SALT LAKE COUNTY HEALTH DEPARTMENT

STANDING ORDERS

Monkeypox/Smallpox Vaccine - JYNNEOS

1. DOSE: SEE BELOW
2. ROUTE: SEE BELOW
3. SITE: ID OR SQ, SEE BELOW
4. AGE: 6 MONTHS OF AGE AND OLDER INCLUDING ADULTS
5. INDICATIONS AND USAGE: PREVENTION OF SMALLPOX AND MONKEYPOX DISEASE

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 (INTRADERMAL)	0.1 mL	2	28 DAYS
STANDARD REGIMEN				
PEOPLE AGE <18 YEARS	SQ (SUBCUTANEOUS)	0.5ML	2	28 DAYS
PEOPLE OF ANY AGE WHO HAVE A HISTORY OF DEVELOPING KELOID SCARS	SQ (SUBCUTANEOUS)	0.5ML	2	28 DAYS

NOTE: **SEE BELOW FOR INTERCHANGEABILITY OF DOSING REGIMENS**

- FOR ALMOST ALL PATIENTS, VACCINATION IS THE THERAPEUTIC THAT SHOULD BE ADMINISTERED. IMMUNE GLOBULIN OR ANTIVIRALS MAY ALSO BE CONSIDERED FOR INFANTS UNDER 6 MONTHS OF AGE, GIVEN THEIR IMMATURE IMMUNE SYSTEMS AND POSSIBLE DECREASED RESPONSES TO VACCINATION.
- INTRADERMAL ADMINISTRATION INVOLVES INJECTING THE VACCINE SUPERFICIALLY BETWEEN THE EPIDERMIS AND THE HYPODERMIS LAYERS OF THE SKIN, TYPICALLY OF THE VOLAR ASPECT (INNER SIDE) OF THE FOREARM. THIS SHOULD PRODUCE A NOTICEABLE PALE ELEVATION OF THE SKIN (WHEAL). PLEASE REFER TO RELATED RESOURCES
- A PERSON WHO PRESENTS FOR THEIR SECOND JYNNEOS VACCINE DOSE WHO IS STILL EXPERIENCING ERYTHEMA OR INDURATION AT THE SITE OF INTRADERMAL ADMINISTRATION OF THE FIRST VACCINE DOSE (E.G., THE FOREARM) MAY HAVE THE SECOND DOSE ADMINISTERED INTRADERMALLY IN THE CONTRALATERAL FOREARM.
- SUBCUTANEOUS ADMINISTRATION INVOLVES INJECTING THE VACCINE INTO THE FATTY TISSUE, TYPICALLY OVER THE TRICEPS IN PEOPLE AGED 12 MONTHS AND OLDER, OR IN THE ANTEROLATERAL THIGH FOR PEOPLE YOUNGER THAN AGE 12 MONTHS. VIDEO ABOUT SUBCUTANEOUS VACCINE ADMINISTRATION.

6. CONTRAINDICATIONS:

CONTRAINDICATION	JYNNEOS	ACAM2000		
		PRIMARY VACCINEES	RE-VACCINEES	HOUSEHOLD CONTACTS
HISTORY OR PRESENCE OF ATOPIC DERMATITIS		X	X	X
OTHER ACTIVE EXFOLIATIVE SKIN CONDITIONS		X	X	X
CONDITIONS ASSOCIATED WITH IMMUNOSUPPRESSION		X	X	X
PREGNANCY		X	X	X
AGED <1 YEAR		X	X	X
BREASTFEEDING		X	X	
SERIOUS VACCINE COMPONENT ALLERGY	X	X	X	
KNOWN UNDERLYING HEART DISEASE (E.G., CORONARY ARTERY DISEASE OR CARDIOMYOPATHY)		X	X	
THREE OR MORE KNOWN MAJOR CARDIAC RISK FACTORS		X		

- GUIDANCE FOR CONTRAINDICATIONS AND PRECAUTIONS
  - A SEVERE ALLERGIC REACTION (E.G., ANAPHYLAXIS) AFTER A PREVIOUS DOSE OF JYNNEOS VACCINE IS A CONTRAINDICATION TO RECEIPT OF A SUBSEQUENT DOSE. REFERRAL TO AN ALLERGIST-IMMUNOLOGIST SHOULD BE CONSIDERED TO ASSESS THE RISKS VERSUS BENEFITS OF ADMINISTERING ANOTHER DOSE.
  - JYNNEOS VACCINE CONTAINS SMALL AMOUNTS OF GENTAMICIN AND CIPROFLOXACIN AND IS PRODUCED USING CHICKEN EMBRYO FIBROBLAST CELLS.
  - PEOPLE WHO HAVE HAD A PREVIOUS SEVERE ALLERGIC REACTION (E.G., ANAPHYLAXIS) FOLLOWING GENTAMICIN OR CIPROFLOXACIN HAVE A PRECAUTION FOR RECEIVING JYNNEOS VACCINE AND SHOULD BE INFORMED ABOUT THE POTENTIAL FOR INCREASED RISK OF ALLERGIC REACTION IF THE VACCINE IS ADMINISTERED.

