Immunization Protocol

Mpox (Jynneos®) Vaccine	
Last Reviewed	25 March 2024
Last Revised	21 May 2024
This order expires	31 March 2025

Table of contents

1. What's new[1]

Storage requirements for Jynneos have been updated. Once thawed, Jynneos can be kept refrigerated (2°–8°C) up to 4 weeks and then must be discarded.

The primary administration route for the 2-dose live, non-replicating modified vaccinia Ankara-Bavarian Nordic (JYNNEOS®) vaccine series is now subcutaneous. However, if requested, adult patients may receive via the intradermal route.

In October 2023, the Advisory Committee on Immunization Practices (ACIP) recommended the JYNNEOS vaccine routinely for individuals at risk for mpox.

5/21/24: Updated CDC webpage links and the graphics in Appendix A.

2. Oregon immunization model protocol

A. Determine patient eligibility for vaccination in accordance with the CDC Vaccine Recommendations.

B. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.

C. Screen clients for contraindications and precautions.

D. Subcutaneous is currently the routinely recommended route of administration for JYNNEOS vaccine. However, if an adult patient 18 years and older requests intradermal administration, the provider may do so.

E. For an adult receiving the vaccine SQ, provide a current Vaccine Information Statement (VIS), answering any questions.

F. For a child <18 years of age or for an adult receiving the vaccine ID, provide an EUA Fact Sheet for Recipients and Caregivers.

G. Record all required data elements in the client's permanent health record.

H. Verify needle length for ID (¼" to ½", 27G) or SQ (5/8", 23–25G) injection.

I. **SQ administration** for a child <18 years of age or an adult: administer a 0.5-mL dose SQ in the fatty tissue over the triceps. For children <1 year of age, administer in the fatty tissue over the anterolateral thigh.[1]

J. **ID administration** for an adult if requested: Administer a 0.1-mL dose ID in the skin of the volar aspect of the forearm.[1] Alternatively, if desired, the 0.1-mL dose may be administered ID in the upper back just below the scapula or at the deltoid. In case of vaccine error, see appendix B.

K. Ask patient to remain seated in the clinic for 15 minutes after vaccination to decrease the risk of injury should they faint. Patients with a precaution because of previous allergic reactions should remain seated for 30 minutes after vaccination.

L. Report all administered vaccinations to ALERT IIS within 72 hours of administration.

Health Officer Signature Date

Health Officer Signature Date

3. Vaccine schedule for mpox vaccine

Dose and Route: 0.5 mL, SQ			
Dose	**Preferred age**	**Minimum acceptable age**	**Minimum acceptable spacing**
1	≥5 months	≥5 months	
2			28 days
Booster			2 years¶

¶ See section 5, Recommendations for use, for booster dose indications

Dose and Route: 0.1 mL, ID			
Dose	**Preferred age**	**Minimum acceptable age**	**Minimum acceptable spacing**
1	≥18 years	≥18 years	
2			28 days
Booster			2 years¶

¶ See section 5, Recommendations for use, for booster dose indications.

4. Licensed mpox vaccine

Product Name	Vaccine Components	Presentation	Acceptable Age Range	Thimerosal
Jynneos	Attenuated, non-replicating *Vaccinia* virus	0.5-mL single[2] or multi-dose vial[1]	≥5 months	None

5. Recommendations for use

Primary pre-exposure prophylaxis:[3]

A. Persons with risk factors related to sexual activity, as indicated in CDC's Mpox Vaccine Recommendations.

B. Clinical laboratory personnel performing diagnostic testing for *Orthopoxvirus*, including those who use PCR assays for diagnosis of *Orthopoxvirus* infection.

C. Research laboratory workers who directly handle cultures or animals contaminated or infected with *Orthopoxviruses* that infect humans, including

mpox, replication-competent vaccinia virus, or recombinant vaccinia viruses derived from replication-competent vaccinia virus strains.

D. Healthcare and public health response team members designated by public health authorities to be vaccinated for preparedness purposes.

Outbreak prophylaxis:[4]

A. For groups following exposure or potential exposure, as indicated at Oregon Health Authority (OHA) Interim Mpox Vaccine Guidance.

B. ACIP recommends the 2-dose Jynneos vaccine series for persons 18 years and older at risk of mpox during an mpox outbreak. Public health authorities determine whether there is an mpox outbreak; a single case may be considered an mpox outbreak at the discretion of public health authorities. Other circumstances in which a public health response may be indicated include ongoing risk of introduction of mpox into a community due to disease activity in another geographic area.

C. In an outbreak setting, vaccine is ideally given pre-exposure but may also be given as post-exposure prophylaxis (PEP). A complete 2-dose vaccine series should be given regardless of timing of exposure.

Booster doses:[3]

A. Persons who are at ongoing risk of occupational exposure to more virulent *Orthopoxviruses*, i.e., *variola virus* or mpox, should receive a booster dose of Jynneos every 2 years.

