Mpox Update for Clinicians

Sonali Kulkarni, MD, MPH
Division of HIV and STD Programs
June 2024

County of Los Angeles Public Health

Overview

- DPH Clinical resources
- Epidemiology
- Clinical presentation
- Testing and reporting
- Treatment
- Infection Control
- Vaccination

LAC DPH Mpox Provider Resources

- Division of HIV and STD Programs Provider Consult Line: 213-368-7441
- Provider Mpox webpage
- http://publichealth.lacounty.gov/acd/mpox/

LAC DPH Mpox Clinical Support

Provider Lines:

Division of HIV and STD Programs Provider Consult Line:

Weekdays, 8:00am-4:30pm: call (213) 368-7441

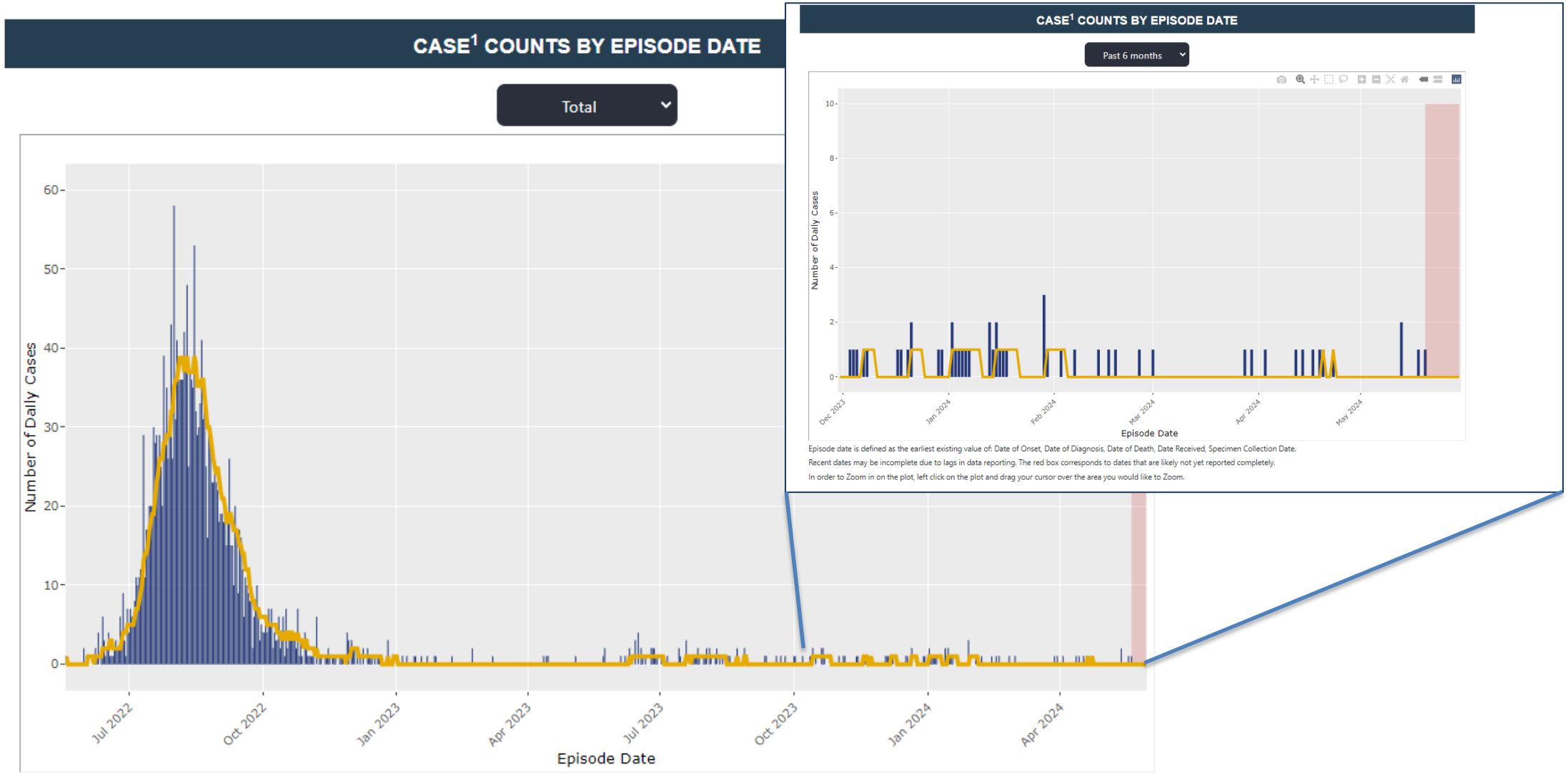
Weekends and holidays, 8:00am-5pm: (213) 974-1234 and ask for the physician on call.

Evening/night –emergent patients only, (213) 974-1234 and ask for the physician on call.

Tpoxx specific questions:

Email: TPOXX@ph.lacounty.gov

Epidemiology



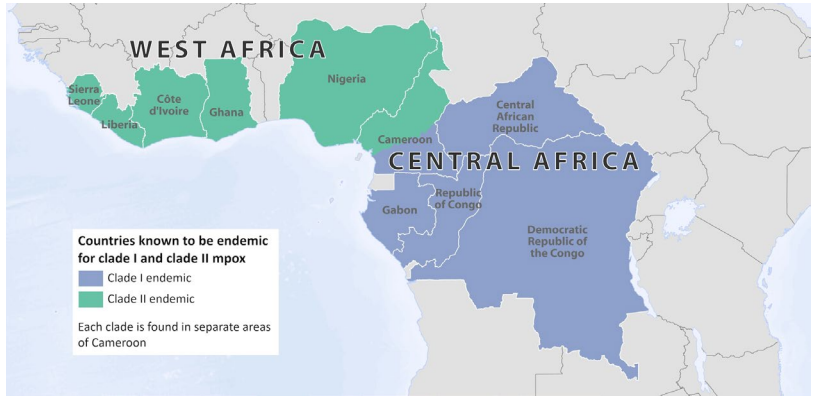
1.LAC DPH Mpox Dashboard is available at http://publichealth.lacounty.gov/media/monkeypox/data/index.htm

Mpox epidemiology

- Global outbreak of mpox since 2022 has been Mpox Clade II
- Regional clusters, waxing and waning across the US and LAC since 2023
- Waning immunity is an unlikely reason
- Increasing 2-dose vaccination coverage and counseling re: other prevention strategies are best ways to prevent cases
- Deaths still being reported nationally, none in LAC since 2022

Clade I Mpox

- Potentially more virulent strain, data suggestive of higher case fatality rate in children
- At this time, no clade I cases identified outside of countries known to be endemic
- Endemic: DRC, Central African Republic, Republic of Congo, Cameroon, Gabon
- Similar to clade II, clade I requires close/sustained contact for transmission (sexual contact is an efficient mode of transmission)
- Jynneos vaccination would be protective
- For pts with suspected mpox and history of travel to DRC, contact LAC DPH so we can facilitate expedited clade specific testing at public health lab



