NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

JYNNEOS Provider FAQ

Updated December 13, 2022
New content as of December 13, 2022, highlighted in yellow

Can patients participate in V-Safe after receiving JYNNEOS vaccination?	**YES.** Flyers are available for printing and online demos are included at this website. How to Complete a V-safe for Monkeypox Vaccine Health Check-In | Monkeypox | Poxvirus | CDC
Is it still required to use the ID administration route to vaccinate all adults except those with contraindications?	**NO**. On 12/9/22, NC DHHS rescinded their previous request to administer JYNNEOS intradermally to all adult recipients unless the client has a medical contraindication to the ID route. This decision was made considering the decreasing incidence of cases, adequate supply statewide of vaccine and to reduce all barriers to care, in alignment with CDC guidance. As of 12/9/22, Public Health Jurisdictions and health care providers should decide whether to offer the intradermal or subcutaneous regimen based on balancing optimal vaccination use and acceptance, feasibility of administration and available vaccine supply
Why is monkeypox now being referred to as mpox?	The WHO, on 11/28/22, in collaboration with other partners determined that the term "monkeypox" could generate negative/stigmatizing situations for those diagnosed or exposed to mpox and that it may delay persons from seeking treatment or vaccination.
Now that there is a new VIS for JYNNEOS can I through the old ones away?	CDC states agencies can continue using the older version of the JYNNEOS VIS until they run out. The new VIS is dated 11/14/22. Vaccine Information Statement: Smallpox/Monkeypox Vaccine (JYNNEOS™): What You Need to Know (cdc.gov)
Does JYNNEOS have to be reconstituted before administration?	No
How many doses are in each vial?	When administering as an ID vaccine, 5 doses/vial. When administering as a SQ vaccine, 1 dose/vial.
Why is there such a short "shelf-life" on this vaccine?	Because there is no preservative included in the formulation.

If when administering the vaccine intradermally and a wheal does not form, should the dose be repeated?	It depends. • If there is no leakage at the area the injection was given and no wheal, then the dose is considered valid. Do not repeat. • If there is leakage of vaccine in area of injection and no wheal, then repeat ID injection at least 2 inches away from the first injection attempt. If successful on 2nd attempt regardless of formation of wheal and NO leakage, then client considered vaccinated. • If there is leakage after the second attempt, then vaccinate on the same day using the SQ route and dosage. CDC guidance updated on 9/28/22: Table 7 https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/errors-deviations.html
May the vaccine be used interchangeably for 2nd doses?	Yes. Dosing regimens are interchangeable, meaning individuals who received their first dose of JYNNEOS subcutaneously can receive the second dose intradermally.
May I combine vaccine from 2 separate vials to make one dose?	No. Vaccine from vials should not be combined.
Are there any data or concerns related to stability and/or the fact that it is a live vaccine, if the vaccine is drawn up in the syringe 1-2 hours before a patient receives the shot?	No data are available for keeping the product in the syringe before use. It is recommended to store the DP at 2-8°C in the original glass vial until right before use, and not drawing up the product into the syringe until right before use.
Do you have any stability data regarding drug product outside of 2-8°C?	Data are available to support a total of 1 hour (or 2 x ½ hour) at +20°C (±3°C) without impact on long-term stability of the product.
What was the CDC's rationale for changing the preferred method of vaccination from SQ to ID? This information has been updated. Please see above. (12/9/22)	The rationale is twofold: 1) based on a study that compared the immunogenicity of recipients vaccinated subcutaneously and intradermally. The immunogenicity attained by both groups of study participants was initially the same after both groups received a 2 dose of the vaccine. Second doses, regardless of administration route is key to acquiring immunity. 2) To increase the number of doses of a limited amount of JYNNEOS vaccine to curb the monkeypox outbreak. This information has been updated. Please see above. (12/9/22)

Is Imvamune the same as JYNNEOS and can they be used interchangeably?	Yes, Imvamune is the same product as JYNNEOS. It is manufactured under that name for the Canadian market and may be used interchangeably with JYNNEOS.
Is the intradermal dosage the same for patients that are HIV+?	Yes.
Can JYNNEOS be given at the same time other vaccines are given?	Yes. There is no interval or spacing requirements with JYNNEOS because even though it is considered a "live vaccine"; it is non-replicating. There is one consideration if administering at the same time as a COVID-19 vaccine. Please read below *CDC's JYNNEOS/POXVIRUS/MPOX* "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) • If an Orthopoxvirus vaccine is offered for prophylaxis in the setting of an Orthopoxvirus (e.g., mpox) outbreak, Orthopoxvirus vaccination should not be delayed because of recent receipt of a Moderna, Novavax, or Pfizer-BioNTech COVID-19 vaccine; no minimum interval between COVID-19 vaccination with these vaccines and Orthopoxvirus vaccination is necessary. • People, particularly adolescent or young adult males, might consider waiting 4 weeks after Orthopoxvirus vaccination (either JYNNEOS or ACAM2000) before receiving a Moderna, Novavax, or Pfizer-BioNTech COVID-19 vaccine, because of the observed risk for myocarditis and/or pericarditis after receipt of ACAM2000 Orthopoxvirus vaccine and mRNA (i.e., Moderna and Pfizer-BioNTech) and Novavax COVID-19 vaccines and the unknown risk for myocarditis and/or pericarditis after JYNNEOS."

