

California Primary Care Association MPX Webinar

California Department of Public Health
MPX Response Branch

Tuesday, August 23, 2022
4:00PM – 5:00PM



Introductions

Leslie Amani, CDPH



Agenda: Tuesday, August 23, 2022

No.	Item	Speaker	Time (PM)
1	Introductions and Resources	Leslie Amani (CDPH)	4:05 – 4:10
2	MPX Current Status	Akanksha Vaidya, M.D. (CDPH)	4:10 – 4:15
3	MPX Clinical	Akanksha Vaidya, M.D. (CDPH)	4:15 – 4:22
4	MPX Testing	Akanksha Vaidya, M.D. (CDPH)	4:22 – 4:30
5	MPX Treatment	Akanksha Vaidya, M.D. (CDPH)	4:30 – 4:37
6	MPX Vaccines	Tarek Salih, M.D. (CDPH)	4:37 – 4:45
7	Storage and Handling	Alan Hendrickson (CDPH)	4:45 – 4:50
Q&A and CPCA Wrap-up			4:50 – 5:00

Resources

Leslie Amani, CDPH



Resources for MPX Vaccine Providers

Health Care Provider Page [Information for Health Care Providers](#)

Communications Toolkit [Monkeypox \(ca.gov\)](#)

Public Materials [Protecting Yourself and Your Community \(ca.gov\)](#)

Isolation Guidance [MPX Home Isolation Guidance for the General Public \(ca.gov\)](#)

Find support for your community with the latest Monkeypox mitigation tools. Please connect with your [Medical and Health Operational Area Coordinator \(MHOAC\)](#) for contract tracing resources and assistance.


CDPH Monkeypox Page: Vaccine Resources

- [Vaccine Q&A](#)
- [Vaccines Page:](#)
 - Resource Links
 - [Allocation Process](#)
- Local Health Departments Page:
 - [*PEP++ Guidance](#)



DIVISION OF COMMUNICABLE DISEASE CONTROL

MONKEYPOX



Home

Q&As

Data

Vaccines

Guidance

Resources

Health Care Providers

Local Health Departments

Information for Health Care Providers

Health care providers are recommended to follow CDC and CDPH's health advisories, including:

- CDC July 30 Health Advisory
- CDC July 28 Health Advisory
- CDC June 14 Health Advisory
- CDPH May 27 Health Advisory
- CDPH May 20 Health Advisory

Check with your local health department (LHD) for more information on case reporting and treatment options available.

Case Definition, Diagnosis and Reporting:

Help identify, test, and diagnose Monkeypox cases with the following resources.

- What Healthcare Professionals Should Know - CDC resource on clinical features of monkeypox, infection control guidelines in healthcare settings, and state health department contacts for reporting.
- Monkeypox Case Definitions - CDC definitions on cases, epidemiologic criteria, and exclusion criteria.
- Clinical Recognition - CDC guidance on key Monkeypox characteristics, clinical prodrome, and rash development.
- CDC Clinical Guidance - CDC guidance for healthcare providers for managing patients with Monkeypox.
- Clinician FAQs - CDC questions and answers about Monkeypox for Healthcare providers.
- Isolation and Infection Control: Home - CDC guidance on the isolation of Monkeypox patients at home.
- Clinical Assist Tool for Monkeypox Evaluation - CDPH guidance tool to aid clinicians in determining monkeypox diagnosis

Infection Control:

Communication Toolkits

CDPH Communication Toolkit Includes:

- What is Monkeypox?
 - English and Spanish
- Fact Sheets
 - Arabic
 - Armenian
 - Cambodian
 - Farsi
 - Spanish
 - Chinese, simplified
 - Chinese, traditional
 - Tagalog
 - Vietnamese



EZIZ MPX Vaccine Resources

Includes:

- Intradermal
- Clinical guidance
- Vaccine information
- Storage and handling
- Standing orders
- Coding information
- Screening Checklist



The screenshot shows the EZIZ website interface. At the top, there's a logo with a family and the text 'EZIZ'. To the right is a search bar with 'ENHANCED BY Google' and a magnifying glass icon. Below the logo is a navigation menu with links: Home, Vaccine Programs, Vaccine Management, Storage Units, Temperature Monitoring, EZIZ Training, and Job Aids & Resources. The main content area is titled 'Monkeypox Vaccination Resources'. It includes a 'Jump to Topic:' section with links to Clinical Guidance and Recommendations, JYNNEOS (Smallpox/Monkeypox) Vaccine Information, Intradermal Vaccination Resources, Other Vaccine Administration Resources, Vaccine Management and Reporting, Vaccine and Adverse Reactions Information, Monkeypox Disease Information and Educational Resources, and Other Resources. Below this is a 'Clinical Guidance and Recommendations' section with links to CDC Monkeypox and Smallpox Vaccine Guidance, Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines during the 2022 U.S. Monkeypox Outbreak (CDC), CDPH Monkeypox Vaccine Page, CDPH Monkeypox Vaccine Prioritization Guidance, CDPH Considerations for Expanded Monkeypox Post-Exposure Prophylaxis (PEP++), MMWR: Use of JYNNEOS for Pre-exposure Vaccination of Persons at Risk for Occupational Exposure to Orthopoxviruses: Recommendations of the Advisory Committee on Immunization Practices, U.S., 2022, and MMWR: Interim Guidance for Prevention and Treatment of Monkeypox in Persons with HIV Infection — United States, August 2022. There's also a 'JYNNEOS (Smallpox/Monkeypox) Vaccine Information' section with text about FDA approval and use, followed by a list of links for vaccine fact sheets, screening checklists, registration forms, and vaccine information statements in English and Spanish. On the left side of the main content area, there's a 'Contact VFC' section with phone numbers, business hours, and links to find a VFC field representative, find other VFC provider offices, and send comments. Below that is a 'Sign up to receive EZIZ news and VFC letters via email' section with an envelope icon. At the bottom left is a 'Frequently Asked Questions' section with an illustration of a healthcare worker and a child.

EZIZ

ENHANCED BY Google

A one-stop shop for immunization training and resources.

Monkeypox Vaccination Resources

Jump to Topic:

- Clinical Guidance and Recommendations
- JYNNEOS (Smallpox/Monkeypox) Vaccine Information
- Intradermal Vaccination Resources
- Other Vaccine Administration Resources
- Vaccine Management and Reporting
- Vaccine and Adverse Reactions Information
- Monkeypox Disease Information and Educational Resources
- Other Resources

Clinical Guidance and Recommendations

- CDC Monkeypox and Smallpox Vaccine Guidance
- Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines during the 2022 U.S. Monkeypox Outbreak (CDC)
- CDPH Monkeypox Vaccine Page
- CDPH Monkeypox Vaccine Prioritization Guidance
- CDPH Considerations for Expanded Monkeypox Post-Exposure Prophylaxis (PEP++)
- MMWR: Use of JYNNEOS for Pre-exposure Vaccination of Persons at Risk for Occupational Exposure to Orthopoxviruses: Recommendations of the Advisory Committee on Immunization Practices, U.S., 2022
- MMWR: Interim Guidance for Prevention and Treatment of Monkeypox in Persons with HIV Infection — United States, August 2022

JYNNEOS (Smallpox/Monkeypox) Vaccine Information

JYNNEOS is FDA-approved for use in adults 18 years and older as a two-dose series, administered subcutaneously. On 8/9/22, FDA granted Emergency Use Authorization as a two-dose series for the following uses:

- Use in children under 18 years of age, administered subcutaneously
- Use in adults 18 years and older, administered **intradermally**.