B. Persons who are at ongoing risk of occupational exposure to less virulent, replication-competent *Orthopoxviruses*, e.g., *vaccinia virus* or *cowpox virus,* should receive a booster dose of Jynneos every 10 years.

C. Persons with ongoing occupational risk who previously received primary vaccination with ACAM2000 may choose to receive Jynneos as a booster dose.

D. Preparedness personnel do not need to receive routine boosters. A dose should be provided at the time of an event.

6. Contraindications:

Serious allergy (e.g., anaphylaxis) to a vaccine component.

Vaccine	Vaccine Excipient Summary[2]
Jynneos (0.5-mL dose)	Host-cell DNA (≤20 mcg), protein (≤500 mcg), benzonase (≤0.0025 mcg), gentamicin (≤0.163 mcg) and ciprofloxacin (≤0.005 mcg).

7. Warnings and precautions:

Persons with acute, moderate, or severe illness with or without fever may choose to delay immunization until symptoms have improved.

8. Other considerations[2]

A. **Myocarditis**: Because of the risk of myocarditis following vaccination with either ACAM2000 or a mRNA COVID-19 vaccine, and the unknown risk for myocarditis after Jynneos, persons, particularly young men, may want to wait 4 weeks after receiving an *Orthopoxvirus* vaccine before receiving a mRNA COVID-19 vaccine. For post-exposure prophylaxis, vaccination with Jynneos should not be delayed because of recent receipt of an mRNA COVID-19 vaccine.

B. **Atopic dermatitis, eczema, or other exfoliative skin conditions**: Persons with exfoliative skin conditions may receive Jynneos, and studies have demonstrated immunogenicity.

C. **Persons with immunocompromising conditions**: Jynneos may be safely given to persons with immunocompromising conditions; however, these persons may be less likely to mount an effective response.

D. **Pregnancy**: Animal models, including rats and rabbits, have shown no evidence of harm to a developing fetus; however, human data on safety during pregnancy are insufficient to determine vaccine risks.

E. **Breastfeeding**: Jynneos is replication-deficient and likely does not present a risk of transmission to breastfed infants. Persons who are breastfeeding may be vaccinated if vaccination is critical.

F. **Children <18 years of age**: Jynneos has received an emergency use authorization for use in children <18 years of age. The correct dose is 0.5 mL administered SQ.[1]

G. **Persons with cardiac risk factors**: Persons with underlying heart disease or with 3 or more cardiac risk factors should be counseled about the theoretical risk of myopericarditis following Jynneos vaccination.

H. **Intradermal Vaccine Administration**: When administering Jynneos intradermally, an obvious, pale, raised bump or bleb should appear under the skin. Absence of a bleb without vaccine leakage may be counted as a full dose.[1]

I. **Extended Local Reaction**: If a patient who returns for dose 2 still has a visible local reaction at the injection site, administer dose 2 in the opposite forearm, or offer SQ administration.[4]

J. **Alternate Injection Sites:** If desired, the skin over the deltoid or on the upper back just below the scapula can be used for an ID injection.[5] An alternate site for a SQ injection is the fatty tissue over the anterolateral thigh muscle.

9. Side effects and adverse reactions

Adverse Event	Frequency
Subcutaneous administration[2]	
Injection site events	
Pain	Up to 84.9%
Redness	Up to 60.8%
Swelling or induration	Up to 51.6%
Itching	Up to 84.9%
Systemic events	
Muscle pain, headache, fatigue	Up to 42.8%
Nausea	Up to 17.3%
Chills	Up to 10.4%
Intradermal administration[1]	
Injection site events	
Redness or induration	Up to 99.5%
Itching	Up to 89%
Pain	Up to 65.4%
Injection site events lasting ≥30 days	Up to 67%
Systemic events	
Muscle pain, headache, fatigue	Up to 51.3%
Nausea	Up to 23%
Chills	Up to 14.7%

10. Storage and handling

All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4832).

Vaccine	Temp	Storage Issues	Notes
Jynneos[1]	Keep frozen at -25°C to -15°C	Do not refreeze Protect from light.	Once thawed, may be kept at 2°–8°C for up to 4 weeks.[2] Multi-dose vials must be used or discarded within 8 hours of first puncture.[1]

11. Adverse events reporting

Report adverse events online to the Vaccine Adverse Events Reporting System (VAERS) at https://vaers.hhs.gov/reportevent.html.

The vaccination provider is responsible for MANDATORY reporting of the following listed events following Jynneos to the Vaccine Adverse Event Reporting System (VAERS):[1]

- Vaccine administration errors even if not associated with an adverse event;
- Serious adverse events (irrespective of attribution to vaccination);
- Cases of cardiac events including myocarditis and pericarditis;
- Cases of thromboembolic events and neurovascular events.