Clinical Presentation

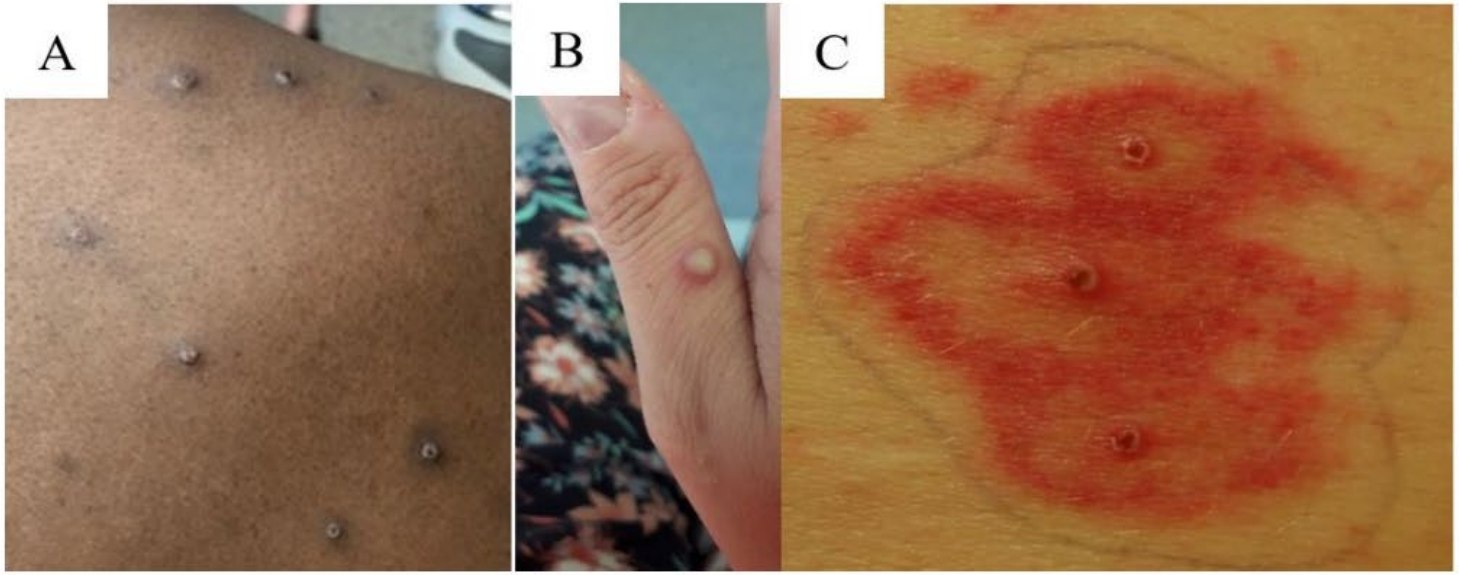
Clinical Symptoms

- Skin rash or exanthem in all patients
- Lesions in different phases of development seen side-by-side
- Rash either scattered or diffuse; sometimes limited to one body site and mucosal area (e.g., anogenital region or lips/face)
- Presenting complaint sometimes anorectal pain or tenesmus; physical examination yields visible lesions and proctitis
- Prodromal symptoms mild or not occurring, or occurring after lesions/rash appears
- Fever, lymphadenopathy not occurring in all patients
- Some co-infections with sexually transmitted infections (STI)

1.Monkeypox: Updates about Clinical Diagnosis and Treatment. June 2022 https://emergency.cdc.gov/coca/calls/2022/callinfo_062922.asp

Lesions observed during May and June 2022*

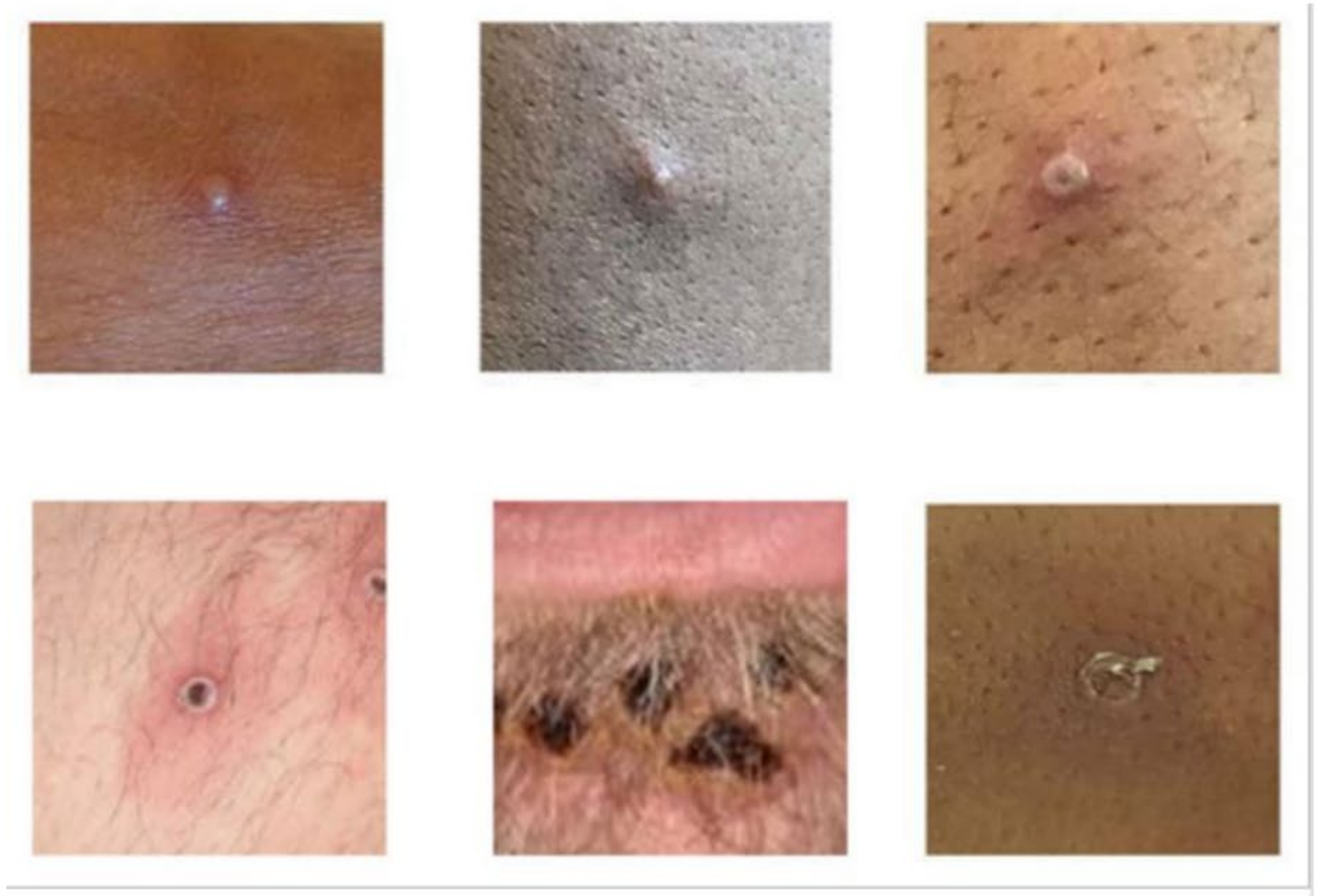
- Firm, deep-seated, well-circumscribed, painful, itchy, sometimes umbilicated
- Small lesions; often not distributed diffusely
- May rapidly progress through stages (papules, vesicles, pustules, and scabs)
- Papulovesicular and pustular lesions may be seen on same body site

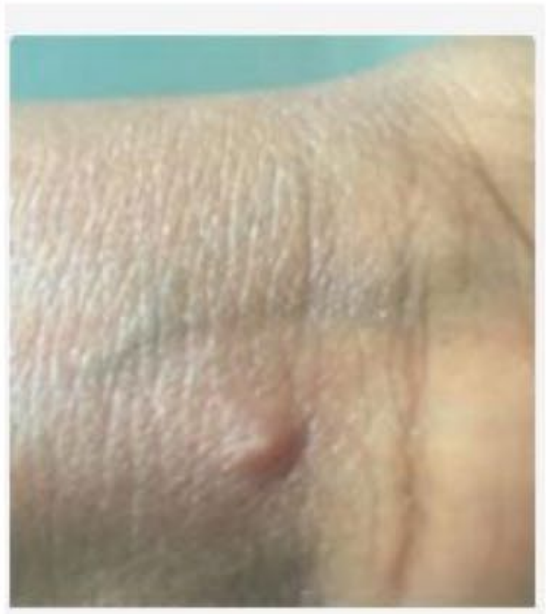


Photos A and B from NHS England High Consequence Infectious Diseases Network; photo C from Reed KD, Melski JW, Graham MB et al. The detection of monkeypox in humans in the Western Hemisphere. Page 346. Copyright © 2004. Massachusetts Medical Society. Reprinted with permission

For additional images:

1) Ogoina D et al. Clinical course and outcome of human monkeypox in Nigeria. Clin Infect Dis. 2020; 71(8): 210-214
2) Antinori A et al. Epidemiological, clinical, and virological characteristics of four cases of monkeypox support transmission through sexual contact, Italy, May 2022. Euro Surveill. 2022 June; 27 (22).