- JYNNEOS Vaccine Fact Sheet | Provider Letter
- Screening Checklist for JYNNEOS Monkeypox Vaccination | Spanish
- Monkeypox Vaccination Registration & Consent Form (adults/minors) | Spanish
- JYNNEOS Vaccine Information Statement (VIS) | Spanish (distribute to recipient prior to vaccination)
- JYNNEOS Package Insert (6/2021)
- JYNNEOS EUA Fact Sheet for Providers (8/2022)
- JYNNEOS EUA Fact Sheet for Recipients and Caregivers (8/2022)

Contact VFC

Phone: 1-877-243-8832
Business hours:
Monday - Thursday: 9 am - 4:30 pm
Friday: 9 am - 4 pm
Fax: 1-877-329-9832

- ▶ Find a VFC field representative in your area
- ▶ Find other VFC provider offices in your area
- ▶ Send us your comments at MyVFCVaccines@cdph.ca.gov

Sign up to receive EZIZ news and VFC letters via email

Frequently Asked Questions

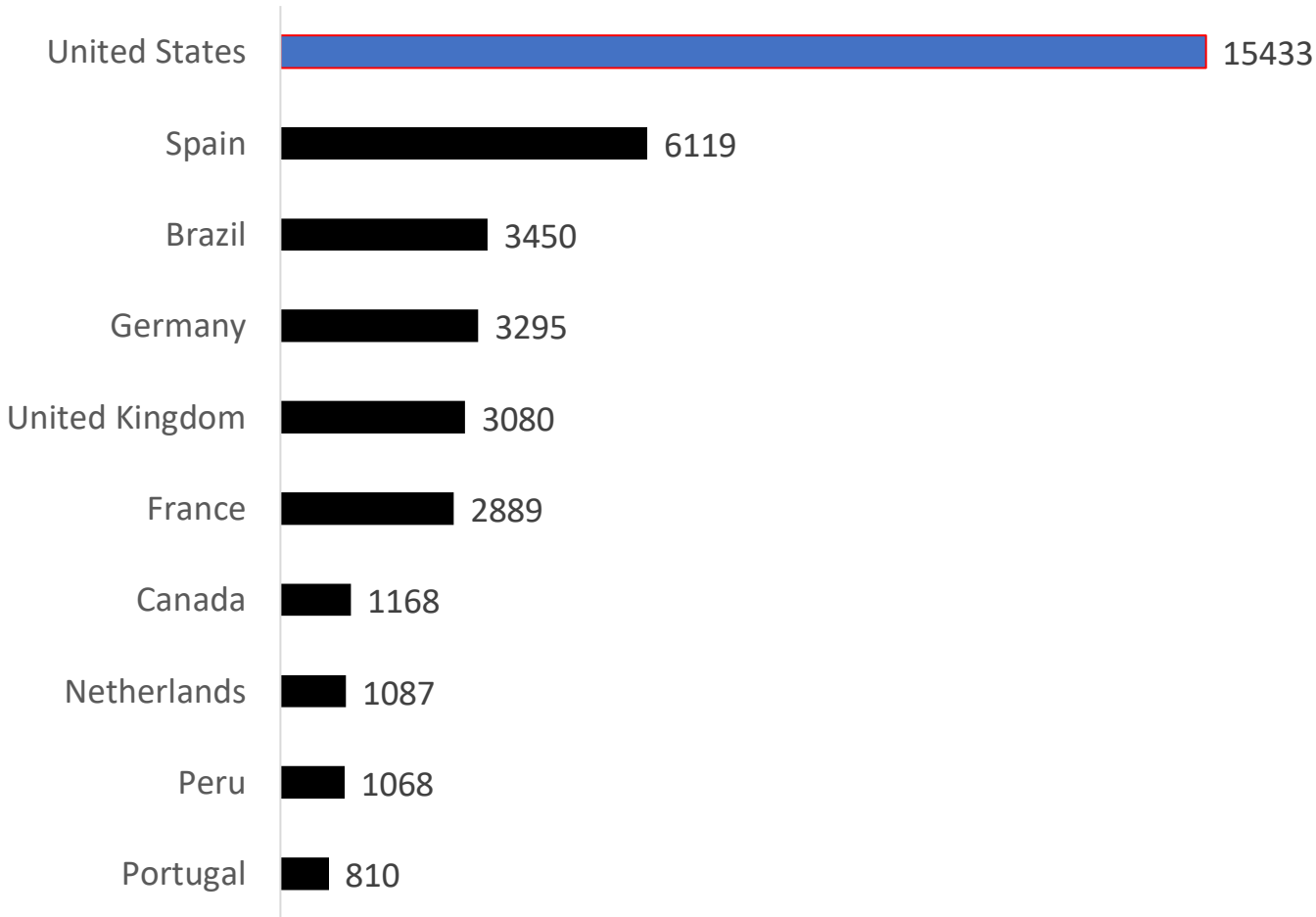
MPX: Current Status

Akanksha Vaidya, M.D., CDPH



Estimated Global MPX Cases as of August 23, 2022

Confirmed Cases as of 8/22/22



Confirmed cases among countries with highest number of cases reported

Globally:

42,954 confirmed cases as of 8/22/22

- From **94** countries*
- **12** deaths**

USA: 14,433 confirmed cases as of 8/22/22

- **52** states, territories & districts*
- No deaths reported

California MPX Cases as of August 23, 2022

3065 confirmed/probable cases

+405 (+13.2%) increase since last report (8/18)

36 local health jurisdictions

+ 0 since last report (8/18)

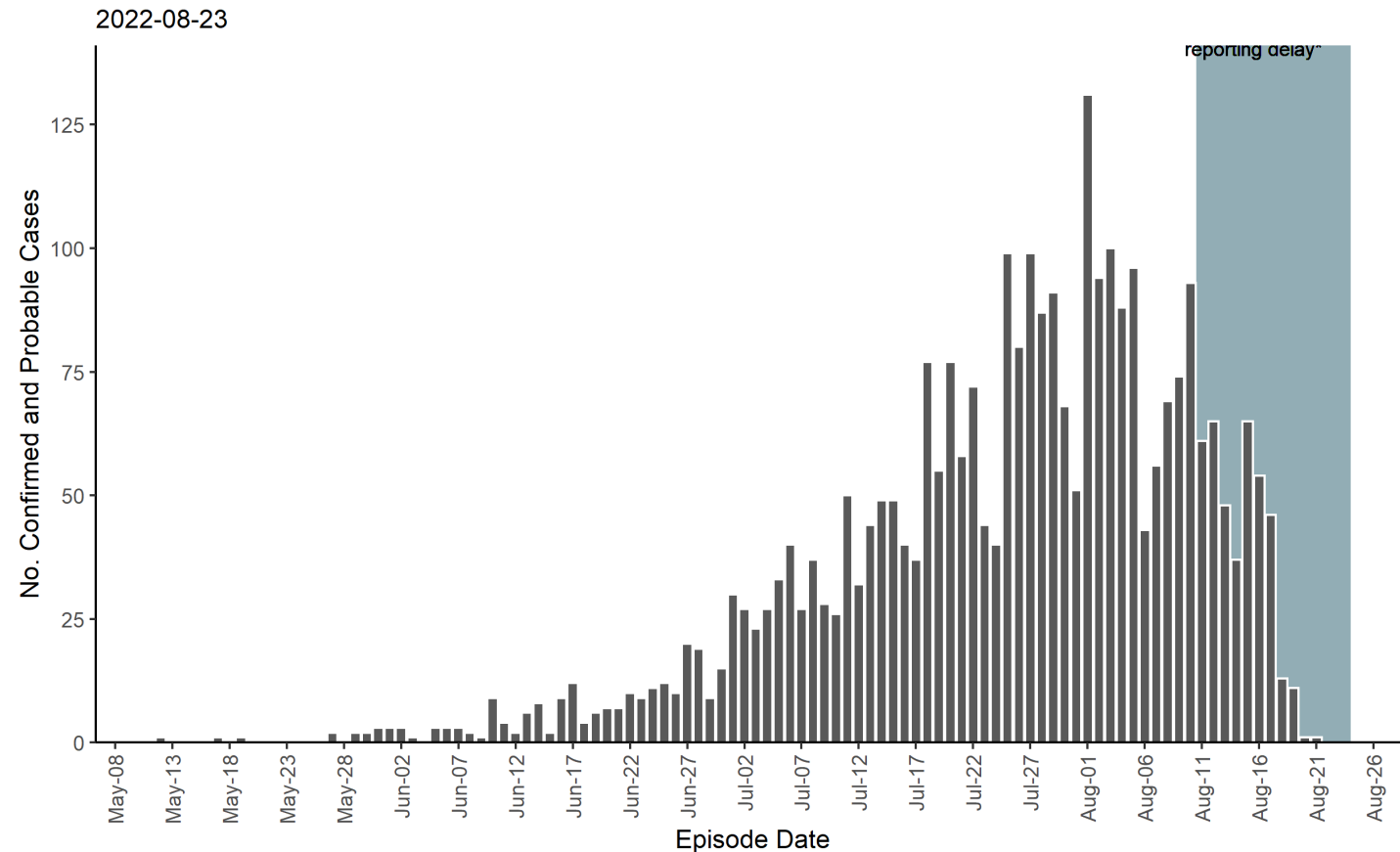
81 hospitalizations

+ 20 since last report (08/18)

