.

Interchangeability of dosing regimens

When necessary, a person aged 18 years or older who received one JYNNEOS vaccine dose with the standard subcutaneous regimen may receive a second dose with the alternative intradermal regimen at the recommended interval (i.e., 28 days) to complete the vaccination series. For example, a person who received only one dose of the standard regimen before the date of initial Emergency Use Authorization for the alternative regimen (August 9, 2022), may receive one dose with the alternative regimen to complete the series. Also, a person whose 18th birthday occurs between their first and second dose may complete the series with the alternative regimen.

Coadministration of JYNNEOS vaccine with other vaccines

Currently, there are no data on administering JYNNEOS vaccine at the same time as other vaccines. Because JYNNEOS is based on a live, attenuated non-replicating orthopoxvirus, JYNNEOS typically may be administered without regard to timing of other vaccines. This includes simultaneous administration of JYNNEOS and other vaccines on the same day, but at different anatomic sites if possible.
However, there are additional considerations if administering a COVID-19 vaccine. (Interim Clinical Considerations for Use of COVID-19 Vaccines)

Patient counseling

Pre-vaccination counseling

Recipients should be informed of the risks and benefits of JYNNEOS prior to vaccination. Healthcare providers should ascertain the medical history of recipients to appropriately determine the route of vaccine administration. Recipients should be counseled about possible side effects from vaccination including injection site pain, redness, swelling, induration, itching, fatigue, headache, nausea, chills, and muscle aches, and be provided with a JYNNEOS vaccine information statement (VIS) or FDA JYNNEOS EUA Fact Sheet, as applicable. There have been reports of prolonged duration of induration or erythema following intradermal administration. Side effects are usually self-limiting.

Post-vaccination counseling

Given the unknown effectiveness of vaccination in this outbreak, people who are vaccinated should continue to take steps to protect themselves from infection by avoiding close, skin-to-skin contact, including intimate contact, with someone who has monkeypox.

Clinical studies have not detected an increased risk for myopericarditis in recipients of JYNNEOS. However, people with underlying heart disease or three or more major cardiac risk factors should be counseled about the theoretical risk for myopericarditis following vaccination with JYNNEOS given the uncertain etiology of myopericarditis associated with replication-competent smallpox vaccines such as ACAM2000.

Safety

Contraindications and precautions

People presenting with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they have recovered to their baseline state of health before vaccination. A person offered JYNNEOS vaccine due to an exposure to monkeypox virus or disease should be vaccinated regardless of concurrent illnesses, pregnancy, breastfeeding, or weakened immune system.

Vaccine providers, particularly when vaccinating adolescents, should consider observing patients (with patients seated or lying down) for 15 minutes after vaccination to decrease the risk for injury should they faint. If syncope develops, patients should be observed until the symptoms resolve.

CDC considers vaccination with JYNNEOS to be either contraindicated (not recommended) or a precaution in the following situations:

Contraindication: History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of JYNNEOS

- *Suggested action*: Do not vaccinate. Referral to an allergist-immunologist should be considered to assess the risks versus benefits of administering a dose.

Precautions: History of severe allergic reaction (e.g., anaphylaxis) following gentamicin or ciprofloxacin, or to chicken or egg protein **AND** are currently avoiding exposure to all chicken or egg products

- JYNNEOS vaccine contains small amounts of gentamicin and ciprofloxacin and is produced using chicken embryo fibroblast cells.
- *Suggested action*: Discuss risks and benefits with potential recipients. They may be vaccinated with a 30-minute observation period. Alternatively, vaccination can be delayed until an allergist-immunologist is consulted, but the impact of delaying vaccination should be considered.

Precaution: Moderate or severe acute illness, with or without fever

- *Suggested action:* Consider deferring vaccination until the acute illness has improved.

CDC's Clinical Immunization Safety Assessment (CISA) Project are available to provide consultation to U.S. healthcare providers and health departments about complex monkeypox vaccine safety questions for their patients. (Clinical Immunization Safety Assessment (CISA) Project).

Reporting of adverse events
Vaccination providers who are administering JYNNEOS under the EUA are **required** to report the following adverse events that occur after JYNNEOS vaccination: vaccine administration errors whether or not associated with an adverse event, serious adverse events (irrespective of attribution to vaccination), cases of cardiac events including myocarditis and pericarditis, and cases of thromboembolic events and neurovascular events.

Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967.

Reporting Vaccine Administrations into the Louisiana Immunization Network (LINKS) Registry
Providers that are currently administering Jynneos vaccine will receive updated guidance from the Office of Public Health Immunization Program regarding entering Jynneos vaccine administrations into LINKS.

For More Information:

- CDC JYNNEOS Vaccine Clinical Guidance
- CDC Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines during the 2022 U.S. Monkeypox Outbreak