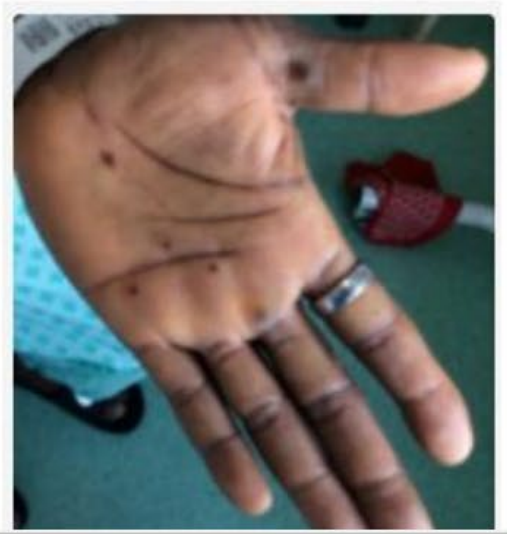
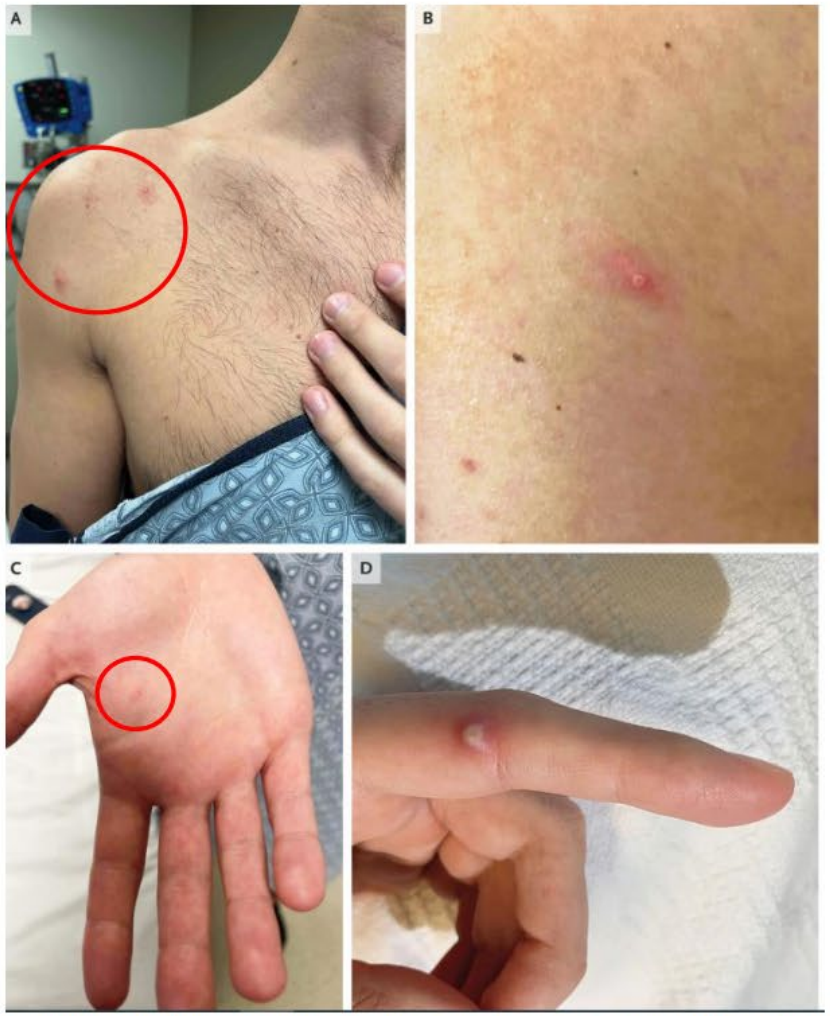


Photo Credit: NHS England High Consequence Infectious Disease Network

Monkeypox lesions, United States 2022

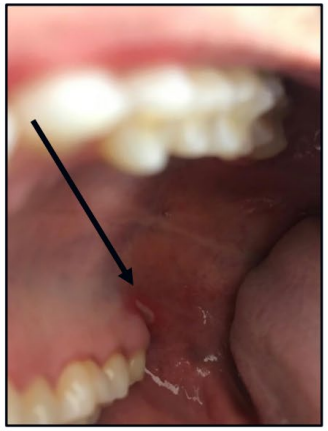


From Basgoz N, Brown CM, Smole SC, et al. Case 24-2022: A 31-Year-Old Man with Perianal and Penile Ulcers, Rectal Pain, and Rash. Epub ahead of print. *Copyright* © Jun 15 2022. Massachusetts Medical Society. Reprinted with permission from Massachusetts Medical Society

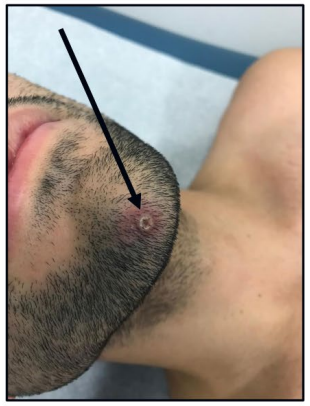
Shared with permission from patients, CDC 2022

Possible presentations

- **Mouth with oral lesion**
  - Small ulcerated area in upper right rear oral cavity; painful when swabbed



- **Chin lesion**
  - One lesion with white rim, dark center, erythematous base

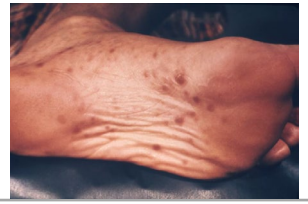
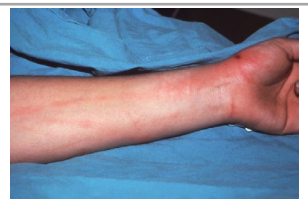
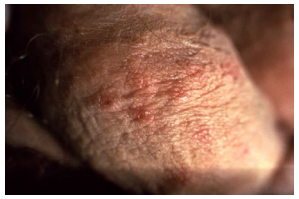
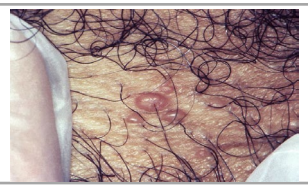
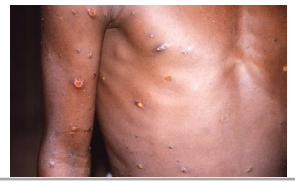


