JYNNEOS¹ Vaccine Resource Guide Smallpox and Mpox Vaccine

Indication for Use	 Standard regimen (<u>subcutaneous</u>): People under 18 years of age. People of any age with history of keloid scarring. Prior to administration for people younger than 6 months, provider should first contact jurisdictional HD. 	 Alternative regimen (<u>intradermal</u>): People 18 years and older.
Number of Doses in Series	2 doses	2 doses
Interval Between Doses	28 days	28 days
Preparation of Vaccine	Allow vaccine to thaw approximately 10 minutes to reach room temperature before use. ^{3,4}	Allow vaccine to thaw approximately 10 minutes to reach room temperature before use. ^{3,4}
Administration	Subcutaneous (Subcut) Injection ⁵ (standard regimen) preferably into the anterolateral thigh for infants less than 1 year of age, or into the upper arm (fatty tissue over triceps) for individuals 1 through 17 years of age.	Intradermal (ID) Injection ⁶ (alternative regimen): Placement site: volar aspect (inner side) of forearm. Alternative sites: deltoid, or upper back below scapula.
Reconstitution	DO NOT DILUTE	DO NOT DILUTE
Dosing Volume	0.5 mL- Swirl the vial gently for at least 30 seconds (this dose volume allows one dose per vial).	0.1 mL- Swirl the vial gently for at least 30 seconds (this dose volume allows up to five doses per vial).
Storage Time in Syringe	Pre-drawn syringes are not routinely recommended but if needed, keep at proper refrigerated temperatures and discard within 8 hours if not administered.	Pre-drawn syringes are not routinely recommended but if needed, keep at proper refrigerated temperatures and discard within 8 hours if not administered.
Storage Requirements in Freezer* -25°C to -15°C (-13°F to +5°F) ³	Expiration: on carton label ^{3,7}	Expiration: on carton label ^{3,7}
Storage Requirements in Refrigerator (DO NOT REFREEZE) * +2°C to +8°C (+36°F to +46°F) ³	Unpunctured Vial: Expiration 8 weeks [Beyond Use Date (BUD)] ^{3,4,7}	Unpunctured Vial: Expiration 8 weeks [Beyond Use Date (BUD)] ^{3,4,7}
	Punctured Vial: Must discard within 8 hours of puncture/vial cap removal. ³	Punctured Vial: Must discard within 8 hours of the first puncture. ³ (refrigerate after each use)

*Important note: All vaccine, whether received refrigerated or frozen, is originally frozen from the manufacturer. If you receive refrigerated vaccine, it is thawed vaccine. Do NOT refreeze, store it in the refrigerator. Thawed vaccine must be used within eight weeks (BUD) from thawing.

¹Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines during the 2022 U.S. Mpox Outbreak | Mpox | Poxvirus | CDC

²Vaccination Administration Considerations for Specific Populations | Mpox | Poxvirus | CDC

³Fact Sheet for Healthcare Providers for JYNNEOS

⁴JYNNEOS Smallpox and Mpox Vaccine Storage and Handling Summary (cdc.gov)

⁵How to administer intramuscular and subcutaneous vaccine injections (immunize.org)

⁶How to administer a JYNNEOS vaccine intradermally (video)

⁷MVA- BN Information Letter (hhs.gov)

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Guidance on Frequently Asked Clinical Questions

- 1. Can JYNNEOS be administered to people who are pregnant or breastfeeding? While there are no data for people who are pregnant or breastfeeding, animal data does not show evidence of reproductive harm; pregnancy or breastfeeding is not a contraindication to receiving JYNNEOS.
- 2. When is the patient considered immune? The patient is considered to have achieved peak immunity 14 days after the second dose of JYNNEOS vaccine.
- 3. Can 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) receive their second dose? Yes, the second dose can be administered intradermally in the contralateral forearm.
- 4. If a person received their first JYNNEOS dose subcutaneously, can they receive their second dose intradermally? 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.
- 5. If the person is going to turn age 18 years between their first and second dose, can both doses be given intradermally? They should be vaccinated according to their age at the time of the visit. (e.g., if they are 17 years of age at the initial visit, they would receive 0.5mL administered subcutaneously; if they turn 18 years of age between their first and second dose, then they would receive 0.1mL administered intradermally to complete the series).
- 6. **The JYNNEOS vial states "single-dose vial." How many doses are in each vial of vaccine?** That depends, when administered using the standard regimen (subcutaneously), it contains one 0.5mL dose. When administered using the alternative regimen (intradermally), it contains <u>up to five</u> 0.1mL doses.
- 7. Is it ok to withdraw up to five doses (0.1mL each dose administered intradermally) out of the JYNNEOS vaccine vial since it was originally approved as a single-dose vial and contains no preservative? Yes. Due to the limited amount of supply, the JYNNEOS vaccine has received Emergency Use Authorization (EUA) to be administered as five doses (0.1mL each dose administered intradermally) to persons 18 years and older. Because the JYNNEOS vaccine does not contain a preservative, the vial stopper should be cleansed with a single use anti-septic swab before each use to avoid contamination. After first puncture, you must document date, initials, and time punctured and time to discard on the vial and refrigerate after each use. In addition, do not pool excess vaccine from multiple vials. If the amount of vaccine remaining in a vial cannot provide a full dose, discard the vial and content.
- 8. Does the JYNNEOS vaccine contain latex? No.
- 9. Can JYNNEOS be pre-drawn and stored in the syringe? Pre-drawn syringes are not routinely recommended, but if used, must be labeled with vaccine name, lot number, date, and time prepared, and preparer's initials, kept refrigerated between 2°C and 8°C (36°F and 46°F), and discarded within 8 hours if not administered.
- 10. Are there any specific population considerations for the administration of JYNNEOS the subcutaneous route? Yes. Consider subcutaneous administration for people of any age who have a history of developing keloid scars.
- 11. If administering the vaccine intradermally and no visible wheal forms, should the dose be repeated? Producing a noticeable pale elevation of the skin (wheal) with the intradermal injection is desirable but not required. However, if an ID is administered and there is a lower-than-authorized dose (leakage) then repeat the ID dose immediately at least 2 inches away from the site of vaccine leakage. If vaccine leakage occurs with two intradermal vaccinations on the same day, administer 0.5 mL subcutaneously. Note: Absence of a wheal without vaccine leakage may be counted as a valid administration.

Note: For questions relating to incorrect site, route, dosage, and storage, please see CDC's Vaccine Administration Errors and Deviations.