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California Department of Public Health

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TO: California Providers of Monkeypox Vaccination Services

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SUBJECT: JYNNEOS monkeypox vaccine, administration and dosing

HIGHLIGHTS

JYNNEOS vaccine:

- Is recommended for prevention of monkeypox in high-risk populations.
- May be administered intradermally for adults (age ≥18 years) and subcutaneously for children (age <18 years) or at any age if a history of keloids.
- Is supplied in vials of ≤5 intradermal doses or 1 subcutaneous dose
- Currently, unopened vials may be stored at 2°C to 8°C (36°F to 46°F) for 8 weeks.
- This letter is intended to provide information about the JYNNEOS vaccine and provide links to CDC, CDPH, FDA, and other resources.

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SUMMARY

In June 2022, the Centers for Disease Control and Prevention (CDC) recommended use of the JYNNEOS vaccine for primary prevention of adults (age ≥ 18 years) considered to be at high risk for monkeypox disease. Further, on August 9, 2022 FDA granted Emergency Use Authorization (EUA) for JYNNEOS vaccine for use in children (age < 18 years) using subcutaneous administration and for JYNNEOS vaccine in adults ≥ 18 years using intradermal administration.

BACKGROUND AND COMPOSITION

Vaccine components include:

- MVA-BN (Modified Vaccinia Ankara-Bavarian Nordic) live, non-replicating virus
- Tromethamine
- Sodium chloride

Each 0.5 mL dose may contain residual host-cell DNA (≤ 20 mcg), protein (≤ 500 mcg), benzonase (≤ 0.0025 mcg), gentamicin (≤ 0.163 mcg) and ciprofloxacin (≤ 0.005 mcg). JYNNEOS is a live vaccine produced from the strain Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN), an attenuated, non-replicating orthopoxvirus. MVA-BN is grown in primary Chicken Embryo Fibroblast (CEF) cells suspended in a serum-free medium containing no material of direct animal origin, harvested from the CEF cells, purified and concentrated by several Tangential Flow Filtration steps including benzonase digestion. JYNNEOS does not contain preservatives. The vial stoppers do not contain latex. More information can be found in the FDA Fact Sheets and Interim Guidance (CDC).

ACIP RECOMMENDATIONS FOR VACCINE USE

Eligible Groups

For the prevention of monkeypox disease in persons at high risk of monkeypox infection JYNNEOS vaccine is approved for individuals 18 years of age and authorized under EUA for use in individuals under 18 years of age. Recent ACIP meeting materials may be referenced at ACIP Vaccine Recommendations. Current Monkeypox vaccine recommendations by ACIP and CDC may be found at Use of JYNNEOS (Smallpox and Monkeypox Vaccine, Live, Nonreplicating) for Preexposure Vaccination.

Minimum Ages and Intervals

- Minimum age for any dose: Not established, previous use
- Minimum interval between dose 1 and 2: 28 days

Contraindications and Precautions

Do not administer JYNNEOS vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of JYNNEOS. People with a history of anaphylaxis to vaccine component (gentamicin, ciprofloxacin, egg protein) are considered to have a precaution to vaccination. Providers should discuss risks and benefits with potential recipients. They may be vaccinated with a 30-minute observation period. Alternatively, taking into account the risk of acquiring monkeypox if the vaccination is delayed, an allergist-immunologist may be consulted before the vaccine is administered.

Additional clinical considerations and information on contraindications and precautions can be found in the CDC Interim Considerations: Safety.

Administration with Other Vaccines

Currently, there are no data on administering JYNNEOS vaccine at the same time as other vaccines. Because JYNNEOS is based on a live, attenuated non-replicating orthopoxvirus, JYNNEOS typically may be administered without regard to timing of other vaccines. This includes simultaneous administration of JYNNEOS and other vaccines on the same day, but at different anatomic sites if possible. Consider offering MenACWY or other recommended vaccines at the same time as JYNNEOS.