No deaths

Hospitalized	n	Percent*
Yes	81	3.6
No	2178	96.4
Missing/Unknown	806	-

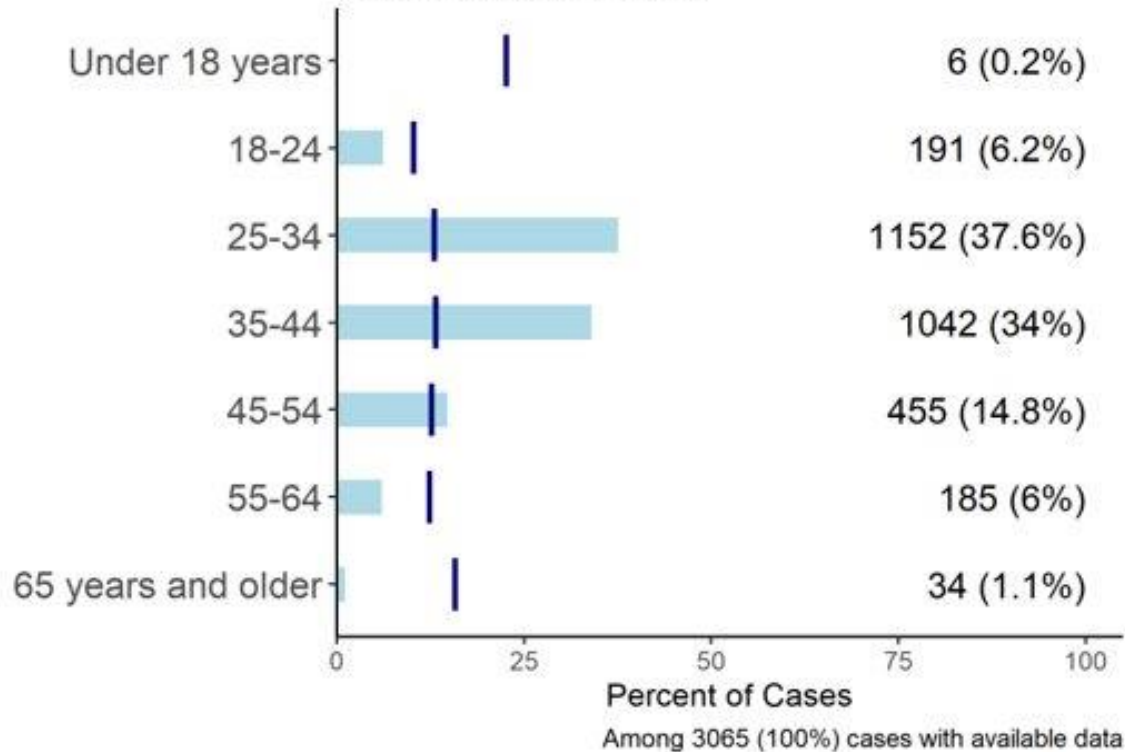
*among cases with reported hospitalization status



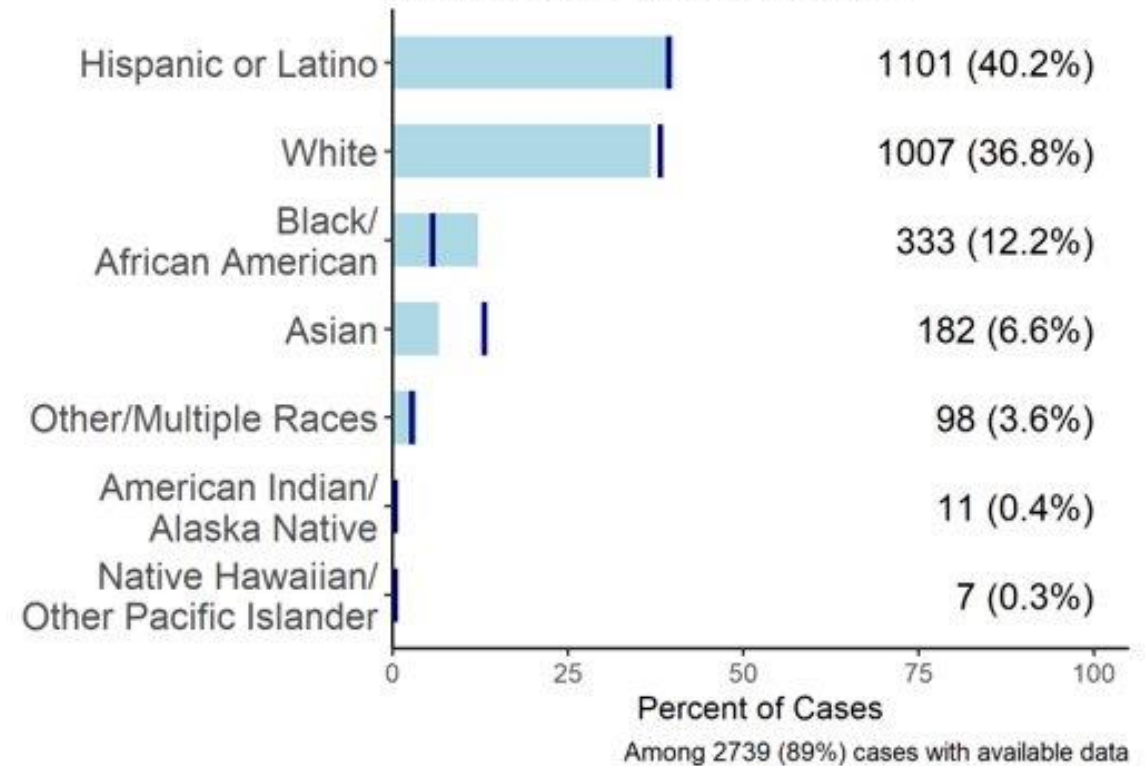
Note: numeric(0) pending episode dates not shown on plot.
*illnesses that began during this time may not yet be reported.

California MPX Cases as of August 23, 2022

Age Distribution Of Cases



Race/Ethnicity Distribution Of Cases



77% of cases under 45 years old
 Median age = 36 years (range: 1-77)
 6 cases <18 years old

= of CA population

MPX Cases by Gender and Sexual Orientation as of August 23, 2022

Gender		
Male	n	%
Male	2958	97.4
Transgender Male	9	0.3
Female	n	%
Female	43	1.4
Transgender Female	14	0.5
Genderqueer/Non-Binary	10	0.3
Unknown	31	-

Sexual Orientation		
	n	%
Gay, lesbian or same-gender loving	1937	63.8
Bisexual	215	7.1
Heterosexual or straight	116	3.8
Different Term	19	0.6
Unknown	778	-

*Percentages calculated out of all cases with available data

**As sex assigned at birth was often not reported, counts of cases in cisgender categories could not be reliably distinguished among the "Male" and "Female" categories of data.