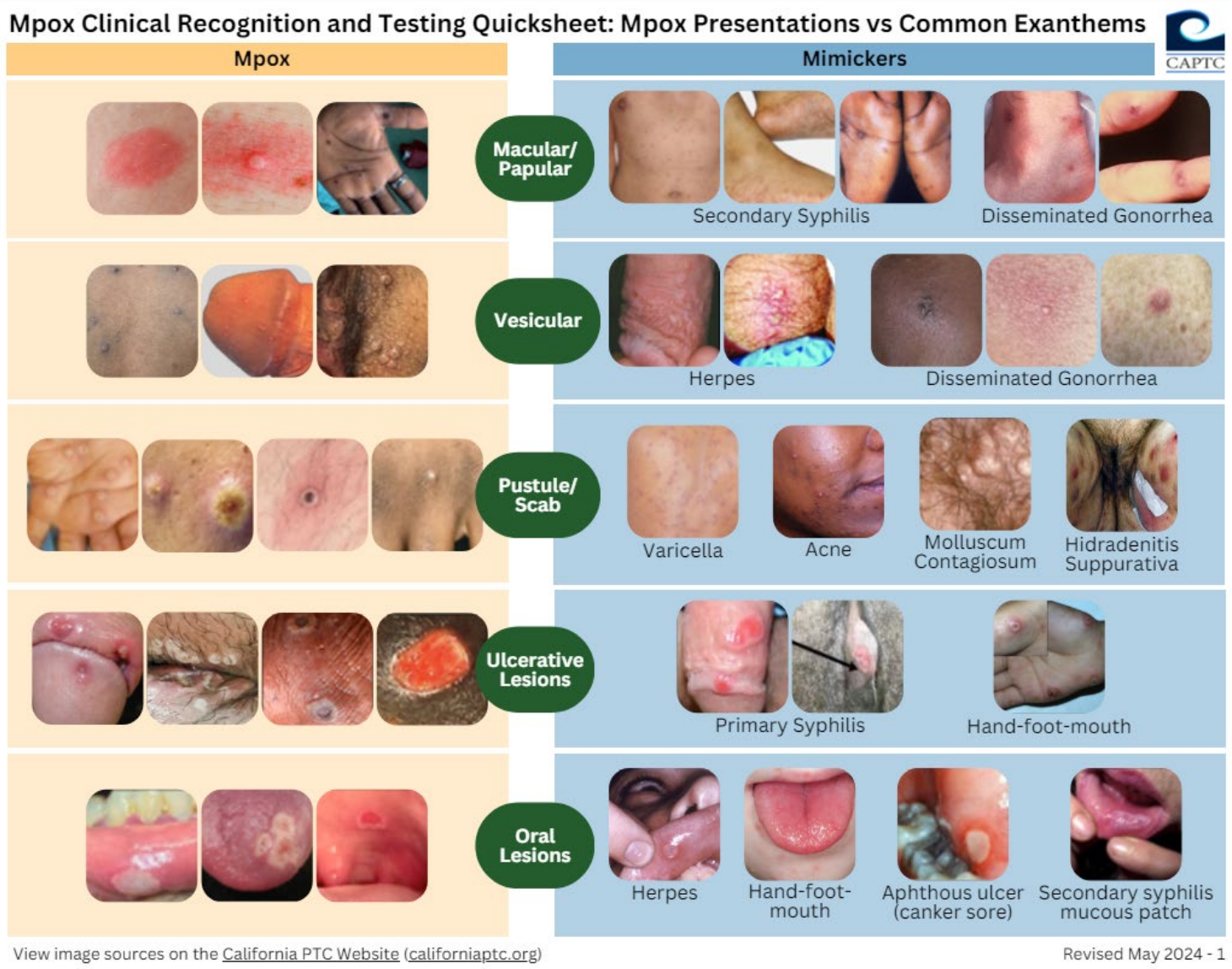
- **Genital exam**
  - Uncircumcised; multiple discrete small papules and macules on the glans penis, coronal sulcus, and distal penile shaft
  - Some skin lesions were flesh-colored and some were pale; no pustules
  - Lesions were firm and slightly rubbery; could not be unroofed
  - Lesions were painful
  - No inguinal lymphadenopathy

1.Monkeypox: Updates about Clinical Diagnosis and Treatment. June 2022 https://emergency.cdc.gov/coca/calls/2022/callinfo_062922.asp

Comparison of STI Skin Rashes with Mpox

County of Los Angeles Public Health

Type of Infection	Incubation Period	Description
Secondary Syphilis 	Can range from 10 to 90 days	Can appear when the primary chancre (ie, painless ulcer) is healing or several weeks after the chancre heals. **Most commonly appears as maculopapular rash on trunk, palms and soles. May be accompanied by mild constitutional symptoms.** Usually does not cause itching. Tends to have more of a peeling appearance, not nodular. Other common secondary syphilis presentations to look for: 1) Condyloma lata which are large, raised, gray or white lesions that develop in warm, moist areas like the mouth, underarm or groin/perianal region, 2) mucus patches, and 3) alopecia.
Disseminated Gonococcal infection 	Not specified	The rash typically has a maculopapular, **pustular, petechial**, or necrotic appearance and usually occurs in the distal extremities (limbs, hands, and feet). Rarely nodular.
Genital Herpes 	The average incubation period for an initial herpes infection is 4 days (range, 2 to 12) after exposure	Herpes lesions typically appear as one or more vesicles, or small blisters, on or around the genitals, rectum or mouth. **Mostly commonly presents in grouped vesicles (e.g, bunch of grapes)**. Often described as “dew on a rose petal.” The vesicles break and leave painful ulcers that may take two to four weeks to heal after the initial herpes infection. Can present on buttocks and be confused with Shingles.
Molluscum Contagiosum 	Two weeks to six months	The lesions, known as Mollusca, are small, raised, and usually white, pink, or **flesh-colored with a dimple or pit in the center. They often have a pearly appearance**. They’re usually smooth and firm. In most people, the lesions range from about the size of a pinhead to as large as a pencil eraser (2 to 5 millimeters in diameter). They may be asymptomatic or become itchy and irritated. Molluscum contagiosum is a self-limited infection; the papules usually disappear spontaneously within 6 to 12 months but may take as long as 4 years to resolve.
Monkeypox 	On average 7-14 days	The evolution of lesions progresses through four stages—macular, papular, vesicular, to pustular—before scabbing over and resolving. Lesions are **well circumscribed, deep seated**, and **often develop umbilication** (resembles a dot on the top of the lesion), they are relatively the same size and same stage of development on a single site of the body**. Fever may occur before rash, and lymphadenopathy is common.** Lesions are often described as **painful** until the healing phase when they become itchy (crusts). Rash is centrifugal (more lesions on extremities, face) and can appear on palms and soles. May present only in genital area; can present as proctitis as well.



1.Reference: https://californiaptc.com/wp-content/uploads/2024/05/Mpox-Short-Job-Aid.pdf

Testing and Reporting

Suspect Mpox?

- Test the rash of any patient with suspected mpox
- Instruct patients to isolate immediately pending test results: http://publichealth.lacounty.gov/acd/docs/MonkeypoxIsolation.pdf
  - Stay in a private room and ideally have separate bathroom
  - Avoid sharing bedding, towels, or any household items with others
- Notify contacts of exposure:
  - *Infectiousness*: onset of prodromal symptoms through resolution of the rash
- Tell patient that a Public Health Nurse will reach out to them within a few days to check on them and identify any high-risk close contacts so they can receive vaccine PEP
- Can resume limited outside activities if
  - They can completely cover their lesions
  - AND
  - have been fever free for 48+ hours, no new lesions
- Otherwise, must wait for rash to resolve = shedding of crusts and observation of healthy pink tissue at all lesion sites

Mpox Testing

- All major commercial laboratories offer testing for mpox
  - Quest Diagnostics, Labcorp, Aegis Sciences, and Sonic Healthcare.
- Public Health Lab testing available for the following cases that need rapid turn around (<2 days):
  - Children or pregnant persons
  - Persons with recent travel from western or central Africa (esp DRC) to test for Clade I
  - Persons experiencing homelessness (PEH) if needed to expedite decisions on the individual's placement
- Obtain approval for PHL testing from LAC DPH