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Angela Dunn, M.D., M.P.H.
Medical Officer

Date

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https://www.cdc.gov/poxvirus/monkeypox/pdf/Storage-and-Handling-Summary.pdf

- ✓ After discussing risks and benefits with the individual, these people may be vaccinated with a 30-minute observation period. Alternatively, taking into account the risk of acquiring monkeypox if the vaccination is delayed, an allergist-immunologist may be consulted before the vaccine is administered.
- ✓ For individuals who have had Stevens-Johnson syndrome (SJS) or Toxic Epidermal Necrolysis (TEN) following either ciprofloxacin or gentamicin, the risk of this type of severe allergic reaction from JYNNEOS vaccine is considered to be low because of the small amounts of the antibiotics in the vaccine. The risks and benefits of the vaccination should be discussed with the individual. Alternatively, taking into account the risk of acquiring monkeypox if the vaccination is delayed, an allergist-immunologist may be consulted before the vaccine is administered.

- People who have had a severe allergic reaction (e.g., anaphylaxis) to chicken or egg protein AND are currently avoiding exposure to all chicken or egg products have a precaution for receiving JYNNEOS vaccine and should be informed about the potential for increased risk of allergic reaction if the vaccine is administered.
  - ✓ After discussing risks and benefits with the individual, these people may be vaccinated with a 30-minute observation period. Alternatively, after taking into account the risk of acquiring monkeypox if the vaccination is delayed, an allergist-immunologist may be consulted before the vaccine is administered.

7. Pregnancy: See above

8. Other:
   - Currently, JYNNEOS is used for two indications:
     - Post Exposure Prophylaxis (PEP): Vaccine to prevent monkeypox given to individuals after exposure to a known case.
     - Post Exposure Prophylaxis for individuals exposed to high risk settings (PEP++): Vaccine to prevent transmission to individuals without known specific exposures, but exposed to high risk situations.
   - Post-Exposure Prophylaxis Guide (PEP)
     - vaccine be given within 4 days from the date of exposure for the best chance to prevent onset of the disease.
     - If given between 4 and 14 days after the date of exposure, vaccination may reduce the symptoms of disease, but may not prevent the disease. However, when coupled with self-isolation and other prevention measures when symptoms first occur, PEP is important for controlling outbreaks and preventing further transmission of monkeypox. Vaccination given after the onset of signs or symptoms of monkeypox is not expected to provide benefit.
     - people who get 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.
   - 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.
   - Two doses of JYNNEOS are required, as this is the only FDA-approved dosing regimen.
   - Exceptions to the two-dose vaccine series
     - In the context of the current monkeypox outbreak, and while the supply of JYNNEOS vaccine is limited:
       - A person who is diagnosed with Monkeypox virus infection after their first dose of JYNNEOS is not recommended to receive the second dose at this time, because Monkeypox virus infection likely confers additional immune protection.
       - A person who would be eligible for vaccination but has been diagnosed with Monkeypox virus infection during this outbreak, which started in the United States on May 17, 2022, is not recommended to be vaccinated at this time, because Monkeypox virus infection likely confers immune protection.
       - An immunocompromised person who is diagnosed with Monkeypox virus infection 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.

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- The vaccine manufacturer has advised that it is not recommended to give the second dose before the minimum interval of 28 days; however, doses may be given up to 4 days before the minimum interval of 28 days (i.e., 24 days after the first dose) based on ACIP's general best practices.
- Based on available clinical study data, the second dose may be given up to 7 days after the minimum interval of 28 days (i.e., 35 days after the first dose).
- If there is a delay in administering the second dose and the interval becomes longer than 35 days, the second dose should be administered as soon as possible based on ACIP's general best practices. There is no need to restart the series.
- Coadministration of orthopoxvirus vaccines with other vaccines:
  - 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, because of the observed risk for myocarditis 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 after JYNNEOS, 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. However, if an orthopoxvirus vaccine is recommended for prophylaxis in the setting of an 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. (See Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC)
- Some vaccines described as "live attenuated" (e.g., Jynneos Smallpox/Monkeypox vaccine) do not replicate and for the purposes of timing and spacing recommendations behave like non-live vaccines. JYNNEOS and other live vaccine can be given either (1) on the same day or (2) at any interval between JYNNEOS and other live vaccine including TST testing. There is **no** minimum interval recommended if JYNNEOS and other live vaccine are not administered on the same day. They can be administered at any interval per NIPINFO@cdc.gov.
- Revaccination After Exposure
  - Persons exposed to monkeypox virus and who have not received the smallpox vaccine within the last 3 years, should consider getting vaccinated.