Gender and Sexual Orientation		
Male	n	%
Male	2958	97.5
Gay or same-gender loving	1906	85.6
Bisexual	210	9.4
Heterosexual or straight	95	4.3
Diverse Term	16	0.7
Unknown	731	-
Transgender Male	9	0.3
Gay or same-gender loving	2	40.0
Bisexual	3	60.0
Heterosexual or straight	0	-
Diverse Term	0	-
Unknown	4	-
Female		
Female	43	1.4
Gay, lesbian or same-gender loving	3	12.5
Bisexual	2	8.3
Heterosexual or straight	19	79.2
Diverse Term	0	-
Unknown	19	-
Transgender Female	14	0.5
Gay, lesbian or same-gender loving	4	50.0
Bisexual	0	0.0
Heterosexual or straight	2	25.0
Diverse Term	2	25.0
Unknown	6	-

Gender and Sexual Orientation cont.	n	%
Genderqueer/Non-Binary	10	0.3
Gay, lesbian or same-gender loving	7	100.0
Bisexual	0	-
Heterosexual or straight	0	-
Diverse Term	0	-
Unknown	3	-
Unknown	31	
Total	3065	

MPX Clinical

Akanksha Vaidya, M.D., CDPH



MPX Background and History

- Famous relative: Smallpox (variola virus)
 - Smallpox illness is severe
 - First vaccine
 - First disease eradicated
- Monkeypox thought of as a less deadly smallpox
- Prior U.S. MPX outbreak associated with pet prairie dog exposure / no human-to-human transmission



How is MPX Transmitted?

Monkeypox can spread to anyone through close, personal, often skin-to-skin, contact.

- **Direct contact** with rash, scab, or body fluids from a person with MPX (**most common**)
 - Sexual Transmission: Not traditional STI but sex involves close/intimate contact
 - ***Overall, not easily transmitted.*** Generally, close physical contact exposure is described
- Indirect contact. i.e., touching objects such as clothing, bedding, or towels used by a person with MPX
 - Less common, sensitive to UV light and disinfectants
- Contact with respiratory secretions
 - Prolonged, face-to-face contact (less common)

Signs and Symptoms: Classic Symptoms

Incubation period: Average 7-14 days (can range from 5-21 days)

Prodromal symptoms (flu-like symptoms) followed 1- 3 days later by characteristic rash

Rash progression, **shortly after** prodrome:

- Macules → Papules → Vesicles → Pustules → Scabs

Rash presentation:

- Tongue/Mouth → Face → Arms/Legs → Hands/Feet (including palms/soles)

Signs and Symptoms: Classic Symptoms

RASH DESCRIPTION: Well circumscribed, umbilicated lesions

Macule →



Papule →



Vesicle →



Pustule →



Scab



Current Cases

- **Prodrome:** Mild or not occurring. Systemic symptoms may start at the same time as a rash.
- **Rash location:** Often occurring in the genital and perianal areas and not spreading
- **Rash stages:** Lesions at different stages may be present at the same time.
- **Rash characteristics:** Often painful, pruritic
- **Other symptoms:** Proctitis (anal pain/pruritis). Co-infection with sexually transmitted infections (STIs).

MPX Case Series from 16 Countries

- **Median incubation period:** 7 days (in 23 people with clear exposure)
- MPX DNA was detected in 29 of the 32 persons in whom seminal fluid was analyzed
- Among HIV negative, 57% using HIV PrEP
- **Tecovirimat** provided to 5%
- 13% Hospitalized; no deaths
- **Serious complications:**
 - Pharyngitis limiting oral intake(5) and
 - Myocarditis (2)

B Oral and Perioral Lesions



CDC MMWR* May - July 2022

- 1,195 cases described
- Among 358 men with sexual history information:
 - 94% reported sex or intimate contact with a man
- **Symptoms:**
 - Rash: 100% (46% genital then face/arms/trunk)
 - Top 5 most common other symptoms: fever, chills, lymphadenopathy, malaise, myalgia
- Among 334 persons with data on HIV status, 41% had HIV
- **Severe Disease:** 8% hospitalized, no deaths

Diagnosis: When to Suspect Monkeypox

CDC Suspect Cases:

New Characteristic Rash

Note atypical presentation of rash, can appear similar to other STIs or VZV*

OR

Has prodrome symptoms + at least 1 Epi Criteria (within 21 days) and high clinical suspicion:

- Close contact with people with similar rash or confirmed monkeypox
- Close contact with individuals in a social network with monkeypox activity
- Travel to a country with confirmed monkeypox cases
- Contact with a dead or live wild animal or exotic pet

Diagnosis: History and Exam

History of Present Illness:

Sequence of clinical manifestations

Social History:

- Travel history
- Sexual history
 - Close/intimate contact with men in at-risk social networks:
 - Connections through online websites or apps
 - Connections at social venues such as bars, parties or bathhouses
- Other Exposures
 - Any contacts with a similar rash

Diagnosis: History and Exam

Physical Exam:

- Thorough skin exam
- Ensure oral mucosa and genital/perianal areas are also examined
- Scattered lesions may be present

Diagnosis: Main Points

- High index of suspicion for Monkeypox in someone with:
 - New rash **or**
 - Symptoms and epidemiologic risk factors
- Monkeypox rash and symptoms may mimic other STIs
- Co-infections with STIs and monkeypox have been seen.
 - Testing for both monkeypox and other STIs if rash is not classic for MPX

MPX Testing

Akanksha Vaidya, M.D., CDPH



MPX Testing Widely Available

Requires PCR Test of Swab from Rash

- Commercial lab testing has greatly expanded access to testing:
 - LabCorp, Aegis, Sonic, Mayo, Quest, Associated Regional and University Pathologists (ARUP)
- Public Health Labs
- Additional testing in CA: Stanford Medicine and Renegade Lab
- Nationwide capacity ~80,000/week

Multiple Commercial Labs Started MPX Testing

The “five” CDC Commercial labs testing

- **LabCorp**, Aegis, Sonic Healthcare(Westpac), Mayo*, using CDC Orthopox assay with CDC confirmation (all vs. 10% samples-TBD)
- **Quest** (7/13) – using in-house test; testing hub in California
 - Real-Time PCR for non-variola orthopoxviruses and monkeypox virus (West African clade)
 - No need for CDC confirmation
- **Turn Around Time: 2-5 days**

* Primarily for Mayo Clinic providers, expectation to expand beyond

When to use Public Health labs vs. Commercial labs

- Use commercial lab capacity whenever possible
- Local public health labs provide testing for
 - Under insured
 - **High priority specimens** (e.g., related to a cluster/outbreak, severe illness/hospitalized, pediatric) to ensure samples available for sequencing
 - LHJs should continue to approve specimens being sent to Local Public Health Labs.

Different Specimens Types among Commercial Labs

- Dry swab vs. viral transport medium vs. both
- Note: Unroofing of lesion not needed
- 1 vs 2* swabs per lesions
 - (*2 specimens so that CDC confirms, need to confirm may go)
- **Check specific website of commercial lab**
- *CPT 87798 (infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism).*

Other Labs with MPX Testing

- Stanford Medicine's Clinical Virology Laboratory offers Orthopox and MPX PCR
 - In addition to lesions, can also test blood and urine
- UC Hospitals developing tests: UC Davis, UC San Diego, UCLA, and UC Irvine

For Monkeypox Testing, Use Lesion Swab Samples to Avoid Results: FDA Safety Communication

- **Date Issued: July 15, 2022**
- The U.S. Food and Drug Administration (FDA) is advising people to use swab samples taken directly from a lesion (rash or growth) when testing for the monkeypox virus. The FDA is not aware of clinical data supporting the use of other sample types, such as blood or saliva, for monkeypox virus testing. Testing samples not taken from a lesion may lead to false test results.