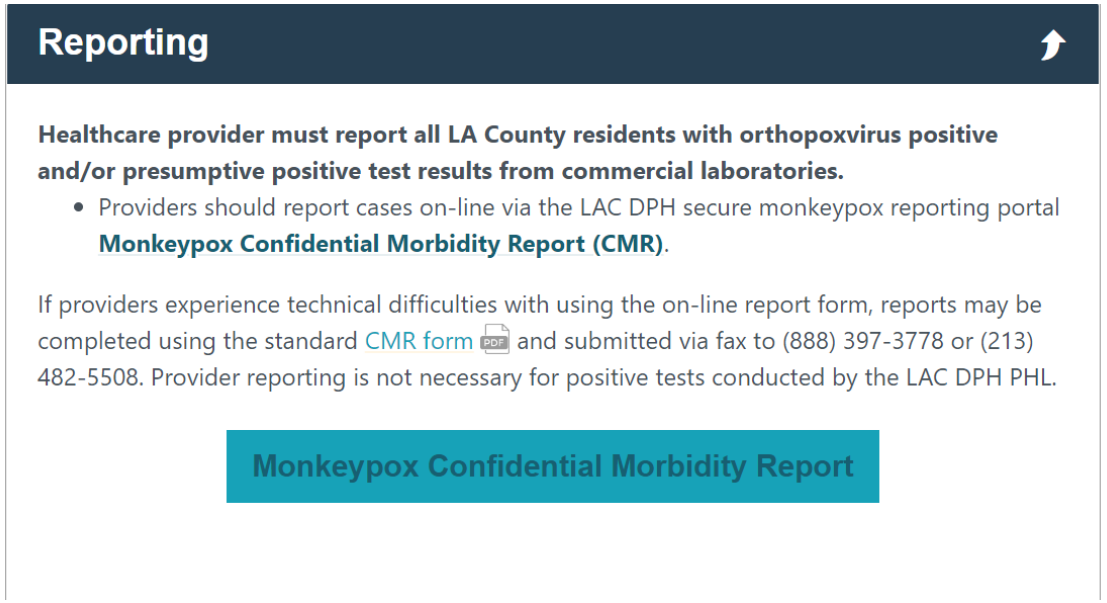
http://publichealth.lacounty.gov/acd/monkeypox/#monkeypox-virus-testing

Mpox testing technique

- Use sterile, synthetic swabs (including but not limited to polyester, nylon, or Dacron), to collect two swabs from each lesion; preferably from different locations on the body or from lesions with different appearance. Do not use cotton swabs.
- Vigorously swab the lesion to collect adequate DNA.
- Do not de-roof the lesion before swabbing.
- Lesion swabs may be collected in viral transport media (VTM) or universal transport media (UTM) tubes. Lesion swabs can also be placed in an empty sterile screw cap tube or sterile screw cap specimen cup for transport of a dry swab.

Reporting

- Mpox is mandated to be reported by laboratories AND providers.
- Laboratories automatically report to LAC DPH.
- Healthcare providers must complete a Confidentiality Morbidity Report form at http://publichealth.lacounty.gov/acd/monkeypox/index.htm#reporting
- Simple online portal to report



Treatment

Suspected or confirmed Mpox: Treatment

- Majority of cases of mpox will resolve without antiviral medication
- Symptom management
  - Oral analgesics (acetaminophen, ibuprofen)
  - Keep lesions clean and dry
  - Itching- calamine lotion, petroleum jelly, antihistamines
  - Oral lesions- salt water rinses, special mouthwashes
  - Painful anorectal lesions- stool softeners, anal gels, sitz baths, topical lidocaine

1.CDPH Suggested

Tecovirimat (Tpoxx)

- Tpoxx formulations: Oral and IV
- **FDA-approved for smallpox treatment in adults and children only**
  - Based on animal efficacy data and safety data in 359 healthy adults
- **No approved treatment by the FDA for mpox**
  - Tpoxx has been shown effective against other orthopoxviruses in animal challenge models
  - Anticipated potential treatment benefit based on animal efficacy uses and previous Tpoxx administration during prior outbreaks
  - **Led to offering access to ORAL stockpiled Tpoxx via the following routes**
    - NIH's STOMP Trial (Study of Tecovirimat for Human Mpox Virus)
    - CDC-Expanded Access Investigational New Drug (CDC EA-IND)/Compassionate use

Reference: CDC: https://www.cdc.gov/poxvirus/mpox/clinicians/tecovirimat-ea-ind.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fpoxvirus%2Fmpox%2Fclinicians%2Fobtaining-tecovirimat.html

Current Tpoxx Access

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

- Clinical trial (NIH) for oral Tpoxx to evaluate safety and efficacy
- **Preferred strategy for clinicians and local health jurisdictions to access oral Tpoxx**
- Enrollment is critical:
  - Show Tpoxx efficacy against mpox
  - FDA approval
  - Commercial availability

- Decline voluntary enrollment in STOMP
- Ineligible for STOMP
  - Prior Tpoxx use
  - Illness duration > 14 days
  - Require IV Tpoxx treatment

STOMP Clinical Trial (NIH)

County of Los Angeles Public Health

STOMP Study of Tecovirimat for Mpox

California PTC

What is STOMP and why refer?

- **STOMP (www.stomptpoxx.org) is a clinical trial of oral tecovirimat (TPOXX) safety and efficacy.**
- It is the preferred strategy for clinicians and local health jurisdictions to access oral TPOXX.
- Enrollment is critical to show TPOXX efficacy against mpox for FDA approval and commercial availability.

Who qualifies?

- Any patient with *presumptive or laboratory-confirmed* mpox disease, of any severity, whose symptoms began ≤ 14 days prior to enrollment, and who have ≥1 active lesion(s).
- Patients without prior use of oral or IV TPOXX, and not likely to need IV TPOXX as therapy.
- Persons with HIV not planning to initiate cabotegravir/rilpivirine (Cabenuva®) during or within 2 weeks of study completion.

What to say?

Participation can be in-person and/or 100% remote via video. Travel is not required.

Participants will be compensated with cash and/or gift card(s).

Pregnant people, children and participants with severe mpox, immunosuppression, or specific skin conditions (e.g. eczema) receive TPOXX.

Participants with mild to moderate mpox are randomized to receive TPOXX or placebo, 2:1. Neither the clinical study team nor the participant will be notified of randomization (double-blinded). If symptoms worsen, participants may be switched to TPOXX open-label study.

Participants are monitored via in-person or video appointments, questionnaires, and symptom diaries.

Participants usually receive TPOXX/ placebo within 24 hours after enrollment.

How to help patients enroll?

1. **Order/collect confirmatory human mpox virus PCR testing** a positive test result is required for continued participation following enrollment.

2. **Call the Mpox Study Hotline +1 (855) 876-9997** together with your patient or provide the number directly to your patient.

Language services are not available through the hotline, consider using in-clinic interpretation services.

Most study sites can enroll Spanish-speaking participants. Other languages are enrolled in accordance with IRB-approved procedures.

What else for patients?

- Offer JYNNEOS® vaccination as post-exposure prophylaxis (PEP) to all patients exposed to mpox who do not yet have symptoms contributable to mpox. It is most effective if provided <14 days of exposure.
- Provide the patient with return precautions in the case that STOMP enrollment is unsuccessful and symptoms continue.

Scan to visit the STOMP website

Reference: https://californiaptc.com/wp-content/uploads/2023/09/STOMP-Provider-Guide-Revised-9.21.23-FINAL.pdf

CDC EA-IND Forms and Submission Changes

- All forms will be submitted directly to CDC
- No need to send forms to LACDPH

Informed Consent

- Explain that Tpoxx is an investigational new drug (IND) and not approved for mpox treatment
- Patient signs and completes form
- **If sending to outpatient community pharmacy:** Fax/email informed consent form
- **Store in patient record (No need to submit to CDC or LACDPH)**

FDA Form 1572

- **One 1572 form per facility suffices for all Tpoxx treatments**
- Facility completes and signs form
- **Keep on file and send 1 copy to the following organizations within 7 days:**
  - CDC: regaffairs@CDC.gov or upload via the Sharepoint site
  - Community Pharmacy (if dispensing through them)

Patient Intake Form (Form A)

- Provider needs to complete this form for each patient
- **Send 1 copy to the following organizations within 7 days:**
  - ~~LACDPH: TPOXX@ph.lacounty.gov~~
  - CDC: regaffairs@CDC.gov or upload via the Sharepoint site
  - Community Pharmacy (if dispensing through them)

Clinical Outcome Form (Form B)

- Progress and outcome information post-treatment
- **Send 1 copy to the following organizations:**
  - ~~LACDPH: TPOXX@ph.lacounty.gov~~
  - CDC: regaffairs@CDC.gov or upload via the Sharepoint site

Serious Adverse Events Reporting Form

- Report life-threatening or serious adverse events with Tpoxx
- **Send 1 copy to the following organizations within 72 hours of the event:**
  - ~~LACDPH: TPOXX@ph.lacounty.gov~~
  - CDC: regaffairs@CDC.gov or upload via the Sharepoint site

CDC: Tpoxx IND Registry

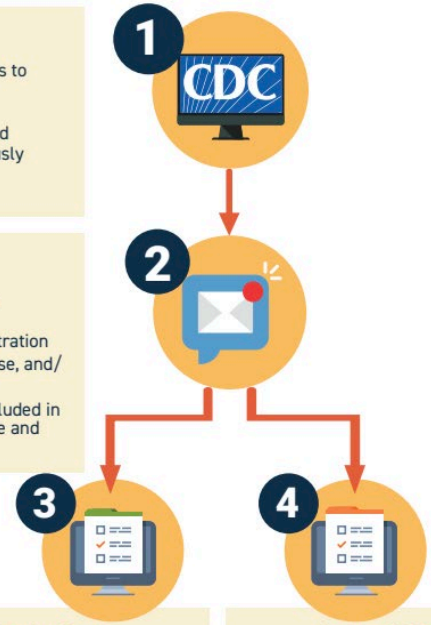
Tecovirimat (TPOXX) IND Registry for Providers and Facilities

Why register?

