**Purpose and Policy**

To reduce morbidity and mortality from monkeypox disease by enabling licensed clinical staff at the San Francisco Department of Public Health to assess and vaccinate persons who meet eligibility criteria for the JYNNEOS vaccine, without the need for examination or direct order by the supervising physician at the time of the encounter.

**Vaccine and Status**

**JYNNEOS**

* Approved by FDA in 2019 for **ages 18+ years**
* Smallpox and Monkeypox Vaccine, Live, Attenuated Replication-Deficient Vaccinia Virus
* 2-dose primary series, 4 weeks apart.
* Manufactured by Bavarian Nordic A/S, Denmark

**Vaccine Components**

* No material of direct animal origin
* No preservatives or latex
* Vaccine contains live virus plus residual amounts of host-cell DNA, chick and/or egg protein, benzonase, gentamicin, and ciprofloxacin.

**Indications for Vaccination**

**FDA Licensure:** For prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection.

Vaccination for persons age less than 18 years may occur only under an FDA investigational protocol (IND).

**PEP Indication:** CDC recommends that JYNNEOS can be given for Post-Exposure Prophylaxis (PEP) of monkeypox within 4 days from the date of exposure to prevent onset of the disease. If given between 4-14 days after the date of exposure, vaccination may reduce the symptoms of disease, but it may not prevent the disease. See [Monkeypox and Smallpox Vaccine Guidance | CDC](https://www.cdc.gov/poxvirus/monkeypox/clinicians/smallpox-vaccine.html)

**PrEP Indication:** CDC recommends JYNNEOS as Pre-Exposure Prophylaxis (PrEP) for persons at occupational risk for exposure to orthopoxviruses including monkeypox. See [MMWR 2022](https://www.cdc.gov/mmwr/volumes/71/wr/mm7122e1.htm)

* Research laboratory personnel who directly handle orthopoxvirus-infected specimens or animals, or replication-competent orthopoxvirus strains
* Clinical laboratory personnel performing diagnostic testing for orthopoxviruses
* Healthcare personnel who administer smallpox vaccine or care for patients infected with orthopoxviruses

Additional persons may also be eligible for PrEP doses in accordance with state- and/or county-level guidance.

**Booster Doses**

Persons who are at **ongoing risk for occupational exposure** and who received a primary series with JYNNEOS or with smallpox vaccine (DRYVAX or ACAM2000) should receive booster dose(s) of JYNNEOS.

* At risk of ongoing exposure to smallpox or monkeypox virus: booster every 2 years
* At risk of ongoing exposure to vaccinia or cowpox virus: booster at least every 10 years.

**Vaccine Storage & Preparation**

JYNNEOS is a suspension for injection, with each 0.5-mL dose supplied in a single-dose vial.

* Store frozen at -25°C to -15°C (-13°F to +5°F) until expiration date on vial label.
* Store refrigerated at 2°C-8°C for up to 8 weeks (this differs from package insert – see [Provider Letter](https://aspr.hhs.gov/SNS/Documents/MVA-BN-Information-Ltr-Effective-14June2022.pdf)).
* Store in original package to protect from light.
* Allow vaccine to thaw and reach room temperature before use.
* Once thawed, may be kept in refrigerator at +2°C to +8°C (+36°F to +46°F) for 12 hours. Don’t refreeze.

**Vaccine Administration**

Primary series: 0.5 mL SQ at 0, 4 weeks

* When thawed, JYNNEOS is a milky, light yellow to pale white colored suspension.
* Inspect visually for particulate matter and discoloration prior to administration and do not administer if present
* Swirl the vial gently before use for at least 30 seconds.
* Withdraw a dose of 0.5 mL into a sterile syringe and administer by subcutaneous (SQ) injection, preferably into the upper arm (triceps or deltoid area).
* Administer a second dose 4 weeks later.
* Second doses may be delayed while Jynneos is in short supply, in accordance with state- and/or county-level guidance. In these instances, the series does not need to be restarted.

**Contraindications**

Per CDC, JYNNEOS is contraindicated in persons with a serious allergy to a vaccine component. This includes persons who have had a severe allergic reaction (e.g., (anaphylaxis) to egg, gentamicin, or ciprofloxacin, or following a previous dose of JYNNEOS.

**Warnings and Precautions**

**Allergic reactions.** Since severe allergic reactions to JYNNEOS are possible, appropriate medical treatment (epinephrine, oxygen) must be available to manage possible anaphylactic reactions. The risk for a severe allergic reaction should be weighed against the risk for disease due to smallpox or monkeypox.

**Immunocompromised Persons**

JYNNEOS is safe to administer to immunocompromised persons, however they may have a diminished immune response to the vaccine.

**Pregnancy**

Data are insufficient to determine vaccine-associated risks in pregnancy. In animals who received JYNNEOS, there has been no evidence of harm to the developing fetus.

**Breastfeeding**

It is not known whether JYNNEOS is excreted in human milk or is safe in breastfed infants. However, per CDC it is unlikely to present a risk of transmission to breastfed infants and can be administered to women who are breastfeeding if vaccination is critical.

**Adverse Events**

Common adverse reactions include

* Pain, redness, swelling, itching, and/or induration at the injection site
* Myalgia, fatigue, headache, nausea, and/or chills.
* Fever is uncommon.

In clinical trials, serious adverse events were rare and occurred in JYNNEOS recipients at about the same frequency as those who received placebo.

Clinical studies did not detect an increased risk for myocarditis among JYNNEOS recipients. However, per CDC, persons with underlying heart disease or 3 or more major cardiac risk factors should be counseled about the theoretical risk for myocarditis following JYNNEOS.

**Timing With COVID-19 Vaccine**

CDC recommends that adolescent or young adult males should consider waiting 4 weeks after JYNNEOS vaccination before receiving an mRNA COVID-19 vaccine, due to theoretical concerns regarding myocarditis.

However, if JYNNEOS is recommended for PEP in an outbreak setting, administration of JYNNEOS should not be delayed because of recent receipt of an mRNA COVID-19 vaccine.

No other vaccine-vaccine interactions are known to be of concern.

**Development of Immunity**

Peak antibody response is achieved 2 weeks after the second dose of the 2-dose JYNNEOS series. Rates of seroconversion are high, therefore for immunocompetent persons effective vaccination can be assumed and routine antibody titer testing after JYNNEOS is not recommended.

Durability of immune response to JYNNEOS after one dose is unknown.

**Replication-Deficient Vaccine**

The live, attenuated (weakened) vaccinia virus in JYNNEOS is replication-deficient and does not cause clinical infection in recipients.

JYNNEOS, as a replication-deficient vaccine, does not require the precautions associated with other live vaccines.

**Additional Information**

Provide [current VIS](https://www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.html) prior to vaccine administration

Report clinically significant adverse events to [VAERS](https://vaers.hhs.gov/index.html).

**For More Information**

[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 (cdc.gov)](https://www.cdc.gov/mmwr/volumes/71/wr/mm7122e1.htm)

[Information For Clinicians | Monkeypox | Poxvirus | CDC](https://www.cdc.gov/poxvirus/monkeypox/clinicians/index.html)

[CDPH monkeypox vaccination resources](https://eziz.org/resources/monkeypox/)

**Authorization**

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Signature Date

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