

Appendix C: Track A Requirements for Vaccine Administration

All Track A Applicants must be prepared to adhere to the following:

Deliverable 1: Develop Monkeypox Vaccination Program

Operate vaccination clinics for persons who are at high risk for monkeypox

Providers will be expected to vaccinate persons at high risk for monkeypox while maintaining patient confidentiality and assuring protection of staff and patients from monkeypox transmission. Vaccination opportunities should be easily accessible to the community, close to SEPTA services if occurring at fixed locations, and ADA accessible.

Both fixed and mobile services may be proposed. Sites that are created in new service locations that increase patient access will be viewed most favorably, as will mobile access points.

Hours of operation for vaccination services may be variable and should be described in detail by the Provider. PDPH is particularly interested in services provided during evenings, nights, and/or weekends, which may be more convenient for the population of focus. Providers must:

- Develop a written protocol or plan for providing vaccinations.
 - Describe how the Provider will communicate with individuals before, during, and after vaccination.
 - Describe how clinics will be scheduled, promoted, and operated.
- Establish infection control procedures to protect staff and patients.
 - Describe PPE usage.
- Communicate information about clinics to PDPH, including dates, times, locations, and collaborating organizations.

The Provider must address health equity. This includes outreach plans to communicate with patients before, during, and after vaccination. Providers are expected to describe how outreach will be directed to Philadelphia residents, particularly the communities described in the RFP.

Manage vaccine and supplies as provided by the CDC and/or PDPH

Monkeypox vaccine (JYNNEOS) will be provided by PDPH. JYNNEOS has specific storage and handling requirements that Providers must be able to meet. Providers must:

- Agree to and sign the CDC Monkeypox Vaccine Provider Agreement.
- Train on vaccine storage and handling procedures, as may be required by PDPH.
- Store and handle vaccines according to the manufacturer's guidelines.
- Undergo inspections and submit refrigerator/freezer temperature monitoring logs to PDPH, as might be required.
- Order vaccine per the instructions provided by the PDPH Immunization Program.
- Report vaccine inventory on a daily basis per the instructions provided by the PDPH Immunization Program.

Provide a safe environment for staff and patients

Provider should operate the vaccination clinic and environment in a manner that assures safety for staff and patients.

Provider is responsible for conducting health screenings for patients prior to vaccination. Persons with suspected illness should be excluded until the person has been screened for possible monkeypox infection. Provider is responsible for purchasing and maintaining consistent sourcing of personal PPE appropriate for vaccination activities.

Provide staff to support clinic operations

Provider must staff the vaccination site to meet the needs of the community served. Providers must:

- Maintain adequate staffing to accomplish vaccination registration, address patient questions and concerns, manage and administer vaccine, and collect required data elements for reporting.
- Employ staff who are culturally and linguistically appropriate for the population(s) to be served.

Deliverable 2: Administer Monkeypox Vaccination to Philadelphia Residents

Medical oversight

Administration of vaccines must be performed by an authorized licensed/certified vaccinator and performed consistent with standards of medical care. Documentation of the license and/or certification of the proposed vaccinators must be submitted by Providers prior to receiving any vaccine. The vaccination clinic must be under the direction or oversight of a Pennsylvania licensed physician, surgeon, or osteopath (the “Medical Director”). The Medical Director does not need to be physically on site at all times but must be available to vaccinators to answer questions and address concerns of patients and staff. The Medical Director may issue Standing Orders that allow qualified immunizers to administer vaccinations without a patient-specific order.

Provider must submit documentation with RFP submission demonstrating the qualifications of the Medical Director, including a copy of professional license.

Criteria for eligibility

Provider must comply with vaccination eligibility criteria as established by PDPH. Providers should make every effort to direct their vaccination outreach to Philadelphia residents. However, non-Philadelphia residents should not be turned away.

Counsel patients about monkeypox vaccine before vaccination

Patients must be educated about monkeypox vaccine before administration. Providers must:

- Provide intended vaccine recipient with the appropriate FDA Emergency Use Authorization (“EUA”).
- Answer intended vaccine recipient’s questions or concerns.
- Provide vaccination regardless of health insurance status or other protected status (see City of Philadelphia Fair Practices Ordinance).
- Agree to vaccinate patients regardless of patient’s insurance status and not withhold vaccine if a patient cannot afford to pay administration fee.

Administration of monkeypox vaccine

Providers must follow the FDA Emergency Use Authorization (EUA) for Providers that is specific to the JYNNEOS vaccine. In addition, medical guidelines for patient screening should be established at each site.

- Screen patient for contraindications to vaccination.
- Maintain familiarity with vaccine products, eligibility criteria, and vaccine contraindications, as these may continue to change.
- Prepare vaccine for injection in accord with manufacturer’s recommendations, as provided in the EUA for Providers.
 - Providers must ensure staff are trained in intradermal administration

- Administer the vaccine according to manufacturer’s recommendations, as provided in the EUA for Providers, and in a manner that is consistent with accepted medical practices.

Observation post-administration of monkeypox vaccine

Although acute adverse events are rare following vaccination, the Provider must be prepared to handle urgent post-vaccination events.

- Create a response protocol for serious allergic events, e.g., anaphylaxis, that might follow monkeypox vaccination.
- Train all clinical staff about responding to anaphylaxis.
- Maintain medical supplies for treating anaphylaxis, including injectable epinephrine. Advanced levels of treatment are not required. Initiating a response through 9-1-1 Emergency Medical Services is adequate.
- Establish a 15-minute observation for all patients following vaccination. For patients with histories of any serious allergy, the observation period should be increased to 30 minutes.
- Observation periods can be conducted in non-clinical areas and involve non-clinical staff; however, a clinician must always be ready to respond.
- Report all serious adverse events to monkeypox vaccination to PDPH.

Documentation post-administration of monkeypox vaccine

- The person administering the vaccine must complete all required data in the Vaccine Administration Record or its equivalent, such as in an Electronic Health Record.
- When collecting screening criteria, Provider must collect gender, race and ethnicity. The patient may choose to “prefer not to say,” but these data elements are a reporting requirement.
- Immunization records for all vaccines administered in the City are reportable to PhilaVax, the City’s Immunization Information System.
- Provide a completed vaccination card to the recipient.

Second dose vaccine requirements

Monkeypox vaccines that are currently authorized by FDA EUA require a second dose. The recommended interval between doses is 28 days. Providers must:

- Advise the patient on when the second dose is due.
- If possible, provide an appointment for the return visit for the second dose of vaccine.
- Implement a reminder-recall system for patients who miss second dose appointments.