An online registry is available for providers and affiliated medical facilities providing tecovirimat (TPOXX) under the CDC-held expanded access Investigational New Drug (IND) protocol to register. All providers must register with the TPOXX IND Online Registry.

- The TPOXX IND Online Registry enables compliance with IND regulations.
- Providers must be registered to access electronic TPOXX IND forms that are required for completion and submission to CDC. The secure electronic forms include:
  - Form FDA 1572 (Statement of Investigator)
  - Patient Intake Form
  - Clinical Outcome Form
- The online registry provides an up-to-date list of participating providers and facilities under the TPOXX IND protocol.

Steps to Register and Access Electronic Patient Intake and Clinical Outcome Forms



Register Online

- Register as participating providers and facilities to be covered under the CDC-held TPOXX IND protocol.
- The electronic Form FDA 1572 can be completed through the online registry if it was not previously submitted to CDC.

Complete Verification

- Upon registration, the provider will receive the first email from "CDC TPOXX IND <noreply@dcipher.cdc.gov>" confirming registration as a participating provider to prescribe, dispense, and/or administer TPOXX under the CDC-held IND.
- Please complete the brief verification steps included in the email to access the electronic Patient Intake and Clinical Outcome Forms.

Access Patient Intake Form

- Upon verification, a provider will receive a second email with a secure link to electronically fill out the Patient Intake Form.
- The secure link can be accessed multiple times to complete the form for each patient treated.
- For each patient treated with TPOXX, providers must submit this form to CDC within 7 calendar days of therapy initiation.

Access Clinical Outcome Form

- Upon verification, a provider will receive a third email with a secure link to electronically fill out the Clinical Outcome Form.
- The secure link can be accessed multiple times to complete the form for each patient treated.
- For each patient treated with TPOXX, providers should submit this form to CDC within 3-7 calendar days of completing tecovirimat treatment.

Note: For security reasons, the electronic Patient Intake and Clinical Outcome forms must be completed and submitted in one sitting, and the links to these forms expire **180 days** from issuance. Providers with expired links who need access to these forms can email regaffairs@cdc.gov to request new secure links.

For any questions regarding the TPOXX IND Online Registry and/or electronic forms, please email regaffairs@cdc.gov.

www.cdc.gov/poxvirus

CS 334280-K | 5/25/2023

CDC EA-IND Tpoxx Eligibility Criteria Are Changing!

Tpoxx Eligibility Categories

- Severe mpox clinical manifestations at presentation
- High risk of severe mpox clinical manifestations
- Special populations

Stricter criteria changes under the eligibility categories!

- Emphasis on protracted/life-threatening illness
- Concern for Tpoxx resistance
  - LA County Tpoxx resistance cluster
- Most patients that were placed on Tpoxx were due to severe pain with 50% of pain resolving in 2 days
  - Tpoxx patient diaries (n = 150) : Got better on 1 dose?
- Utilization of STOMP trial low!
  - Need to have human efficacy data

CDC EA-IND: Severe Mpox clinical manifestations at presentation

- Emphasis on criteria that can contribute to **protracted/life-threatening illness**
- Lesions ≥ 25% of body surface area = Disseminated infection
- Specific anatomic area listing removed, consider case-by-case between clinician and CDC
- Hospitalization and surgical involvement removed

Severe Mpox clinical manifestations at presentation

Revised CDC EA-IND Criteria

People with protracted or life-threatening manifestations of Mpox at presentation

- **Severe Disease (1 of the following):**
  - Lesions affected ≥ 25% of body surface that may be confluent, necrotic, or hemorrhagic in appearance, and/or cause sepsis
  - Ocular or periorbital infection irrespective of the time since infection onset
  - Disease resulting in airway compromise or affecting the nervous system
  - Cardiac (e.g. myocarditis) or neurologic disease (e.g. encephalitis)
- **Tpoxx may be considered on a case-by-case basis for an unusual situation wherein CDC consult team and/or CDC Principal Investigator in discussion with treating clinician deem treatment under the EA-IND may potentially be beneficial**
  - Consideration is expected to be rare
  - Intended for unusual situations associated with the disease that could result in **clear long-term sequalae (ex: urethral stricture)**

Current CDC EA-IND Criteria: Severe Disease

- **Severe Disease**
  - Hemorrhagic disease
  - Large number of lesions that are confluent
  - Necrotic lesions
  - Severe lymphadenopathy (necrotizing or obstructing such as in airways)
  - Multiple organ system involvement with associated co-morbidities (ex: pulmonary involvement with nodular lesions, sepsis, encephalitis, myocarditis, ocular or periorbital infections)
  - Other conditions requiring hospitalization
- **Anatomic areas that result in serious sequalae that include scarring and strictures**
  - Pharynx causing dysphagia, inability to control secretions, need for parenteral feeding
  - Penile foreskin
  - Vulva
  - Vagina
  - Urethra
  - Anorectum
    - Lesions interfering with bowel movements (for example: severe pain)
  - Severe infections (incl secondary bacterial skin infections) especially those requiring surgical intervention

CDC EA-IND: High risk of severe mpox clinical manifestations

- HIV eligibility criteria has specific CD4 count requirement

High risk of severe mpox clinical manifestations
Revised CDC EA-IND Criteria

• **Severe immunocompromised conditions defined as:**
  ○ **HIV with CD4 < 200 or other comparable severe immunocompromise**
  ○ Leukemia or lymphoma
  ○ Generalized malignancy
  ○ Solid organ transplantation
  ○ Therapy with alkylating agents within 180 days prior to mpox illness onset
  ○ Antimetabolites within 180 days prior to mpox illness onset
  ○ Radiation therapy within 180 days prior to mpox illness onset
  ○ Tumor necrosis factor inhibitors within 180 days prior to mpox illness onset
  ○ High-dose corticosteroids (equivalent of 20 mg or greater of prednisone for at least 14 days) within 90 days prior to mpox illness onset
  ○ Being a recipient with hematopoietic stem cell transplant < 24 months post-transplant or >= 24 months but with graft-versus-host disease or disease relapse or having a autoimmune disease with immunodeficiency as a clinical component
• **Active skin conditions (at higher risk for disseminated infection)**
  ○ Atopic dermatitis
  ○ Active exfoliative skin conditions (eczema, burns, impetigo, active varicella zoster virus infection, psoriasis, or keratosis follicularis (Darier disease)