12. References

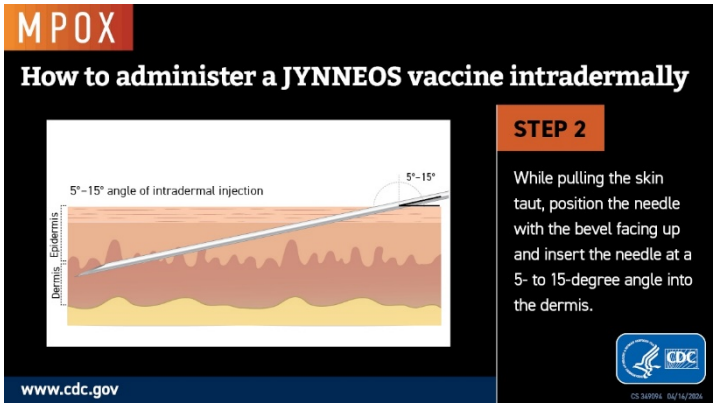
1. Jynneos Emergency use authorization (EUA) fact sheet, August 16, 2022. Available at: www.fda.gov/media/160774/download. Accessed 25 Mar 2024.
2. Bavarian Nordic A/S. Jynneos package insert, March 2023. Available at: www.fda.gov/media/131078/download. Accessed 25 Mar 2024.
3. Rao AK, Petersen BW, Whitehill F, et al. Use of Jynneos (smallpox and monkeypox vaccine, live, nonreplicating) for preexposure vaccination of persons at risk for occupational exposure to orthopoxviruses: Recommendations of the Advisory Committee on Immunization Practices — United States, 2022. MMWR 2022; 71:734–42. Available at: www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7122e1-H.pdf. Accessed 21 May 2024.
4. CDC. Mpox Vaccination Guidance, last updated 22 April 2024. Available at: https://www.cdc.gov/poxvirus/mpox/interim-considerations/overview.html. Accessed 21 May 2024.
5. CDC. Jynneos Smallpox and Monkeypox Vaccine Alternate Regimen: Preparation and Administration Summary (Intradermal Administration), last reviewed 27 Sep 2022. Available at: www.cdc.gov/poxvirus/mpox/files/interim-considerations/guidance-jynneos-prep-admin-alt-dosing.pdf. Accessed 21 May 2024.

To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 971-673-0300 and 711 for TTY. For other questions, consult with the vaccine recipient's primary health care provider or a consulting physician.

Electronic copy of this standing order is available at:

www.oregon.gov/oha/ph/preventionwellness/vaccinesimmunization/immunizationproviderresources/pages/stdgordr.aspx

13. Appendix A



Available at: https://www.cdc.gov/poxvirus/mpox/interim-considerations/jynneos-ID.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fpoxvirus%2Fmpox%2Finterim-considerations%2Fjynneos-vaccine.html. Accessed 21 May 2024.

14. Appendix B

Interim recommendations for Jynneos vaccine administration errors and deviations.

Adapted from CDC's Interim Clinical Considerations, updated 22 April 2024. Accessed 21 May 2024.

Type	Administration Error / Deviation	Interim Recommendation
Site	Incorrect site (e.g., a site other than triceps or thigh area for subcutaneous administrations or a site other than the volar aspect of forearm or the upper back just below the scapula 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). Repeated dose should be placed at least 2 inches away from the inadvertent site placement.
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 a higher-than-authorized dose is administered (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 a lower-than-authorized dose is administered ***intradermally*** (e.g., recipient pulled away, leakage out of a syringe, 0.1 mL administered subcutaneously). NOTE: Absence of a wheal without vaccine leakage may be counted as valid administration.	Repeat intradermal dose immediately (no minimum interval) at least 2 inches away from the site of vaccine leakage. If vaccine leakage occurs with two intradermal vaccinations on the same day, administer 0.5mL subcutaneously.
Dosage	A lower-than-authorized dose administered ***subcutaneously*** (e.g., inadvertent subcutaneous administration of 0.1mL, recipient pulled away, or leakage out of syringe).	Repeat dose immediately with the correct dose (no minimum interval). Repeated dose should be placed at least 2 inches away from the site of previous injection or at another site.

		However, if a partial dose of vaccine is administered to a patient instead of the intended full volume, the remainder of the dose can be administered on the same clinic day, and the 2 portions can count as 1 full dose.
Intervals	Interval between first and second dose less than the recommended minimum interval.[1]	Repeat dose after the dose given in error by at least the recommended interval of 28 days if the patient is severely immunocompromised. Otherwise, do not repeat dose.[1]
Intervals	Interval between first and second dose greater than the recommended minimum interval.	Do not restart the series and administer the second dose as soon as possible. While available clinical data show that 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), there is no maximum interval, and the second dose should be given as soon as possible to complete the series.
Storage and Handling	Dose administered after improper storage and handling (i.e., temperature excursion)	Contact the manufacturer[2] 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).
Storage and Handling	Dose administered past the expiration/beyond-use date	Contact the manufacturer[2] 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).

[1]Vaccine doses administered up to 4 days before the minimum interval may be counted and do not need to be repeated.

[2]Contact information for manufacturer:
Email: medical.information_US@bavarian-nordic.com
U.S. phone number: 844-422-8274
U.S. fax number: 843-422-8274