

County of Santa Cruz

HEALTH SERVICES AGENCY

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JYNNEOS MPOX Vaccine Clinical Guidance

Santa Cruz County Public Health Revised 8.23.2022

Vial NDC number: 50632-001-01

CPT Codes: https://www2a.cdc.gov/vaccines/IIS/IISStandards/vaccines.asp?rpt=cpt

JYNNEOS Package Insert: https://www.fda.gov/media/131078/download

JYNNEOS (VIS) Vaccine Information Statement (for patients over 18 years, subcutaneous administration- English): https://www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-

monkeypox.pdf

JYNNEOS VIS (Spanish): https://www.immunize.org/vis/pdf/spanish_smallpox_monkeypox.pdf

JYNNEOS EUA FACT SHEET FOR HCP: https://www.fda.gov/media/160774/download

JYNNEOS EUA FACT SHEET FOR RECIPIENTS: https://www.fda.gov/media/160773/download

Indications

- FDA-approved indication for monkeypox in adults 18 and older.
- The vaccine is a live-attenuated, non-replicating vaccine and poses no risk to the HCP.
- FDA EUA approval for intradermal (ID) administration in adults 18 years and older https://www.fda.gov/media/160774/download
- FDA EUA approval for subcutaneous (SC) administration in pediatrics under 18 years https://www.fda.gov/media/160774/download
- FDA approval for SC administration in people who ID administration is contraindicated for
 - o Refer to the VIS above

Contraindications

- Severe allergic reaction (anaphylaxis) to a prior dose of JYNNEOS or a vaccine component.
- Vaccine components: MVA-BN live virus, tromethamine, sodium chloride, residual amounts of Chicken Embryo Fibroblast host-cell DNA and protein, benzonase, gentamicin, and ciprofloxacin.
- History of severe allergic reaction to chicken or egg protein and are currently avoiding exposure to all chicken or egg products.
- Moderate or severe acute illness with or without fever
- Current MPOX symptoms rash and illness
- Monkeypox, Interim Considerations https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html#safety
- Please refer to the JYNNEOS FDA Package Insert (https://www.fda.gov/media/131078/download) for full details.

Coadministration

- JYNNEOS typically may be administered without regard to timing of other vaccines.
 - People, particularly adolescent or young adult males, might consider waiting 4 weeks after orthopoxvirus vaccination before receiving a COVID-19 vaccine, because of the observed risk for myocarditis and/or pericarditis.
 - CDC | Jynneos Coadministration Guidance

Post Exposure Prophylaxis (PEP)

- If received between 0-4 days of exposure JYNNEOS can support preventing Monkeypox.
- If received between 5-14 days of exposure JYNNEOS can support reducing the severity of symptoms if symptoms of Monkeypox were to develop.
- individuals with risk factors that increase their likelihood for exposure in areas where monkeypox is spreading may be considered for vaccination PEP++ Guidance

Storage & Handling

- The vaccine is stored at standard frozen temperature -25°C to -15°C (-13°F to +5°F).
- Store in the original package to protect from light.
- Do not re-freeze a vial once it has been thawed.
- Once thawed in the fridge, the vaccine may be kept at +2°C to +8°C (+36°F to +46°F) for 8 weeks.
 - o Please do not thaw until patient appointment is confirmed to preserve shelf-life.
 - o Punctured vials may be stored in the refrigerator for up to 8 hours.
 - o Room temperature: Between 8°C and 25°C (46°F and 77°F). Unpunctured vials may be held at room temperature for up to 6 cumulative hours.
- Do not use the vaccine after the expiration date shown on the vial label.
- <u>JYNNEOS Smallpox and Monkeypox Vaccine Intradermal Vaccine Preparation and Administration</u> Summary: ALTERNATIVE DOSING REGIMEN (cdc.gov)

Vaccine Preparation & Administration

- Allow the vaccine to thaw and reach room temperature before use.
- Swirl the vial gently before use for at least 30 seconds.
- For adults over 18 years, administer JYNNEOS by intradermal injection (ID), to right or left volar surface of the forearm
 - Each dose (0.1 ml) is withdrawn from 0.5 ml vial for ID administration (total of 5 doses from each vial)
 - Injection site may be covered with loose bandage or Band-Aid
- For adults over 18 years with a contraindication to ID administration or persons under 18 years
 of age, administer JYNNEOS by subcutaneous injection, preferably into the upper arm (triceps).
 - A course consists of 2 doses, 4 weeks apart.
 - o Each dose (0.5 mL) is supplied in a single-dose vial for subcutaneous injection

JYNNEOS Vaccine administration Error and Deviations CDC

Vaccine Administration Errors and Deviations | Monkeypox | Poxvirus | CDC

Administration Reporting

- Screening Checklist for JYNNEOS Monkeypox Vaccine:
 - o English: https://eziz.org/assets/docs/MPX-registration-consent-form.pdf

- o Spanish: https://eziz.org/assets/docs/MPX-registration-consent-form-SP.pdf
- JYNNEOS is available in CAIR and should be **input into CAIR following vaccination to keep the patient's vaccine record updated.**
 - o https://cair.cdph.ca.gov
- Patients should receive a copy of proof of vaccination received
 - https://eziz.org/assets/docs/IMM-75LK.pdf

Guidelines for reporting vaccine adverse events

- JYNNEOS Vaccine | Monkeypox | Poxvirus | CDC
- Adverse events can be reported to VAERS
 - O VAERS: https://vaers.hhs.gov/ Phone: 1-800-822-7967
 - VAERS & VERP Flyer (CDPH): https://eziz.org/assets/docs/IMM-1153.pdf
- Administration errors can be reported to VERP
 - VERP: https://www.ismp.org/form/verp-form

Monkeypox Resources

- Santa Cruz County Monkeypox Information: www.santacruzhealth.org/monkeypox
- Monkeypox vaccination resource page (CDPH): https://eziz.org/resources/monkeypox/
- Monkeypox (CDC): https://www.cdc.gov/poxvirus/monkeypox/index.html
- Social Gatherings, Safer Sex and Monkeypox:
 https://www.cdc.gov/poxvirus/monkeypox/pdf/Social Gatherings Safer Sex2-508.pdf