Current CDC EA-IND Criteria

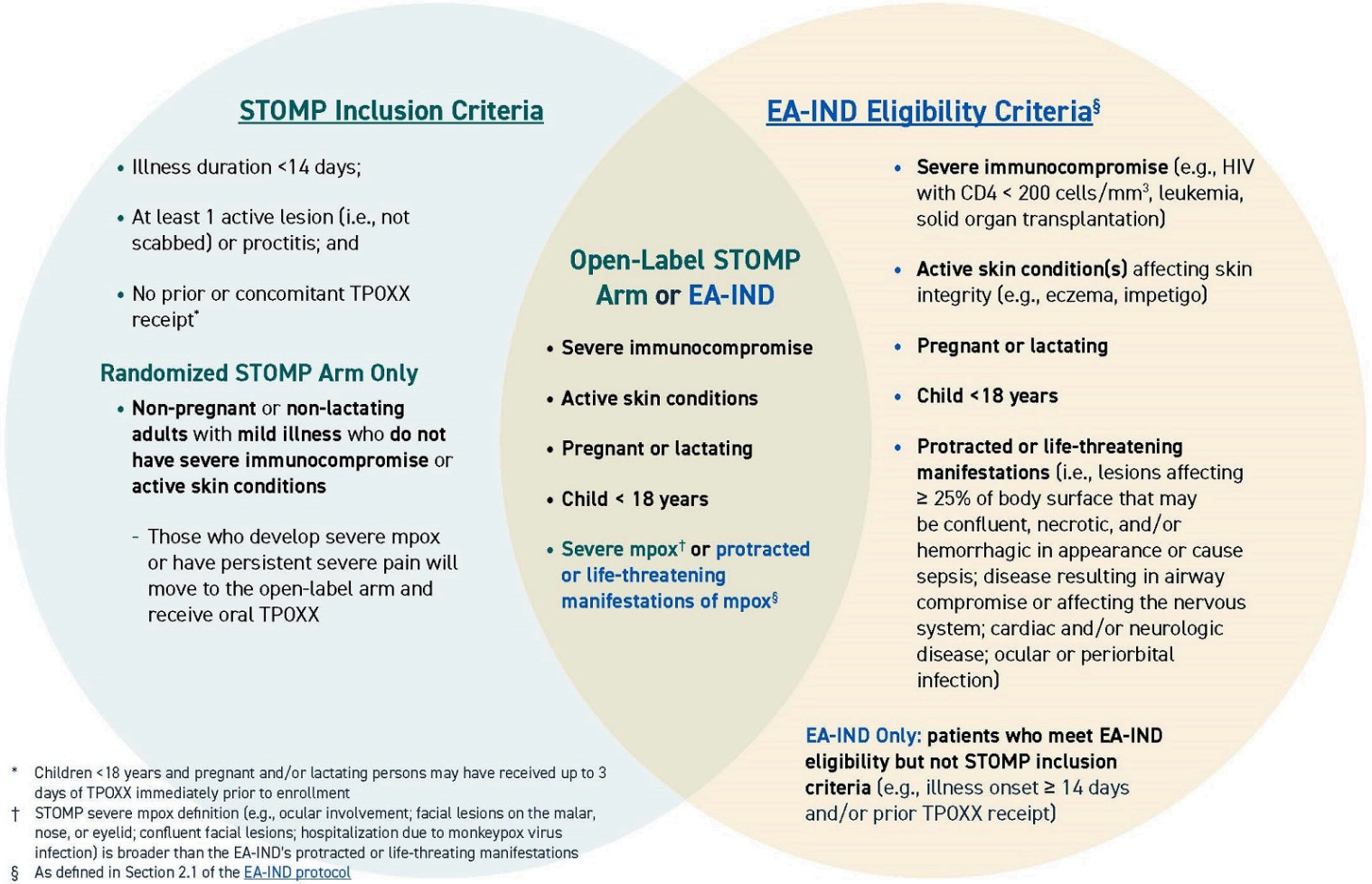
• **Severe immunocompromised conditions defined as:**
  ○ Advanced or poorly controlled HIV
  ○ Leukemia or lymphoma
  ○ Generalized malignancy
  ○ Solid organ transplantation
  ○ Therapy with alkylating agents within 180 days prior to mpox illness onset
  ○ Antimetabolites within 180 days prior to mpox illness onset
  ○ Radiation therapy within 180 days prior to mpox illness onset
  ○ Tumor necrosis factor inhibitors within 180 days prior to mpox illness onset
  ○ High-dose corticosteroids (equivalent of 20 mg or greater of prednisone for at least 14 days) within 90 days prior to mpox illness onset
  ○ Being a recipient with hematopoietic stem cell transplant < 24 months post-transplant or >= 24 months but with graft-versus-host disease or disease relapse or having a autoimmune disease with immunodeficiency as a clinical component
• **Active skin conditions (at higher risk for disseminated infection)**
  ○ Atopic dermatitis
  ○ Active exfoliative skin conditions (eczema, burns, impetigo, active varicella zoster virus infection, psoriasis, or keratosis follicularis (Darier disease)

CDC EA-IND: Special Populations

Special Populations
Revised CDC EA-IND Criteria
• Pregnant or breastfeeding individuals regardless of illness severity or underlying comorbidities • Children (< 18 years) regardless of illness severity or underlying comorbidities
Current CDC EA-IND Criteria
• Pregnant or breastfeeding people • Pediatric populations, particularly patients younger than 1 year of age

CDC EA-IND vs NIH STOMP: Eligibility Criteria

Oral TPOXX Via NIH's STOMP vs. CDC's EA-IND Protocol



Reference: CDC: https://www.cdc.gov/poxvirus/mpox/clinicians/tecovirimat-ea-ind.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fpoxvirus%2Fmpox%2Fclinicians%2Fobtaining-tecovirimat.html

LACDPH TPOXX Pharmacy Network (May 2024)

LACDPH TPOXX PHARMACY NETWORK

Tecovirimat (TPOXX) is the first-line medication mpox treatment under an EA-IND protocol. The below pharmacies are part of LACDPH's TPOXX network and maintain a minimum inventory of TPOXX doses for dispensing monitored by LACDPH. For more information about TPOXX click the link CDC-TPOXX Treatment Guidance Page

TPOXX dispensing requirements include:
1. Prescription - *Ordering provider to e-prescribe or call in prescription*
2. Patient intake form - *See link below*
3. Patient informed consent form - *See link below*
4. Form 1572 from the provider - *See link below*

Access the electronic form through the Tecovirimat IND Online Registry. To Complete the patient, dispensing requirements include

Please contact one of the pharmacies below for dispensing. For any other questions, contact PharmProvMgt@ph.lacounty.gov

Participating pharmacy locations

986 PHARMACY TEMPLE CITY
9612 Las Tunas Dr.
Temple City, CA 91780
(626) 309-5052
Hours:
M-F: 9am - 6pm
Sat: 9am - 4pm
Sun: Closed

CARSON PHARMACY
21720 S Vermont Ave Ste 101
Torrance, CA 90502
(310) 328-0982
Hours:
M-F: 9:30am - 6:30pm
Sat: 9:30am - 4pm
Sun: Closed

COSMED PHARMACY
6521 Van Nuys Blvd
Van Nuys, CA 91401
(818) 933-2010
Hours:
M-F: 9am - 7pm
Sat: 9am - 4pm
Sun: Closed

EDDIE'S PHARMACY
8408 Beverly Blvd
Los Angeles, CA 90048
(310) 358-2400
Hours:
M-F: 9am - 6pm
Sat: 9am - 1pm
Sun: Closed

ELEMENTS PHARMACY
12602 Ventura Blvd
Studio City, CA 91604
(818) 762-2055
Hours:
M-F: 9am - 6pm
Sat: 9am - 4pm
Sun: Closed

HEALTHRX PHARMACY
1844 E. RTE 66
Glendora, Ca 91740
(626) 335-4777
Hours:
M-F: 9am - 7pm
Sat: 10am - 3pm
Sun: Closed

LA COMPOUNDING PHARMACY
8600 W 3rd St #1
Los Angeles, CA 90048
(310) 362-4122
Hours:
M-F: 9am - 5pm
Sat-Sun: Closed

MEDEX PHARMACY
8441 Foothill Blvd
Los Angeles, CA 91040
(818) 925-1321
Hours:
M-F: 9am - 7pm
Sat: 9am - 2pm
Sun: Closed

MICKEY FINE PHARMACY
433 N Roxbury Dr
Beverly Hills, CA 90210
(310) 271-6123
Hours:
M-Th: 8:30am - 6:30pm
Fri: 8:30am - 6pm
Sat-Sun: 9am - 2pm