9. Vaccine Storage, Handling and Administration:
   JYNNEOS
   - Keep frozen at -25°C to -15°C (-13°F to +5°F).
   - Unopened vials of JYNNEOS may be stored at 2-8°C up to 8 weeks from thawing
   - Do not re-freeze a vial once it has been thawed.
   - Once the vial is punctured and a dose is withdrawn, if it is not used in its entirety, it should be stored at +2°C to +8°C (+36°F to +46°F) and discarded within 8 hours of the first puncture.
   - Store in the original package to protect from light.
   - When thawed, JYNNEOS is a milky, light yellow to pale white colored suspension.
   - Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered.
   - Swirl the vial gently before use for at least 30 seconds. Withdraw a dose of 0.5 mL into a sterile syringe for injection.
   - Administer JYNNEOS by subcutaneous injection, preferably into the upper arm (deltoid).

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ORTHOPOXVIRUS VACCINES	
JYNNEOS	**ACAM2000**
JYNNEOS contains a live virus that does not replicate efficiently in human cells.	ACAM2000 is a live Vaccinia virus vaccine that is replication competent.
Administered as two subcutaneous injections four weeks apart.	Administered as one percutaneous dose via multiple puncture technique with a bifurcated needle.
The immune response takes 2 weeks after the second dose for maximal development. The duration of immunity after two doses of JYNNEOS is unknown.	The immune response takes 4 weeks for maximum development. The duration of immunity after two doses of JYNNEOS is unknown.
Safe for administration to people with HIV and atopic dermatitis.	Following a successful inoculation, a lesion (known as a "take") will develop at the site of the vaccination; the lesion may take up to 6 weeks or more to heal.
Booster doses are recommended every 2 or 10 years if a person remains at continued risk for exposure to smallpox, monkeypox, or other orthopoxviruses. Your health care provider can give you more information.	Booster doses are recommended every 3 or 10 years if a person remains at continued risk for exposure to smallpox, monkeypox, or other orthopoxviruses. Your health care provider can give you more information.

Interim recommendations for JYNNEOS vaccine administration errors and deviations

Type	Administration error/deviation	Interim Recommendation
Site	Incorrect site (e.g., a site other than triceps area for subcutaneous administrations or a site other than the volar aspect of forearm for intradermal administrations)	Do not repeat dose. Inform the recipient of the potential for local and systemic adverse events.
Route	Incorrect route resulting in lower-than-authorized dose administered (e.g., inadvertent subcutaneous administration of 0.1 mL, when intradermal route was intended).	Repeat dose immediately via intended route (no minimum interval).
Route	Other incorrect route (e.g., intramuscular administration).	Do not repeat dose. Inform the recipient of the potential for local and systemic adverse events.
Dosage	If the incorrect dosage is administered, resulting in a higher-than-authorized dose (e.g., >0.1 mL administered ID).	Do not repeat dose. Inform the recipient of the potential for local and systemic adverse events.
Dosage	If the incorrect dosage is administered, resulting in a lower-than-authorized dose (e.g., recipient pulled away, leaked out of a syringe, 0.1 mL administered subcutaneously).	Repeat dose immediately (no minimum interval). However, if a half-volume dose of vaccine is administered to a patient instead of the intended full volume, another half-volume dose can be administered on the same clinic day, and the 2 halves can count as 1 full dose.
Storage and handling	Dose administered after improper storage and handling (i.e., temperature excursion) Dose administered past the expiration/beyond-use date	Contact the manufacturer for information on the stability of the vaccine. If the manufacturer does not have data to support the stability of the vaccine, repeat the dose immediately (no minimum interval).

Email: medical.information_US@bavarian-nordic.com or U.S. phone number: 1-844-422-8274 (Bavarian-Nordic-manufacture)

Important Notes:

- ALL VACCINATORS MUST READ
  - SLCoHD Jynneos Vaccine Standing Order
  - https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html#interim
  - JYNNEOS Vaccine Information Statement (VIS) [151 KB, 2 pages]
  - https://www.fda.gov/media/160774/download
- EVERY CLIENT MUST RECEIVE Jynneos Vaccine Information Statement via hard copy or online copy
- Watch video on Administering JYNNEOS Intradermally https://www.youtube.com/watch?v=TLv1mR6mECQ
- Pre-Authorization paperwork is **no longer** a requirement for minors to get vaccine per Dr. Nolan

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