

JYNNEOS Smallpox and Monkeypox Vaccine

STANDARD REGIMEN Preparation and Administration Summary (Subcutaneous Administration)

General Information

Vaccine: JYNNEOS Smallpox and Monkeypox vaccine

Single-dose vial

Diluent: None

Dosage: 0.5 mL

Age Indications

All ages (NOTE: during this outbreak, the alternative regimen is preferred for people 18 years of age and older without a history of developing keloid scars)

- Prior to administration in persons less than 18 years of age, clinicians should first contact their jurisdictional health department ([Jurisdictional Contacts](#)) to facilitate consultation with CDC.

Vaccination Schedule

Administer two doses of JYNNEOS (0.5 mL each) 28 days (4 weeks) apart

- For more details on the dosing interval, refer to <https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html#dosing>.

Administration

Subcutaneous (subcut) injection into the fatty tissue over the triceps area in the upper arm in persons greater than 12 months of age, or the anterolateral thigh for infants younger than 12 months of age

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.
 - » **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.
- Do NOT refreeze thawed vaccine.
- Use beyond-use date labels for this vaccine 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: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/

Prepare and Administer the Vaccine

1. Assess recipient status:
 - » Screen for contraindications and precautions.
 - » Review vaccination history.
 - » Review 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 stability of the vaccine by contacting the manufacturer.



5. With the vial upright, gently swirl the vaccine for 30 seconds.



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.



Prepare and Administer the Vaccine (continued)

7. Using a new, sterile alcohol prep pad, cleanse the stopper of the vaccine vial.
8. Choose the correct equipment for subcutaneous injection: use sterile syringe with a 23-25 gauge, 5/8" needle. **Always use a new, sterile needle and syringe for each injection.**
9. Ensure the needle and syringe are secured tightly together to prevent the vaccine from inadvertently leaking during preparation and administration.
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 (0.5mL).
 - » 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. Bring the dose of vaccine from the designated preparation area immediately to the patient treatment area for administration.
12. 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: <https://www.cdc.gov/poxvirus/monkeypox/clinicians/infection-control.html>
13. Select and cleanse vaccination site, which is the fatty tissue over the triceps in the upper arm in persons greater than 12 months of age, or the anterolateral thigh in infants younger than 12 months of age.
14. Administer the vaccine by subcutaneous (subcut) injection. While pinching up the skin and underlying fatty tissue, insert the needle at a 45-degree angle into the subcutaneous tissue and slowly inject the vaccine. Avoid reaching the muscle.
15. Immediately place the needle and syringe in a sharps disposal container. Do not recap the needle.
16. A bandage may be placed over the injection site as needed.
17. Observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope:
 - » **30 minutes:** People 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 people
18. Counsel patients to return in 28 days (4 weeks) for the second dose of vaccine if the dose administered is the first dose.

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.