PRICE CARE PHARMACY
10837 Downey Ave
Downey, CA 90241
(562) 825-5923
Hours:
M-F: 10am - 5:30pm
Sat-Sun: Closed

WHITE MEMORIAL MEDICAL PLAZA PHARMACY
1701 E Cesar E Chavez Ave Suite 109
Los Angeles, CA 90033
(323) 221-6000
Hours:
M-F: 8:30am - 6:30pm
Sat: 9am - 1:30pm
Sun: Closed

LACDPH Tpoxx Stock (June 2024)

- Stockpiled Tpoxx at EOC: 5704 bottles
  - One bottle = 42 pills
  - 1 pill = 200mg dosage
  - Ex: 86 to < 264 lbs
    - 600mg q 12 hrs x 14 days
    - 14 days = 84 pills = 2 bottles
- **If STOMP declined,** health care systems/pharmacies/clinics can access through LACDPH DHSP
  - Coordinate with EOC to deliver
- **Please utilize the STOMP study call center phone line**

Any logistical or clinical TPOXX needs

Email: TPOXX@ph.lacounty.gov

Provider Line

Weekdays, 8:00am-4:30pm: call (213) 368-7441

Weekends and holidays, 8:00am-5pm: call (213) 974-1234 and ask for the physician on call.

Evening/night –emergent patients only, call (213) 974-1234 and ask for the physician on call.

Infection Control

Mode of transmission & precautions in healthcare facilities

- Practical guidance based upon exposure risk

  for routine swabbing and care:

  - Surgical mask + Gloves
  - N95, gown & eye protection for aerosol generating procedures
  - Among 313 HCP exposed to mpox in Colorado, none were infected despite low use of recommended PPE or post-exposure prophylaxis through vaccination. Providers wearing appropriate PPE, particularly when in physical contact with mpox patients, are expected to have very low likelihood of mpox acquisition.
  - The majority of occupationally acquired mpox infections in HCP have occurred through sharps injuries from attempts at unroofing mpox lesions. Unroofing lesions is not necessary and not advised.

Preventing Occupational Mpox Transmission in Outpatient Clinics

	CDC guidance	Resource-scarce alternative
Patient Placement	Single-person room upon entry into clinic and throughout visit (no special air handling required)	• Shared waiting room until single room available • Patient masked and all lesions covered in shared spaces • Exam Rooms cleaned with standard cleaning and disinfection procedures (using product with an EVP** claim) between patient visits
Bathroom	Dedicated bathroom for suspect/confirmed mpox patients	Shared bathroom cleaned routinely with standard cleaning and disinfection procedures (using product with an EVP** claim)
PPE	All healthcare personnel (HCP) who enter patient room: gown, gloves, eye protection (goggles or face shield) & N95 or higher respirator	• Full PPE used only by HCP who will have physical contact with patient. • In some settings, before donning full PPE, clinician wearing surgical mask briefly enters room to obtain history and visualize lesions. If mpox suspected, provider dons full PPE prior to close inspection or sampling of lesions.
Waste Management	Per U.S. DOT regulations for Hazardous Materials	Per institutional protocol

https://californiaptc.com/wp-content/uploads/2023/11/Preventing-Occupational-Monkeypox-Transmission_2023-11-08_withVersionDate_Digital.pdf

Exposure Risk	High Risk	Intermediate Risk	Low/Unknown Risk	No Risk
Definition	1. Unprotected contact between an exposed individual's broken skin or mucous membranes and mpox skin lesion. 2. Inside the patient's room or within 6 feet of a patient with mpox during aerosol-generating procedure from oral secretions (e.g., CPR, intubation), or activities that may resuspend dried exudates (e.g., shaking soiled linens), without wearing an N95 respirator and eye protection.	1. Being within 6 feet for a total of 3 hours or more (cumulative) of an unmasked patient with mpox without wearing a facemask or respirator. 2. Unprotected contact between an exposed individual's intact skin and the skin lesions or bodily fluids, or soiled materials (e.g., linens, clothing). 3. Activities resulting in contact between clothing and skin lesions or bodily fluids, or soiled materials (e.g., during turning, bathing, or assisting with transfer) while not wearing a gown.	Healthcare worker not wearing a mask, but the exposure was less than 3 hours.	Healthcare worker was wearing gloves and mask for all contact with patients and did not meet any of the above exposure categories.
Monitoring	Active monitoring x 21 days.	Active monitoring x 21 days	Self-monitoring x 21 days.	None
Post-exposure prophylaxis	Recommended • Vaccination within 4 days or by 14 days • Daily contact with healthcare facility human resources or infection control for 21 days after exposure • Symptom screen daily • Exposed personnel may continue to work or go outside their homes • Any potential symptoms must be reported ASAP to LACDPH	Discuss risk/benefit with MD • Vaccination within 4 days or by 14 days • Daily contact with healthcare facility human resources or infection control for 21 days after exposure • Symptom screen daily • Exposed personnel may continue to work or go outside their homes • Any potential symptoms must be reported ASAP to LACDPH	No	No

Monitoring for Mpox

- No risk = no required monitoring
- Low risk exposures should self-monitor
- Intermediate and high-risk exposures
  - Vaccination within 4 days or by 14 days
  - Daily contact with healthcare facility HR/IC for 21 days after last exposure
  - Symptom screen daily
  - Exposed people may continue to work or go outside their homes
  - Any potential symptoms must be reported ASAP to LACDPH

Vaccination

Mpox Vaccination

- October 2023: ACIP recommendation for routine vaccination of adults at risk of mpox
- Persons at risk
  - Gay, bisexual, and other men who have sex with men, transgender people, or non-binary people who, in the past 6 months, have had one of the following:
    - New diagnosis of >= 1 STI
    - More than one partner
    - Sex at a commercial venue
    - Sex in association with a large public event in a geographic area where mpox transmission is occurring
  - Sexual partners of persons with the risks described above
  - Persons who anticipate experiencing any of the above

1.https://www.cdc.gov/poxvirus/mpox/vaccines/vaccine-recommendations.html

Mpox vaccination

- Two injections, 28 days apart (range 24-35 days)
- Those <18 yo, subcutaneous injection only approved
- Vaccine recommendations unchanged
  - Not recommended for those who recovered from mpox
  - Not recommended for who already received 2 Jynneos doses
- Coverage of eligible population
  - 40% 1 dose coverage, 25% 2 dose coverage

Mpox Vaccination

- Vaccination currently available free from LAC DPH
- Jynneos commercialization transition to be completed August 1, 2024
  - Full coverage for Medicare or Medicaid beneficiaries
  - Commercial insurance- expect private insurance plans to fully cover within ACIP recs; plans obligated begins 1 plan year after ACIP rec

DPH Mpox Vaccine Incentive Program- Expanded Eligibility

Patients in Regular Care

- Patients who are in regular HIV care are eligible for two $50 gift cards: one given after each of the two-dose series.
- **(NEW)** Patients receiving Pre-Exposure Prophylaxis (PrEP) and Post-Exposure Prophylaxis (PEP) treatment are eligible for two $50 gift cards: one given after each of the two-dose series

HIV Patients Out-of-Care >=7 Months

- Patients who have been out-of-care will be eligible for two $100 gift cards: one given after each of the two-dose series.

Interested in Participating?

It's not too late to sign up to participate in the Mpox Vaccine Incentive Program. If you would like to enroll, please register here.

Contacts

Marcus Carreon mcarreon2@ph.lacounty.gov
Michelle Vazquez Godinez mvazquezgodinez@ph.lacounty.gov

Any mpox clinical questions

Provider Lines:

Division of HIV and STD Programs Provider Consult Line:

Weekdays, 8:00am-4:30pm: call (213) 368-7441

Weekends and holidays, 8:00am-5pm: (213) 974-1234 and ask for the physician on call.

Evening/night –emergent patients only, (213) 974-1234 and ask for the physician on call.

Tpoxx specific questions:

Email: TPOXX@ph.lacounty.gov

QUESTIONS?

skulkarni@ph.lacounty.gov