

Health Advisory Intradermal Vaccination with JYNNEOS Rationale, Policy, and Implementation

August 18, 2022 (Corrected)

Situational Update

An Emergency Use Authorization (EUA) is now in effect for administering JYNNEOS vaccine via the intradermal (ID) route to eligible persons ages 18 years and older. This Advisory sets forth SFDPH rationale and policy for implementing ID administration of JYNNEOS in San Francisco, in alignment with CDC and CDPH guidance.

Rationale

<u>FDA has authorized intradermal (ID) administration of vaccine</u> to persons aged 18 years and older as a dose-sparing policy that will allow as many as five 0.1-mL doses to be administered from each 0.5-mL single-dose vial of JYNNEOS.

Guidance from CDC endorses intradermal (ID) vaccination of adults against MPX.

Please see this <u>CDPH interim guidance dated 8/15/2022</u>. Throughout 2022 supplies of JYNNEOS are expected to be limited. The number of doses available at the standard 0.5 mL volume are insufficient to protect prioritized populations at risk of contracting Monkeypox (MPX) during the current epidemic. Therefore, ID dosing of JYNNEOS vaccine is recommended by CDPH for all eligible adults who are able to receive the vaccine via ID administration.

Scientific Basis. ID dosing of JYNNEOS (0.1 mL) was compared with subcutaneous (SC) dosing (0.5 mL) in a head-to-head randomized trial of healthy adults aged 18-38 years. Immunogenicity was evaluated using 2 plaque-reducing neutralizing antibody titers (PRNT) and 2 enzyme-linked immunosorbent assays (ELISA). As <u>reported by FDA</u> and <u>as published</u>, immune responses to 0.1-mL ID and 0.5-mL SC dosing were essentially identical.

Impact. By implementing ID dosing of JYNNEOS for all adults who are able to receive the vaccine by this route, San Francisco is best able to progress rapidly with immunization of persons who fall under current SF Eligibility Criteria and to plan for expansion of JYNNEOS eligibility in SF in the near future.



Policy and Implementation

All SF sites receiving and administering JYNNEOS vaccine must shift to ID dosing for persons aged 18 years and older.

Sites must administer JYNNEOS by the ID route to all those who are able to receive an ID dose, including persons with HIV and/or immune compromise, and may not offer patients the option of receiving an SC dose.

Contraindications and precautions to JYNNEOS apply to both ID and SC dosing routes.

Among adults without a contraindication to JYNNEOS, only <u>persons who have a history of developing keloid scars may receive JYNNEOS by the SC route.</u> All potential vaccinees should be asked individually about their history of forming keloid; self-attestation is acceptable.

Dose Reporting. SFDPH will communicate directly with SF sites administering JYNNEOS about changes to utilization reporting that will accommodate both ID and SC doses.

Mitigation of Wastage. JYNNEOS doses may be used only within 8 hours after first puncture of the vial and any doses remaining after that time must be discarded.

All JYNNEOS recipients must meet the most current <u>SF Monkeypox Vaccine Eligibility</u> criteria, without exception.

Strategies recommended to completely use all 0.1-mL doses in each vial include:

- Clustering vaccination visits in groups of five within 8-hour periods
- Maintaining standby lists of persons who meet current <u>SF Monkeypox Vaccine Eligibility</u> and can be available to receive a dose on short notice

Low dead-volume tuberculin syringes are recommended for the extraction of five 0.1-mL ID doses from JYNNEOS 0.5-mL vials. When regular tuberculin syringes are used, experience shows that it may be difficult to extract more than four full doses per vial. *Tip: push all air out of the barrel of the empty syringe before entering the needle into the JYNNEOS vial.* Partial or residual doses should not be combined from multiple vials to obtain a dose.

Immunization Technique. Since JYNNEOS vials contain no preservative, care should be taken to follow aseptic technique (perform hand hygiene before handling vials, clean vial stopper with alcohol before each puncture) and keep vaccine vials continuously at refrigerated temperatures (36-46°F) except when withdrawing doses.

Proper ID administration technique is important to minimize inadvertent underdosing, leakage from the injection site, or subcutaneous injection of vaccine which could reduce the level of



immunity generated by a dose and require revaccination. See <u>CDC guidance for addressing</u> <u>errors and deviations with JYNNEOS administration</u>. For example, if a lower-than-authorized dose is administered, it can be repeated on the same day.

Training resources for proper administration of ID doses are available at this <u>CDC site</u>. San Francisco sites offering JYNNEOS vaccination can receive local assistance from SFDPH in developing ID administration training plans for their vaccinator staff by registering <u>at this link</u> or visiting our <u>MPX Provider page</u>.

Additional JYNNEOS Information

Pediatric. The EUA allows persons ages 17 years of age and younger (no lower age limit) to receive JYNNEOS, but only by the SC route; ID administration is not authorized for minors. The SC dose to be administered is 0.5 mL regardless of age or weight. Additional guidance will be forthcoming regarding conditions under which adolescents in SF may be able to receive JYNNEOS if a parent or guardian is not available to sign consent.

Eligibility. The current version of <u>SF Monkeypox Vaccine Eligibility</u> is posted – please check this site for future updates.

CDC offers additional guidance on therapeutics for pediatric monkeypox cases.

<u>Additional Resources</u>

SFDPH Monkeypox Page for SF Providers www.sfcdcp.org/monkeypoxhcp

CDC JYNNEOS Resources <u>JYNNEOS Vaccine | Monkeypox | Poxvirus | CDC</u>

To view or sign up for SFDPH Health Alerts, Advisories, and Updates visit www.sfcdcp.org/healthalerts