However, there are additional considerations if administering JYNNEOS vaccine and a COVID-19 vaccine. (Interim Clinical Considerations for Use of COVID-19 Vaccines)

- If an orthopoxvirus vaccine is offered for prophylaxis in the setting of an orthopoxvirus (e.g., monkeypox) outbreak, orthopoxvirus vaccination should not be delayed because of recent receipt of a Moderna, Novavax, or Pfizer-BioNTech COVID-19 vaccine; no minimum interval between COVID-19 vaccination with these vaccines and orthopoxvirus vaccination is necessary.
- People, particularly adolescent or young adult males, might consider waiting 4 weeks after orthopoxvirus vaccination (either JYNNEOS or ACAM2000) before receiving a Moderna, Novavax, or Pfizer-BioNTech COVID-19 vaccine, because of the observed risk for myocarditis and/or pericarditis after receipt of ACAM2000 orthopoxvirus vaccine or Moderna, Pfizer-BioNTech and Novavax COVID-19 vaccines and the unknown risk for myocarditis or pericarditis after JYNNEOS.

Best practices for multiple injections include:

- Label each syringe with the name and the dosage (amount) of the vaccine, lot number, initials of the preparer, and exact beyond-use time, if applicable.
- Administer each injection in a different injection site; separate injection sites by 1 inch or more, if possible.
- Administer the JYNNEOS vaccine and vaccines that may be more likely to cause a local reaction in different limbs, if possible.

Review ACIP's general best practices and CDC Pink Book for further information.

DOSAGE AND ADMINISTRATION

Intradermal administration of 0.1mL is authorized under EUA for persons 18 years and older. During this outbreak with limited JYNNEOS vaccine supply, the intradermal route is preferred, but subcutaneous administration may be acceptable in certain situations. People of any age with a history of developing keloid scars and individuals younger than 18 years of age should receive the vaccine via the subcutaneous route.

If a person declines intradermal administration and/or if intradermal administration poses a barrier to vaccination would not otherwise be vaccinated, it is acceptable to administer the vaccine subcutaneously.

Subcutaneous administration of 0.5mL is approved for use in adults and authorized under EUA for people aged <18 years

The minimum interval between the first and second dose is 28 days.

Intradermal Injection Technique
Intradermal administration involves injecting the vaccine superficially between the epidermis and the hypodermis layers of the skin, typically of the volar aspect (inner side) of the forearm. This should produce a noticeable pale elevation of the skin (wheal). Please refer to related resources, including intradermal administration teaching tools and the Preparation & Administration Summary for the General Population.

Use of low dead space syringes and needles (ex: 26 or 27 gauge with ¼" to ½" needle) for intradermal injection will also help to maximize the number of available doses.

Storage and Handling

Unpunctured vial stored in	Viability
Freezer (-25°C to -15°C)	Until printed expiration date
Refrigerator (2°C to 8°C)	8 weeks
Room temperature (8°C to 25°C)	6 hours

Do not refreeze. After the first needle puncture, hold the vial between 8°C to 25°C (46°F to 77°F) for up to 6 hours. Discard the vial 6 hours after the first puncture.

Handling: Flip cap off at indicated area using thumb and forefinger at 90°angle. Cap may stay on metal crimp or remove completely.

For reference, please refer to the CDC JYNNEOS Storage and Handling Summary

REACTOGENICITY AND ADVERSE EVENTS

In smallpox vaccine-naïve healthy adults who received JYNNEOS subcutaneously, the most common (>10%) solicited injection site reactions were pain (84.9%), redness (60.8%), swelling (51.6%), induration (45.4%), and itching (43.1%); the most common solicited systemic adverse reactions were muscle pain (42.8%), headache (34.8%), fatigue (30.4%), nausea (17.3%), and chills (10.4%).

In smallpox vaccine-naïve healthy adults who received JYNNEOS intradermally, the most common (>10%) solicited reactions were erythema at injection site (99.5%), induration at injection site (99.5), itchiness (89.0%), pain at injection site (65.4%), feeling tired (51.3%), headache (41.4%), muscle aches (30.4%), nausea (23.0%), underarm pain (20.9%), change in appetite (20.4%), joint pain (17.8%), chills (14.7%), and underarm swelling (10.5%).