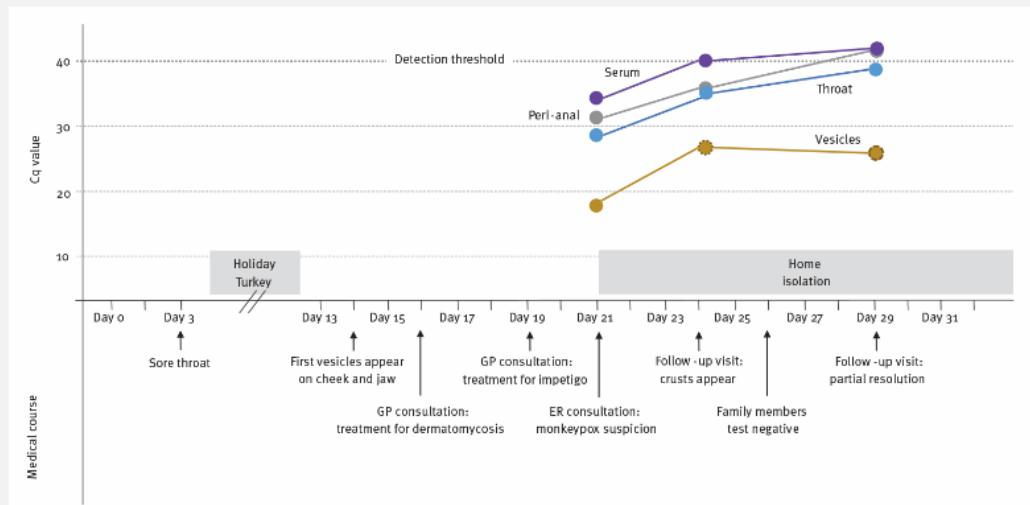


Non-Lesion Testing...For the Future

- **May be helpful**, especially early in course of illness
- But NOT validated yet
- Literature suggests non-lesion material could be helpful (serum, throat, peri-anal)
- Studies underway

Case report child in Netherlands

Figure 2. Timeline of key medical observations related to PCR quantification cycle values, paediatric monkeypox patient, the Netherlands, June 2022



[Click to view](#)

Cq: quantification cycle; ER: emergency room; GP: general practitioner.

The Cq value of the throat swab increased over time, indicating a potentially reduced risk of respiratory transmission. The clinical course of our patient showed fast resolution of the pox into crusting, no systemic signs of infection and no new lesions. Nevertheless, the Cq value of the vesicles remained relatively low (Cq = 27 on Day 29). It is unclear whether this reflects active replication of infectious virus.

MPX Treatment

Akanksha Vaidya, M.D., CDPH



Tecovirimat (TPOXX)

- **Antiviral medication with activity against MPX**
 - Not FDA-approved for MPX; available from CDC through an expanded access protocol
- **Consider TPOXX for:**
 - People with severe disease or at risk of severe disease (e.g., weakened immune systems, children < 8 years, pregnant or breastfeeding women, certain skin conditions)
 - People with complications from disease (e.g., pain, proctitis, oropharyngitis), locations of concern (e.g., eye, genitals)
- **Supportive care** of symptoms should be offered to all MPX patients

Supportive Care

- **Skin lesions, pruritis:** Calamine lotion, oral antihistamines
- **Oral lesions:** Magic mouthwash, benzocaine/lidocaine gels
- **Genital and anorectal lesions:**
 - Sitz baths, rectal lidocaine/hydrocortisone
 - Stool softeners
 - Anticipatory guidance: Seek care if bleeding, difficulty urinating, or retracting foreskin
 - Proctitis pain: May require opioids
- **Nausea/vomiting**
 - Anti-emetics

Tecovirimat (TPOXX)

- Oral (preferred) and IV formulations, weight-based dosing with no age restriction
- **Treatment course:** 14-day course
- Treatment considerations:
 - Oral formulations must be taken with a high fat diet
- **Few side effects:** most common headache and nausea

Tecovirimat (TPOXX): Adverse Effects and DDIs

- **Drug-Drug Interactions (DDIs):**

- Repaglinide: Hypoglycemia
- Midazolam: Decreased Effectiveness
- ARVs: NNRTIs (Ralpivirine, Doravirine) and CCR5 antagonist (maraviroc)
 - Consider dose increases during TPOXX and 2 weeks afterward
 - [Liverpool website](#) for details

- **Adverse Effects/Contraindications:**

- Oral: Headache, nausea, abdominal pain, vomiting. Neutropenia in 1 study participant
- IV:
 - Do not administer if $\text{CrCl} < 30$ (oral ok with $\text{CrCl} < 30$)
 - Caution in mild or moderate renal dysfunction
 - Infusion site pain, swelling, erythema

MONKEYPOX

Tecovirimat-Treated Patients per Patient Intake Forms*

All United States Data

*As of July 22, 2022

Characteristic	N (%)
Underlying medical conditions	n=233
HIV	90 (38.6%)
Maligancy	1 (0.4%)
Solid organ transplantation	2 (0.9%)
Immunosuppressants or immunomodulators	1 (0.4%)
Other immunosuppressed conditions	5 (2.2%)
Pregnancy	0
History of atopic dermatitis or exfoliative skin condition	1 (0.4%)
Exposure to symptom onset and symptom onset to tecovirimat treatment timelines	
Median time from exposure to symptom onset (days)	6 (0-21)
Median time from symptom onset to tecovirimat administration (days)	8 (1-36)

MONKEYPOX

Tecovirimat-Treated Patients per Patient Intake Forms*

All United States Data

*As of July 22, 2022

Route of Tecovirimat administration	N=233
Oral	208 (89.3%)
IV	1 (0.5%)
Unk/Not reported	24 (10.2%)
Number of lesions at start of tecovirimat	N=233
Less than 10	95 (40.8%)
10-100	119 (51.1%)
Great than 100	13 (5.6%)
Unk/Not reported	6 (2.6%)
Signs/symptoms during course of illness	N=233
Fever	80 (34.3%)
Lymphadenopathy	47 (20.2%)
Malaise	14 (6.0%)
Headache	14 (6.0%)
Weakness	0
Proctitis	14 (6.0%)
Genital lesion(s)	13 (5.6%)
Anal lesion(s)	82 (35.2%)
Facial lesion(s)	42 (18.0%)

MPX Treatment : Access



- Clinicians should reach out to their Local Health Departments/ Medical Health Operational Area Coordinator (MHOAC) if the clinic is interested in being a new Tecovirimat provider.
 - LHJ/MHOAC places orders with CDPH.
- CDPH distributes to providers who have federal reporting requirements
- Over 3,200 treatment courses distributed to approximately 100 treatment locations (Aug 19, 2022)

Tecovirimat (TPOXX) Regulatory Information

- CDC holds an [intermediate-size patient population EA-IND](#) for the use of Tecovirimat to treat MPX
 - provides an umbrella regulatory coverage
 - clinicians and facilities do not need to obtain their own INDs
- Simplified IND process posted to CDC website
 - [Obtaining and Using TPOXX \(Tecovirimat\) | MPX | Poxvirus | CDC](#)
- New option for Tecovirimat as PEP on a case-by-case basis
 - Immunocompromised
 - Allergy to Vaccine

Tecovirimat (TPOXX) Regulatory Information

- CDC Institutional Review Board (IRB) determined that IND use for tecovirimat does not constitute research involving human subjects
 - Local IRB approval is not required
 - CDC IRB will provide a pre-signed reliance agreement if needed
- Clinicians are responsible for completing federally required documentation
 - Required forms: FDA 1572 (one per institution), informed consent (maintain in patient chart), Patient Intake Form (Form A)
 - Only informed consent before treatment (all other forms can be submitted to CDC within 7 days; including FDA 1572)

Clinical Information

- [Case Definition](#)