Is it permissible to administer SQ initially and then ID or vice versa?	Yes, routes are interchangeable.
Is it permissible to administer JYNNEOS to patients that are not in the "high risk" category but in a "lower risk" category?	Yes, you may if this is a policy your agency wants to adopt. You will need to adapt the SO template to reflect your specific agency policy.
Should persons who have had the Smallpox vaccination in the past get vaccinated with JYNNEOS?	It depends. • For the general population, if they meet eligibility criteria for this current outbreak, YES, revaccinate. • For select health care personnel (see standing order template), if it's been greater than 3 years since their last Smallpox vaccination and they meet the eligibility criteria, YES revaccinate.
Do providers have to administer the vaccine intradermally?	The CDC has specifically requested that with the PHASE 4 allocations, JYNNEOS be administered intradermally unless there is a medical contraindication. • Stress to patients that ID administration allows for more persons to be vaccinated. • Studies have shown that ID vs SQ route is just as immunogenic after the 2nd dose is received. • Stress getting the 2nd dose. • As a provider, by administering ID you allow the potential for 4-5 persons to be vaccinated instead of just 1 person if administered SQ.
What is the procedure for disposing of expired or wasted vaccine?	Please follow your agency's procedure as with other vaccines. Do not return.

9/29/22-This guidance no longer applies. Why is patient use of Deflazacort (Calcort) a contraindication for administration of JYNNEOS?	~~This medication is used to treat inflammation stemming from auto-immune diseases, i.e., asthma, arthritis, and allergies and other problems with skin, kidney, heart, digestive system, eyes, or blood in addition to treatment of tumors. It can suppress the immune system and may lessen the body's ability to mount a robust immune response.~~ ~~One of the common side effects of this medication is an itchy, lumpy rash(hives) or a nettle rash(urticaria). Due to this possible side effect, it may confuse the diagnosis of Mpox, and the patient may experience worsening of this side effect.~~
What are the current precautions for JYNNEOS administration?	The precautions to administering JYNNEOS have been revised from the original guidance for a second time. On 9/27 the CDC posted these as the only precautions: • History of severe allergic reaction (e.g., anaphylaxis) to gentamicin or ciprofloxacin • History of severe allergic reaction (e.g., anaphylaxis) to chicken or egg protein AND currently avoiding all chicken and egg products. • History of severe allergic reaction (e.g., anaphylaxis) to any previous medication. • Currently experiencing moderate to severe acute symptoms with or without fever. After discussing risks and benefits with the patient, people with a precaution to vaccination may be vaccinated with a 30-minute observation period or referred for allergist-immunologist consultation prior to vaccination with the exception to the last bullet.

Is there an alternative location to administer JYNNNEOS intradermally beside the forearm?	Yes, on the back under the scapula or over the deltoid muscle.
Are you required to report in VAERS if no wheal forms?	No. Absence of a wheal without vaccine leakage may be counted as valid administration. CDC guidance updated on 9/28/22: Table 7 https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/errors-deviations.html
Should a reason be documented in the EHR if vaccine given SQ vs. ID?	Yes, in EHR. Do not have to indicate a reason in NCIR.
Are clients required to provide proof of identification to be vaccinated?	No. But please ask them if they have received other vaccines, and if so, what name was used.
What is the age parameter for the risk of myocarditis when administering JYNNEOS?	The NC DPH standing order template states in the Contraindications and Precautions section/ Special Groups: 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. ** Through the VAERS reporting system, there have been reported cases of males between the ages of 12 and 18 that have developed myocarditis. All reported cases have resolved. There have been no reported cases of myocarditis in any age group after receiving an mRNA vaccine where the patient has not recovered fully.