Before vaccination, providers should counsel JYNNEOS vaccine recipients about expected local (e.g., pain, swelling, erythema at the injection site) and systemic (e.g., fever, fatigue, headache, chills, myalgia, arthralgia) post-vaccination reactions. Intradermal immunization

can result in local inflammation at the site of injection more frequently than after subcutaneous or intramuscular immunization, occurring in nearly all trial participants who received intradermal MPX vaccine.

Antipyretic or analgesic medications can be taken for the treatment of post-vaccination local or systemic symptoms; these medications should not be used prophylactically for the purposes of prevention of post-vaccination symptoms.

Anaphylactic reactions have been rarely reported following receipt of JYNNEOS vaccines. Administration of antihistamines before JYNNEOS vaccination to prevent allergic reactions is not generally recommended. CDC recommends observation of all vaccine recipients for at least 15 minutes after vaccination, and up to 30 minutes for persons at higher risk of anaphylaxis. Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs.

Fainting (syncope) may occur in association with any injectable vaccine, especially in adolescents. Procedures should be in place to prevent falling injuries and manage syncopal reactions. People should be seated or lying down during vaccination and observed for 15 minutes after vaccination as noted above. If syncope develops, patients should be observed until symptoms resolve.

Limited cases of myocarditis and pericarditis were identified in clinical trials of a previous smallpox vaccine, ACAM2000. However, clinical trials of JYNNEOS did not show an increased risk of myocarditis following vaccination. FDA has authorized and ACIP and CDC have recommended JYNNEOS vaccines in adults on the determination that the benefits of monkeypox vaccination outweigh its risks.

Further information can be found at the FDA Fact Sheet for Healthcare Providers.

VACCINE INFORMATION FACTSHEET

Prior to administering JYNNEOS Vaccine, provide a copy of the "Vaccine Information Fact Sheet for Recipients and Caregivers", available in Spanish, Chinese, Korean, Taglog, and Vietnamese and communicate the information contained in the Fact Sheet. Also available from CDC as "Vaccine Information Statement" and in Spanish.

Documentation of vaccination

Provide a vaccination card to the patient that includes information on how and when to return for the second dose. Administration of each dose must be reported to the state or regional immunization registry.

To help monitor immunization safety, provide the v-safe information sheet to patients and encourage them to participate in v-safe. More information is at www.cdc.gov/vsafe.

Reporting of vaccine adverse events
Vaccination providers who are administering JYNNEOS under the EUA are **required** to report the following adverse events to VAERS that occur after JYNNEOS vaccination:

- 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.

To report to VAERS, visit https://vaers.hhs.gov or call 1-800-822-7967.

ORDERING AND BILLING

At this time, healthcare providers should work with their Local Health Department to obtain JYNNEOS vaccine.

Billing Information
Providers may not charge for JYNNEOS vaccine, provided for free by the United States Government, but may charge an associated administration or facility fee using the same processes for routine vaccines.

- ICD-10 “Z23 Encounter for immunization”
- ICD-10 codes should be available for orthopox infections.
- CPT Codes: 90611 - subcutaneous use. 90622 for intradermal use
- Don’t include the CPT vaccine codes on the claim, because the vaccine is free
- Patient cost sharing applies

Medi-Cal Fee-For-Service and Medi-Cal Managed Care
Please visit Medi-cal benefits page for general information and updates. Vaccine- specific updates can be found in the news section of the Medi-cal page.

Reimbursement for federally qualified health centers (FQHC), rural health clinics (RHC), and tribal/Indian health services are available at the DHCS page.

Provider Agreement
Any person accessing this vaccine is subject to compliance with the terms of the Provider Agreement.

RESOURCES

- FDA Emergency Use Authorization Fact Sheets for JYNNEOS Vaccine
- EZIZ Monkeypox: Information on vaccine management, administration, and more.
- CDPH Monkeypox landing page
- CDC JYNNEOS Vaccine Interim Guidance
- CDC Use of Monkeypox Vaccines in the US - Interim Clinical Considerations
- Additional information on vaccines can be found at http:/www.cdc.gov/vaccines/.