General

- [Signs and Symptoms](#) **UPDATED**
- [CDPH Isolation guidance](#) **UPDATED**
- [Considerations for Reducing MPX Transmission in Congregate Living Settings](#) **UPDATED**
- [MPX Frequently Asked Questions](#)
- [Technical Report: Multi-National MPX Outbreak, United States, 2022](#)

Clinical Resources

For Clinicians

- [Clinical Recognition](#) **UPDATED**
- [Guidance for Tecovirimat Use Under Expanded Access Investigational New Drug Protocol during 2022 U.S. MPX Cases](#) **UPDATED**
- [Information For Healthcare Professionals](#)
- [Clinician FAQs | MPX | Poxvirus | CDC](#)
- [Interim Clinical Guidance for the Treatment of MPX](#)
- [Clinical Considerations for MPX in Children and Adolescents](#)
- [Clinical Considerations for Treatment and Prophylaxis of MPX Virus Infection in People with HIV](#)
- [Clinical Considerations for MPX in People Who are Pregnant or Breastfeeding](#)
- [Obtaining and Using TPOXX \(Tecovirimat\)](#)

MPX Vaccines

Tarek Salih, M.D., CDPH



JYNNEOS Vaccine

- JYNNEOS
 - Given as two dose series 28-days apart
 - Part of Strategic National Stockpile (SNS)
 - Estimates to procure 5.5 million doses by mid-2023
 - Produced by single company (Bavarian Nordic – Denmark)
 - Side effects of injection site reactions (pain/redness/swelling) common
- CDC allocating directly to federal entities, including VA, IHS, Bureau of Prisons, HRSA/selected FQHCs
- Contact your Local Health Jurisdiction (LHJ) if interested in becoming a vaccinator

Vaccine Considerations

- **Post-Exposure Prophylaxis (PEP) for known close contacts of monkeypox cases** who are identified by public health via case investigation, contact tracing, and risk exposure assessments.
- **Post-Exposure Prophylaxis (PEP)++ for individuals with certain risk factors** who are more likely to have been recently exposed to monkeypox even if they have not had documented exposure to someone with confirmed monkeypox.
- **Pre-Exposure Prophylaxis (PrEP) for individuals at occupational risk of monkeypox** according to [Advisory Committee on Immunization Practices \(ACIP\) guidance](#), including laboratory workers who perform monkeypox testing. **At this time, most clinicians in the United States and laboratorians not performing monkeypox testing, are not advised to receive monkeypox PrEP.**

Healthcare Worker (HCW) Vaccination

- Evidence so far is that the risk for transmission to HCWs is low.
- Supplies of vaccine are extremely limited and priority for vaccination is given to persons at risk due to community (non-healthcare) exposures.
- Infection control recommendations (including PPE* recommendations) are available and should be followed.
- CDPH recommends following [ACIP guidance](#) related to PrEP for HCWs. Specifically
 - Research laboratory personnel working with orthopoxviruses;
 - Clinical laboratory personnel performing diagnostic testing for orthopoxviruses; and
 - Orthopoxvirus and health care worker response teams designated by appropriate public health and anti-terror authorities.
- In general, it is not recommended to immunize HCWs.
 - LHJs can work with their local medical providers to offer PrEP to specific “response teams” that frequently care for persons who are at high-risk for monkeypox infection. (For example, clinicians in a sexual health or STI clinic who are responsible for swabbing lesions when suspected cases present for care.) Infection control recommendations should be reviewed and reinforced in this context.
- See CDPH [MPX Vaccine FAQs](#)

JYNNEOS EUA: Intradermal Administration for ≥ 18

- 8/9/22, FDA issued emergency use authorization (EUA) allowing an alternative regimen:
 - **0.1mL given intradermally** (one-fifth of subcutaneous 0.5mL dose)
 - Two-dose schedule four weeks, 28 days, apart.
 - For individuals ≥ 18 years old at high risk of MPX infection.
 - Data reviewed included [clinical study](#) comparing subcutaneous and intradermal (one-fifth dose) administration
 - Similar immune response in both groups.
 - Intradermal administration resulted in ***nearly all*** of recipients with redness, firmness, itchiness or swelling at the injection site, but these side effects were manageable.

JYNNEOS Vaccine: EUA for <18 years old

- 8/9/22, FDA EUA also allows for use of the vaccine in individuals younger than 18 years of age determined to be at high risk of MPX infection
 - For <18 years old, JYNNEOS is administered by ***subcutaneous*** injection.
- If a pediatric high-risk contact case is identified for whom [PEP JYNNEOS is being considered](#), please contact local health department.

Alternative and Standard Vaccine Regimens

Table 2. Vaccination Schedule and Dosing Regimens for JYNNEOS Vaccine

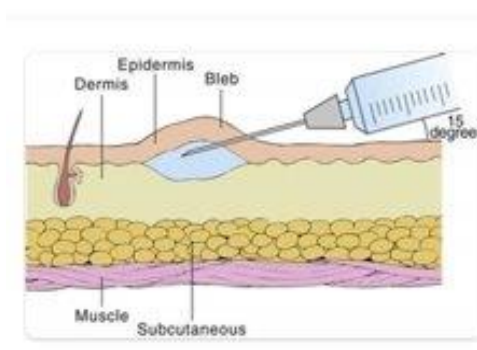
JYNNEOS vaccine regimen	Route of administration	Injection volume	Recommended number of doses	Recommended interval between 1st and 2nd dose
Alternative regimen				
People age ≥ 18 years	ID	0.1 mL	2	28 days
Standard regimen				
<u>People age < 18 years</u>	Subcut	0.5 mL	2	28 days
People of any age who have a history of developing keloid scars	Subcut	0.5 mL	2	28 days

Intradermal Administration

Intradermal (ID)

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 for further details on intradermal vaccine administration.

A person who presents for their second JYNNEOS vaccine dose who is still experiencing erythema or induration at the site of intradermal administration of the first vaccine dose (e.g., the forearm) may have the second dose administered intradermally in the contralateral forearm.



Intradermal Administration

MONKEYPOX

How to administer a JYNNEOS vaccine intradermally

STEP 1

Locate and clean a site for injection in the inner (volar) surface of the forearm.



www.cdc.gov/monkeypox



CS 230451 08/01/2022

MONKEYPOX

How to administer a JYNNEOS vaccine intradermally

STEP 2

While pulling the skin taut, position the needle with the bevel facing up and insert the needle at a 5- to 15-degree angle into the dermis.



www.cdc.gov/monkeypox



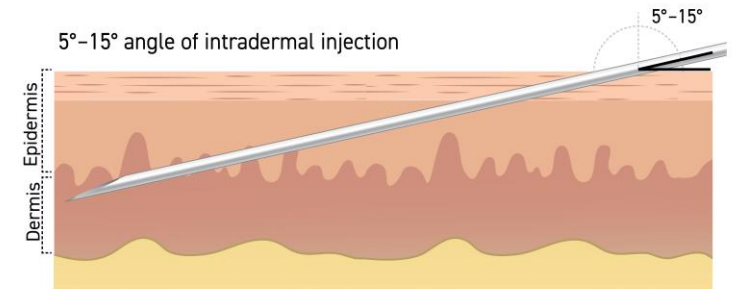
CS 230451 08/01/2022

MONKEYPOX

How to administer a JYNNEOS vaccine intradermally

STEP 2

While pulling the skin taut, position the needle with the bevel facing up and insert the needle at a 5- to 15-degree angle into the dermis.



www.cdc.gov/monkeypox



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Intradermal Administration

MONKEYPOX


How to administer a JYNNEOS vaccine intradermally

STEP 3

Slowly inject 0.1mL intradermally. This should produce a noticeable pale elevation of the skin (wheal).



www.cdc.gov/monkeypox

 CS 333451 08/09/2022

MONKEYPOX

How to administer a JYNNEOS vaccine intradermally

STEP 4

Observe patients for 15 minutes after vaccination or 30 minutes if they have a history of anaphylaxis to gentamicin, ciprofloxacin, chicken or egg protein.



www.cdc.gov/monkeypox

 CS 333451 08/09/2022

JYNNEOS Precautions and Contraindications

- People of ANY age with a history of keloids should be given subcutaneous dosing of JYNNEOS.
- 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.