Is there a minimum specific age for administering Jynneos to children; the CDC page is vague, and the EUA refers to "under 18".	No. The EUA fact sheet nor CDC notes a minimum age (as the product could be needed for PEP due to an exposure at any age), however, CDC does provide the information below: *JYNNEOS* On 9/27/22 CDC updated guidance on vaccinating persons with JYNNEOS SQ. For people >12 months of age: Administer JYNNEOS subcutaneously by pinching up fatty tissue over the triceps area in the upper arm and insert the needle at a 45-degree angle. For infants <12 months of age: Administer JYNNEOS subcutaneously by pinching up fatty tissue over the anterolateral thigh and insert the needle at a 45-degree angle. Contact the NC CDC Branch Epi On-Call at 919-733-3419 prior to vaccinating those less than 6 months of age. *JYNNEOS contains a non-replicating Vaccinia virus. While JYNNEOS has not been studied specifically for children or adolescents, the same non-replicating Vaccinia virus in the JYNNEOS vaccine has been used in studies as part of vaccines against other diseases including tuberculosis, measles, and Ebola. These studies included children as young as 5 months old, and no serious safety concerns were reported. In the United Kingdom in 2018–2019, JYNNEOS was administered to a few young children, including infants, following exposures to mpox, with no known adverse events. JYNNEOS has also been administered to some children in the United States during the current outbreak without any adverse events to date.* *JYNNEOS can be offered for pediatric cases using a single-patient EA IND authorization from the US Food and Drug Administration, which can be acquired in coordination with state and local health departments and CDC.* Clinical Considerations for Monkeypox in Children and Adolescents | Monkeypox | Poxvirus | CDC As a side note: JYNNEOS is under an EUA for individuals under the age of 18. NC law requires written parental consent when administering EUA vaccines to those less than 18 years of age

Do vaccinators or other clinicians obtaining clinical samples from clients suspected to have mpox need pre-exposure vaccination with JYNNEOS?	No. The CDC only recommends that the following professionals receive PrEP: • Clinical laboratory personnel who perform testing to diagnose orthopoxviruses, including those who use polymerase chain reaction (PCR) assays for diagnosis of orthopoxviruses, including mpox virus • Research laboratory workers who directly handle cultures or animals contaminated or infected with orthopoxviruses that infect humans, including mpox virus, replication-competent Vaccinia virus, or recombinant Vaccinia viruses derived from replication-competent Vaccinia virus strains. Infection Control: Healthcare Settings | Monkeypox | Poxvirus | CDC CDC is not currently encouraging pre-exposure vaccination for most U.S. healthcare workers. mpox virus primarily spreads through close contact and does not spread as easily as respiratory viruses (e.g., influenza and SARS-CoV-2 viruses). Proper use of personal protective equipment and infection control practices are likely to be effective at reducing the risk of transmission of the mpox virus when examining a patient or handling contaminated materials. The risk of mpox for most front-line healthcare workers is currently low. However, healthcare workers who have been exposed to mpox may benefit from post-exposure prophylaxis with the JYNNEOS vaccine, ideally within 4 days. CDC is working closely with partners to ensure there are enough vaccine doses available for those who are recommended to receive them. Clinician FAQs | Monkeypox | Poxvirus | CDC To date there have only been a few cases of mpox reported in HCW. Preliminary investigation suggests there was a lack of adherence to recommended PPE and/or needle stick injury after de-roofing a lesion to collect a clinical sample, which is not recommended.
If a client needs a Tuberculin Skin Test (TST) at the same time they present for JYNNEOS vaccine, is it okay to perform both on the same day?	Preferably, ask client to return in 2 weeks for TST. If this delay is unsuitable e.g., expect exposure to TB as well, then administer TST in opposite arm, making sure to document in which arm TST administered. (See standing order template)

NCIR Clinical Considerations

- Providers must track usage of multiple-dose vials to ensure no greater than five 0.1mL doses are drawn from each vial when administering intradermally.
- Once a vial is punctured, any remaining doses in the vial, including partial doses, must be discarded after 8 hours (when stored at 2 to 8 C) following your agency's policies and logged as wasted in NCIR. Instructions can be accessed here.
- Do NOT combine residual vaccine from multiple vials to obtain a full 0.1mL dose.
- Do NOT return wasted/expired vials to McKesson nor the Immunization Branch; dispose of in your facility as you would other biologics.
- Do NOT transfer partial vials to other providers.
- Do NOT use vial adapters due to an increased risk of contamination.
- Dosing regimens are interchangeable, meaning individuals who received their first dose of JYNNEOS subcutaneously can receive the second dose intradermally.
- High-risk individuals with a history of keloid scarring and those under the age of 18 must be vaccinated using the standard subcutaneous route.

