State of California—Health and Human Services Agency
California Department of Public Health

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TO: California Vaccines for Children (VFC) Program Providers

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SUBJECT: JYNNEOS™ Mpox Vaccine is now available through VFC

HIGHLIGHTS

- JYNNEOS™ vaccine is now available for ordering through the VFC Program for VFC-eligible patients 18 years of age.
- JYNNEOS™ vaccine is recommended for those at risk for exposure to mpox.
- The vaccine is administered subcutaneously as a two-dose series, at least 28 days apart.

SUMMARY

JYNNEOS™ vaccine, manufactured by Bavarian Nordic, is now available through the Vaccines For Children (VFC) program for the prevention of mpox (formerly monkeypox). The vaccine is available for ordering via myCAvax for at-risk VFC-eligible patients 18 years of age ONLY but not younger patients at this time.

JYNNEOS™ is supplied in a 10-pack box of single-dose vials (NCD: 50632-0001-03).

ACIP RECOMMENDATIONS FOR VACCINE USE

Eligible Groups

JYNNEOS™ vaccine supplied through the VFC Program is recommended for patients 18 years of age who are at increased risk of mpox, including:

- Gay, bisexual, and other men who have sex with men, or transgender or nonbinary people who in the past 6 months have had:
  - At least one sexually transmitted disease

    - More than one sex partner
    - Sex at a commercial sex venue
    - Sex in association with a large public event in a geographic area where mpox transmission is occurring.
- Persons who are sexual contacts of the persons described above.
- Persons who anticipate experiencing any of the situations described above.

Current mpox vaccine recommendations may be found at Interim Clinical Considerations for Use of JYNNEOS™ Vaccine for Mpox Prevention in the United States.

Contraindications and Precautions

JYNNEOS™ is contraindicated in patients with severe allergic reaction (e.g., anaphylaxis) after a previous dose, or to a vaccine component. JYNNEOS™ vaccine contains small amounts of gentamicin and ciprofloxacin and is produced using chicken embryo fibroblast cells. See package insert for a full list of vaccine ingredients.

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

Administration with Other Vaccines

Currently, there are no data on administering JYNNEOS™ vaccine at the same time as other vaccines. Because JYNNEOS™ is non-replicating, it typically may be administered without regard to timing of other vaccines. This includes simultaneous administration of JYNNEOS™ and other vaccines, including influenza vaccine, at different anatomic sites if possible to simplify identification of potential local reactions. Consider offering MenACWY or other recommended vaccines at the same time as JYNNEOS™.

There is no required minimum interval between receiving any COVID-19 vaccine (i.e., Moderna, Novavax, or Pfizer-BioNTech) and JYNNEOS™ vaccine, regardless of which vaccine is administered first. People (particularly adolescent or young adult males) who are recommended to receive both vaccines might consider waiting 4 weeks between vaccines. This waiting period is due to the observed risk for myocarditis and pericarditis after receipt of ACAM2000 orthopoxvirus vaccine and COVID-19 vaccines, and a hypothetical risk for myocarditis and pericarditis after JYNNEOS™ vaccine. However, if a patient is at increased risk for mpox or severe disease due to COVID-19 disease, administration of JYNNEOS™ and COVID-19 vaccines should not be delayed.

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

Administer JYNNEOS™ by subcutaneous injection, preferably into the upper arm. Two doses (0.5 mL each) of JYNNEOS™ should be administered with a minimum interval of 28 days.

Storage and Handling

Unpunctured vial stored in	Viability
Freezer (-25°C to -15°C)	Until printed expiration date
Refrigerator (2°C to 8°C)	4 weeks*
Room temperature (8°C to 25°C)	6 hours

*The shelf life at refrigerated temperatures for lot #96867 has been extended to 8 weeks. See FDA letter issued May 28, 2024.

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. The cap may stay on the metal crimp, or it may be removed completely.

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 package insert.

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%).

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. 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.

VACCINE INFORMATION FACTSHEET

Before administering JYNNEOS™ Vaccine, provide a copy of the Vaccine Information Statement (VIS) to patients. The JYNNEOS™ VIS is also available 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.

Reporting of vaccine adverse events

Providers are encouraged to report any clinically significant adverse events following vaccination, even if they are not sure if vaccination caused the event, to VAERS, the Vaccine Adverse Event Reporting System. To report to VAERS, visit https://vaers.hhs.gov or call 1-800-822-7967.

VFC VACCINE ORDERING

JYNNEOS™ vaccine (NDC: 50632-0001-03) is now available for ordering through the Vaccines for Children (VFC) Program for VFC-eligible 18-year-old patients recommended to receive the vaccine. You may submit a request for JYNNEOS™ vaccine on the VFC vaccine order form through your myCAvax account. JYNNEOS™ comes in a 10-pack of single-dose vials, with a minimum order quantity of 10 doses. Order limitations may apply.

BILLING FOR VFC VACCINE

Medi-Cal Fee-For-Service (FFS): To bill Medi-Cal FFS for administration of VFC-supplied doses of JYNNEOS™, use the appropriate CPT-4 code for JYNNEOS™ (CPT Codes: 90611 – subcutaneous use; 90622 for intradermal use), followed by the "-SL" modifier, 90611-SL or 90622-SL. Providers will only be reimbursed for the administration fee when using VFC vaccines for Medi-Cal FFS-eligible patients.

For specific information and details on Medi-Cal billing, please refer to the Medi-Cal provider manual on VFC. Providers with questions on Medi-Cal billing policies and procedures and Provider manual information may call the Telephone Service Center (TSC) at 1-800-541-5555.

Medi-Cal Managed Care: Please contact the specific Medi-Cal managed care health plan for information on immunization billing and reimbursement.

Codes for the use of JYNNEOS™

- ICD-10 "Z23 Encounter for immunization"
- ICD-10 codes should be available for orthopox infections.
- CPT Codes: 90611 – subcutaneous use. 90622 for intradermal use

REPORTING VACCINE ADMINISTRATION TO CAIR

All active participants of California's VFC Program are required to enter all vaccine doses administered into CAIR or RIDE, in accordance with AB 1797, and as indicated in the 2023 VFC Provider Participation Agreement. Please make sure all doses administered are reported into a California immunization registry (CAIR or Healthy Futures/RIDE) AND the appropriate VFC Eligibility category is recorded.

Please ensure CAIR Accepted Values for VFC Eligibility Funding Status are reported with your clinic's data exchange information when documenting vaccine administration in the clinic's electronic medical record, and then exchanging information with CAIR or Healthy Futures. NOTE: Administration reported with each order in myCAvax may be compared against doses reported as administered in CAIR prior to re-order approval.

RESOURCES

- FDA Package Insert
- JYNNEOS CDPH Vaccine Fact Sheet
- EZIZ Mpox: Information on vaccine management, administration, and more
- CDPH Mpox Page
- Interim Clinical Considerations for Use of JYNNEOS™ Vaccine for Mpox Prevention in the United States | Mpox | Poxvirus | CDC
- Additional information on vaccines can be found at http:/www.cdc.gov/vaccines/