Coadministration 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.
- 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.

2nd Vaccine Doses

- At this time, given the scarce supply of JYNNEOS vaccine, LHJs and providers should prioritize first doses of vaccine for persons at risk.
- This strategy should be followed even if second doses are consequently administered at an interval greater than 28 days. There is no maximum time window for a valid second dose.
- As more vaccine doses are available in the coming weeks, LHJs and providers can expand offering second doses to those requesting them.
- In the meantime, if/when second doses are provided, when possible, prioritize persons who are immunocompromised or at high risk for complications of monkeypox.
- Individuals who are living with HIV (particularly those with CD4 count $< 200/\text{mm}^3$ or an opportunistic infection) or other conditions that cause immunocompromise should be prioritized for vaccination, including second doses.

MPX Vaccine Equity Considerations

- There is a need to balance equity considerations with volume of vaccinations administered
- Event-based and mass vaccination activities may be less equitable, but also may reach those at immediate risk of exposure
- Primary care providers are well-placed to offer other recommended vaccinations to this population such as meningococcal, COVID-19 Vaccines, and influenza vaccines.
- Strategies that may support vaccine equity
 - Appointment-based vaccination activities; reserved appointments for priority groups
 - Proactive offer of vaccine to persons at high risk of exposure (e.g., sex workers)
 - Partnerships as described on previous slide

Resources

MPX Documentation and Billing

- Providers may bill for MPX vaccine administration
- MPX-specific CPT codes are posted by the AMA: [Orthopoxvirus and monkeypox coding & Guidance](#)
- Providers may **not** charge for the MPX vaccine, as it is provided free of charge by the federal government
- Vaccine doses administered **MUST** be reported to the immunization registry as soon as possible, ideally on the day of administration.
- Please work with your vaccination partners to ensure they are documenting in a timely fashion!
- We are using the registry to track administration progress by county.
- My Turn is now available.
 - You may continue to record monkeypox vaccine doses into the CAIR Mass Vax module.

★ What's Next in My Turn? - Release 29.1

New updates for My Turn Public and Clinic launched on August 15th.



Release Highlights



My Turn Public

- ✓ Eligible patients who are 18 years and older can schedule Monkeypox vaccine appointments for both doses with a gap of 4 weeks between each dose.
- ✓ Patients can view and use the new Eligibility Interactive Chart (both Desktop and Mobile versions available) in English and 13 other languages to identify their eligibility for the available COVID vaccines.

Release Highlights



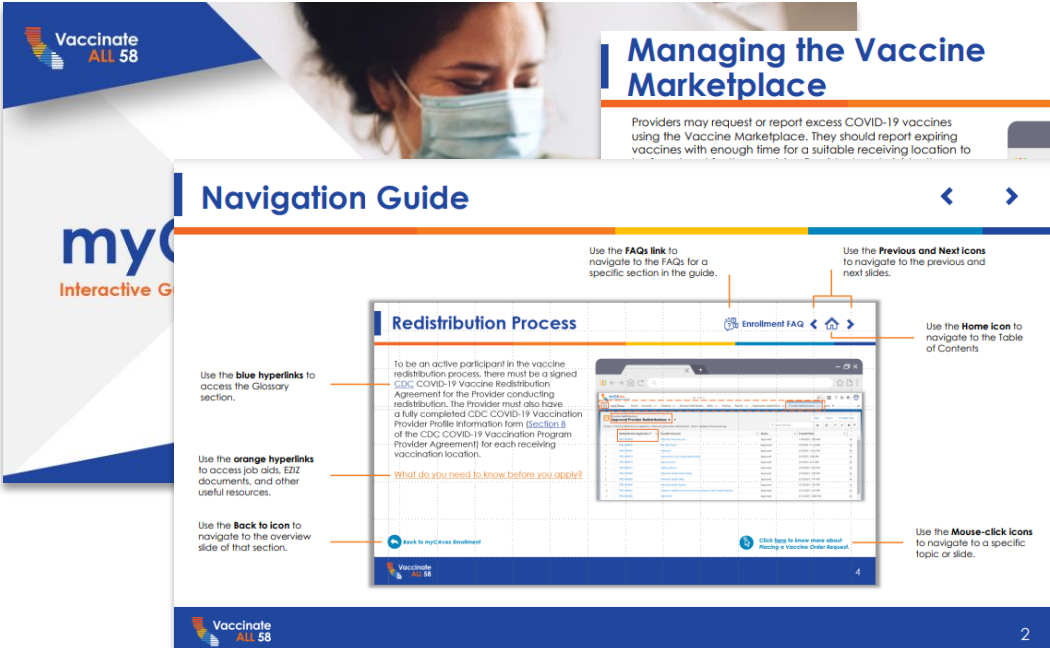
My Turn Clinic

- ✓ Vaccine Administrators can identify an existing patient's records when creating a walk-in appointment which can reduce the chances of duplicate records.
- ✓ Walk-in appointment flow for COVID-19, Flu, and Monkeypox display new values for the Gender field
- ✓ Clinic Managers can create Monkeypox JYNNEOS (18+) vaccine supply, vaccine inventory, edit patient's IIS Monkeypox appointment records, filter, single edit, and cancel Monkeypox JYNNEOS (18+) Appointments

★ View the Updated myCAvax Interactive Guide in the Knowledge Center

The latest version of the [myCAvax Interactive Guide](#) has been published to the Knowledge Center. The document now includes a quick navigation guide, an introduction to the Provider Operations Manual, and information on the Vaccine Marketplace and courier services. Explore the guide to learn more!





Navigation Guide

Use the **FAQs link** to navigate to the FAQs for a specific section in the guide.

Use the **Previous and Next icons** to navigate to the previous and next slides.

Use the **Home icon** to navigate to the Table of Contents.

Use the **blue hyperlinks** to access the Glossary section.

Use the **orange hyperlinks** to access job aids, EZIZ documents, and other useful resources.

Use the **Back to icon** to navigate to the overview side of that section.

Use the **Mouse-click icons** to navigate to a specific topic or slide.


Redistribution Process

To be an active participant in the vaccine redistribution process, there must be a signed CDC COVID-19 Vaccine Redistribution Agreement for the Provider conducting redistribution. The Provider must also have a fully completed CDC COVID-19 Vaccination Provider Profile Information form (section 3 of the CDC COVID-19 Vaccination Program Provider Agreement) for each receiving vaccination location.

What do you need to know before you apply?

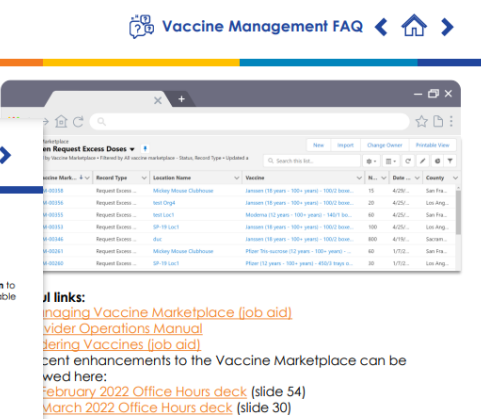
[Back to myCAvax Dashboard](#)

[Click here to know more about Placing a Vaccine Order Request.](#)



Managing the Vaccine Marketplace

Providers may request or report excess COVID-19 vaccines using the Vaccine Marketplace. They should report expiring vaccines with enough time for a suitable receiving location to