Resources: updated-10/21/22

The NC Division of Health Benefits (DHB) has recently published a new Medicaid Bulletin article:

- mpox Vaccine (Jynneos™) HCPCS Code 90611: Billing Guidelines

Providers are encouraged to review this information. All bulletin articles, including those related to COVID-19, are available on DHB's Medicaid Bulletin webpage.

Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines during the 2022 U.S. Monkeypox Outbreak | Monkeypox | Poxvirus | CDC -updated 9/28//22

- Updated guidance on Components of the U.S. National Vaccination Strategy Used in the U.S. Monkeypox Outbreak
- Updated guidance on Intradermal (ID) Administration of the JYNNEOS vaccine (Alternative Regimen)
- Updated guidance in Vaccination Schedule and Dosing Regimens for JYNNEOS Vaccine for those younger than age 18 years.
- Updates to Coadministration of JYNNEOS vaccine with tuberculin skin test
- Updated Contraindications and Precautions for Use of ACAM2000 Vaccine (Table 5)
- Updated guidance on JYNNEOS and ACAM2000 Vaccination Administration Considerations for Specific Populations (Table 6)
- Updated Vaccine Administration Errors and Deviations (Table 7)
  CDC Vaccine Errors and Administration Table 7/ updated 9/28/22

CDC's JYNNEOS VACCINE webpage is continuously updated to include topics i.e.

- JYNNEOS EUA Fact Sheet for Healthcare Providers
- How to administer a JYNNEOS vaccine Intradermally Video
- Images on Administering JYNNEOS Intradermally
- JYNNEOS Preparation and Administration Summary (Alternative Regimen)
- Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines during the 2022 U.S. Monkeypox Outbreak

CDC's New Communications tool: Reducing Stigma NEW 9/9/22

CDC New and/or Updated:

Use this website for finding the latest in prevention and patient education, studies, etc. https://www.cdc.gov/poxvirus/monkeypox/whats-new.html

- 12/5/22 Monkeypox Vaccination Program Provider Agreement
- 12/2/22 2022 Monkeypox Outbreak Global Map
- 12/2/22 2022 U.S. Map & Case Count
- 11/30/22 U.S. Monkeypox Case Trends Reported to CDC
- 11/28/22 Treatment
- 11/25/22 Monitoring and Risk Assessment for Persons Exposed in the Community
- 11/25/22 Clinician FAQs
- 11/23/22 Workplaces and Businesses
- 11/23/22 Toolkits for Community, Work, and School
- 11/22/22 Monkeypox Vaccine Equity Pilot Program
- 11/21/22 Information for Health Departments
- 11/18/22 Monkeypox Technical Reports
- 11/17/22 How to Complete a V-safe for Monkeypox Vaccine Health Check-In
- 11/17/22 How to Enroll or Access Your V-safe for Monkeypox Vaccine Account
- 11/17/22 How to Add a Dependent in V-safe for Monkeypox Vaccine
- 11/17/22 V-safe after Vaccination Health Checker for Monkeypox Vaccine
- 11/17/22 Clinical Considerations for Monkeypox in Children and Adolescents
- 11/15/22 Stories from the Monkeypox Response
- 11/14/22 Strategies for Talking with Patients about Vaccinations for Monkeypox
- 11/10/22 Epidemiologic Features of the Monkeypox Outbreak and the Public Health Response — United States, May 17–October 6, 2022
- 11/10/22 African Rodent Importation Ban
- 11/10/22 Clinical Considerations for Treatment and Prophylaxis of Monkeypox Virus Infection in People with HIV

- 11/9/22 Demographics of Patients Receiving TPOXX for Treatment of Monkeypox
- 11/4/22 Completing a Death Certificate in the Setting of Monkeypox
- 11/4/22 Information For Healthcare Professionals
- *Clinical Considerations for Treatment and Prophylaxis of Monkeypox Virus Infection in People with HIV, Updated October 31, 2022*- updated monkeypox treatment information
- Treatment Information for Healthcare Professionals Updated October 31, 2022
- Clinician FAQs-updated 10/31/22
- *MMWR-Epidemiologic and Clinical Features of Children and Adolescents Aged <18 Years with Monkeypox — United States, May 17–September 24, 2022,Weekly / November 4, 2022 / 71(44);1407–1411*
- *MMWR-Severe Monkeypox in Hospitalized Patients — United States, August 10–October 10, 2022, Weekly / November 4, 2022 / 71(44);1412–1417. On October 26, 2022, this report was posted online as an MMWR Early Release.*

Vaccination

- Considerations for Mpox Vaccination
- ASPR: Operational Planning Guide