



JYNNEOS Smallpox and Monkeypox Vaccine

ALTERNATE REGIMEN Preparation and Administration Summary (Intradermal Administration)

General Information

Vaccine: JYNNEOS Smallpox and Monkeypox vaccine

1 vial: up to 5 doses

Diluent: None

Dosage: 0.1 mL (NOTE: This is different than subcutaneous dose.)

Age Indications

Persons 18 years of age and older who do not have a history of keloid scars

Vaccination Schedule

Administer two doses of JYNNEOS (0.1 mL each) 28 days (4 weeks) apart

- For more details on the dosing interval, refer to www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html.

Administration








Intradermal (ID) injection into the volar surface of the forearm

- If the volar aspect of the forearm is not an option (e.g., strong patient preference), ID administration may be done at the upper back below the scapula, or at the deltoid.

Thawing Frozen Vaccine

- Frozen vaccine takes 10 minutes to thaw and must be thawed before using. Use vials in the refrigerator before removing more vials from the freezer. Once thawed, either:
 - » **Refrigerate:** Between 2°C and 8°C (36°F and 46°F).
 - *Unpunctured* vials may be stored in the refrigerator for up to 8 weeks.
 - *Punctured* vials may be stored continuously in the refrigerator for up to 8 hours.
 - » **Store at room temperature:** Between 8°C and 25°C (46°F and 77°F).
 - *Unpunctured* vials may be held at room temperature for up to 6 cumulative hours.
 - There is no data to support vaccine stability of *punctured* vials at room temperatures. Punctured vials should stay in the fridge between each dose.
- Do NOT refreeze thawed vaccine.
- Use CDC's beyond-use date (BUD) labels to track storage times. Pre-drawn syringes are not routinely recommended but if needed:
 - » Label syringes with vaccine name, lot number, date and time prepared, and preparer's initials
 - » Keep refrigerated between 2°C and 8°C (36°F and 46°F)
 - » Discard within 8 hours if not administered.
 - » For additional guidance on pre-drawn syringes see: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

Prepare and Administer the Vaccine

1. Assess recipient status:
 - » Screen for contraindications and precautions. Persons less than 18 years of age or persons of any age with a history of developing keloid scars should not receive JYNNEOS vaccine intradermally
 - » Review vaccination history and medical considerations.
2. Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if used), and any time hands become soiled.
3. Frozen vaccine must be thawed for 10 minutes before using.
4. Check the expiration date and/or beyond-use date. Do not use expired vaccine, unless you were able to confirm. With the vial upright, gently swirl the vaccine for 30 seconds.
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6. Examine the vaccine. It should be a milky, light yellow to pale white colored suspension. Do not use if liquid contains other particulate matter or is discolored.
7. Using a new, sterile alcohol prep pad, cleanse the stopper of the vaccine vial.
8. Choose the correct equipment for intradermal injection: attach either a 26 gauge or 27 gauge, 1/4, 3/8, or 1/2 inch needle with a short bevel to the syringe. **Always use a new, sterile needle and syringe for each injection.**
9. Ensure the needle and syringe are secured tightly together to prevent
10. Puncture the septum of the vial and ensure the bevel or tip of the needle is in the vaccine.
 - » Pull back the plunger to withdraw vaccine from the vial
 - » Remove air bubbles
 - » Ensure the syringe is filled with the correct amount (0.1mL). Do NOT withdraw more than 0.1 mL
 - » Do NOT combine residual vaccine from multiple vials to obtain a dose.
 - » 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
11. For new vials, note the date and time the vial was first punctured. Once the vial is punctured, you must discard it after 8 hours. Place vial back in fridge between every dose. Do not keep vial outside at room temperatures.
12. Bring the dose of vaccine from the designated preparation area immediately to the patient treatment area for administration.
13. Use standard precautions when administering vaccine. Ask vaccine recipients to wear a face covering, if tolerated. For more information on infection prevention and control, refer to: www.cdc.gov/poxvirus/monkeypox/clinicians/infection-control-healthcare.html
14. Select and cleanse vaccination site two to four inches below the antecubital fossa (elbow on the volar forearm or alternate sites listed below).
15. Administer the vaccine by intradermal (ID) injection into the volar surface of the forearm. If the volar aspect of the forearm is not an option (e.g. strong patient preference), ID administration of vaccine may be done at the upper back below the scapula or at the deltoid. Administer into clean and intact skin.* Refer to this video for guidance: www.youtube.com/watch?v=TLv1mR6mECQ
16. While pulling the skin taut, position the needle bevel facing upward and insert the needle at a 5-to 15-degree angle into the dermis. Slowly inject 0.1mL intradermally. A noticeable pale elevation of the skin (wheal) is desirable but not required.
17. Immediately place the needle and syringe in a sharps disposal container. Do not recap the needle.
18. A bandage may be placed over the injection site as needed.
19. Observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope:
 - » **30 minutes:** Persons with a history of anaphylaxis to gentamicin, ciprofloxacin, chicken or egg protein (AND are currently avoid exposure to all chicken or egg products)
 - » **15 minutes:** Can consider for all other persons
20. Counsel patients to return for in 28 days (4 weeks) for the second dose of vaccine if the dose administered is the first dose.

* For persons with tattoos, avoid vaccination in the area where there is a recent (<1 month) tattoo. If tattoos cover both arms, choose a space that doesn't have pigment (i.e., ink). However, if the tattoo cannot be avoided, the vaccine can still be administered through the tattoo.

Document Vaccination

Document in each vaccine recipient's record Vaccine Administration Data elements as provided in the HHS Monkeypox Vaccination Program Provider Agreement and report these data at least weekly through either

1. the Immunization Information System (IIS) of the state, local, or territorial jurisdiction or
2. another system designated by CDC according to CDC documentation as may be posted on the Provider Agreement update webpage (www.cdc.gov/poxvirus/monkeypox/clinicians/provider-agreement.html).

Be Prepared to Manage Medical Emergencies

Be familiar with identifying immediate allergic reactions, including anaphylaxis, and be prepared to treat these events at the time of vaccine administration.

- Have a plan in place to contact emergency medical services immediately in the event of a severe acute vaccine reaction. Because anaphylaxis may recur after patients begin to recover, monitoring in a medical facility for several hours is recommended, even after complete resolution of symptoms and signs.

Report Adverse Events to VAERS

Vaccination providers are responsible for MANDATORY reporting of the following listed events following JYNNEOS vaccination to VAERS:

- 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
- Cases of thromboembolic events and neurovascular events

Reporting is encouraged for any clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at vaers.hhs.gov or by calling 1-800-822-7967.