Vaccine Management FAQ

Request Excess Doses

Request ID	Request Type	Location Name	Vaccine	Quantity	Expiry Date	County
0-00001	Request Excess	Midway Medical Clinic	Janssen 120 years - 100+ years - 10002 dose	10	4/20/22	San Fra.
0-00002	Request Excess	Midway Medical Clinic	Janssen 120 years - 100+ years - 10002 dose	20	4/20/22	Los Ang.
0-00003	Request Excess	Midway Medical Clinic	Moderna 120 years - 100+ years - 14001 dose	80	4/20/22	San Fra.
0-00004	Request Excess	Midway Medical Clinic	Moderna 120 years - 100+ years - 14001 dose	80	4/20/22	Los Ang.
0-00005	Request Excess	Midway Medical Clinic	Moderna 120 years - 100+ years - 14001 dose	80	4/20/22	San Fra.
0-00006	Request Excess	Midway Medical Clinic	Moderna 120 years - 100+ years - 14001 dose	80	4/20/22	Los Ang.
0-00007	Request Excess	Midway Medical Clinic	Moderna 120 years - 100+ years - 14001 dose	80	4/20/22	San Fra.
0-00008	Request Excess	Midway Medical Clinic	Moderna 120 years - 100+ years - 14001 dose	80	4/20/22	Los Ang.
0-00009	Request Excess	Midway Medical Clinic	Moderna 120 years - 100+ years - 14001 dose	80	4/20/22	San Fra.
0-00010	Request Excess	Midway Medical Clinic	Moderna 120 years - 100+ years - 14001 dose	80	4/20/22	Los Ang.

Useful links:

- [Managing Vaccine Marketplace \(job aid\)](#)
- [Provider Operations Manual](#)
- [Ordering Vaccines \(job aid\)](#)

Recent enhancements to the Vaccine Marketplace can be viewed here:

- [February 2022 Office Hours deck \(slide 54\)](#)
- [March 2022 Office Hours deck \(slide 30\)](#)

CDC Monkeypox Resources

- [CDC Vaccines](#)
- [JYNNEOS CDC Guidance Page](#)
- [CDC COCA Call 08/11/22](#)
- [JYNNEOS storage and handling](#)
- JYNNEOS Standing Orders: [Alternative \(ID\)](#) and [Standard \(SC\)](#)
- [CDC Clinician FAQs](#)
- [Intradermal Injection Video](#)
- [JYNNEOS Updated Package Insert \(FDA\)](#)



MPX Storage and Handling

Alan Hendrickson, CDPH



JYNNEOS Storage and Handling (1)

- CDPH & Los Angeles receive JYNNEOS from the SNS
- CDPH receives and ships JYNNEOS as frozen product. (Please return the Credo Cube and DDL as soon as possible.)
- HHS procurement of JYNNEOS:
 - To date, ~ 500,000 vials have been procured
 - 1 July, HHS placed an order for 2.5 million doses
 - 15 July HHS placed an additional order for 2.5 million doses
 - Deliveries expected through mid to late 2023

JYNNEOS Storage and Handling (2)

- Bavarian Nordic, Denmark
- 0.5 mL multi-dose (5 dose) vial (20 vials/carton)
- Store in original package to protect from light



- Keep frozen at $-20^{\circ}\text{C} \pm 5^{\circ}\text{C}$
- Do not **re-freeze** a vial once it has been thawed
- Shelf Life/Beyond Use Dates (BUD):
- Expiry at frozen temperatures ($-20^{\circ} \pm 5^{\circ}\text{C}$)
- Eight (8) weeks at refrigerated temperature (2°C to 8°C)
- One (1) hour at normal room temperature (20°C)

JYNNEOS Storage and Handling (3)

- All JYNNEOS vaccines will be shipped in a Pelican Biothermal Credo Cube with a Digital Data Logger (DDL).
- Due to our limited supply of Credo Cubes, it is imperative to return all parts of the Cube, the Data Logger, and Glycol bottle back to the CDPH warehouse ASAP, within 24 hours of receiving the shipping label provided.



JYNNEOS Storage and Handling (4)



See anything like this?
Please report it.

Medical.information_US@bavarian-Nordic.com

US phone number: 1-844-4BAVARIAN (844-422-8274)

US fax number: 1-833-4BAVARIAN & cc mpoxvaccine@cdph.ca.gov

JYNNEOS Storage and Handling (5)

Instruction for flipping off cap

Instruction for flipping off cap for MVA-BN.

1. On the cap there is a mark for where to flip up the yellow plastic cap, see figure 1a and 1b.

Figure 1a

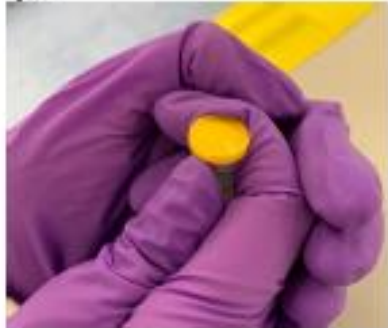


Figure 1b



2. Hold the vial in your hands and use your thumb to flip up the cap where indicated. See figure 2.

Figure 2



Page 1 of 2

3. Carefully open/flip off the yellow cap to a 90° angle. See figure 3a and 3b.

Figure 3a



Figure 3b



4. Let the cap stay on the metal crimp cap or alternatively flip it all the way off and let the metal crimp cap stay on the stopper/vial to ensure stopper is still fixed to the vial. See figure 4.

Figure 4



5. Extract volume for vaccination using a needle and syringe through the indicated circle on the rubber stopper.

[PDF with instructions re uncapping](#) is in LHD SharePoint, LHJ Toolkit→ Pep & PrEP Vaccine Information folder

Tecovirimat (TPOXX) Storage and Handling

Oral TPOXX

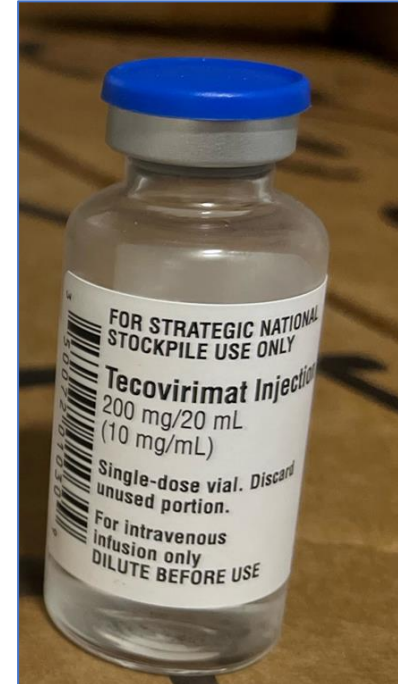
- Provided in 42 capsule bottle
- Store at 20°C to 25°C
- Excursions 15°C to 30°C are permissible
- Expiry not printed on the bottle. Will be provided with shipment or see [Lot Numbers and Expiration Dates for SNS-held Jynneos vaccine](#)



Tecovirimat (TPOXX) Storage and Handling

TPOXX Injection

- Supplied in 30 mL single-dose vial
- Store at 2° C to 8° C
- 24 hours at 20° C to 25° C is permissible
- Expiry not printed on the vial. Will be provided with shipment or see [Lot Numbers and Expiration Dates for SNS-held oral TPOXX \(tecovirimat\)](#)



Needle/Syringe Combinations

- CDC Recommendation: Tuberculin syringe with a 27-gauge needle, 1/4 to 1/2" but expanded to a "26 gauge or 27 gauge, 3/8", 1/4 to 1/2" needle with a short bevel to the syringe"
- The SNS* is not shipping ancillary supplies, but they are available for purchase through normal supply channels
- Low dead-space needle/syringe combination required for 5 doses
- Providers are reporting administering 3 to 5 doses per vial
- Single dose or better = no wastage
- Visit eziz.org/resources/monkeypox/#Q3 for storage and handling and so much more

Additional MPX Resources

- [Information for Health Care Providers](#)
- [MPX: Get the Facts](#)
- [What is MPX?](#)
- [CDC FAQs](#)
- [Tecovirimat Guidance](#)
- [Tecovirimat: New Treatment Provider Process](#)
- [Laboratory Testing Guidance](#)

Questions / Comments

CDPH MPX Team

Thank you!

