



# Mpox in the U.S.: Resources for HIV Clinicians

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This document is intended as a resource for clinicians regarding mpox and special considerations for people with HIV. The information is compiled from the <u>Centers and Disease Control and Prevention</u> and other sources and will be updated as more information and data become available. Additional resources are available from the IDSA Mpox <u>webpage</u>.

# **Table of Contents**

2022 Outbreak

Infection Prevention and Control in Health Care Settings

**Diagnosis & Testing** 

Vaccination

**Treatment** 

**Isolation and Prevention Measures for Patients** 

**Guidance for Key Populations** 

Coverage/Ryan White HIV/AIDS Program Guidance

Acknowledgements

#### 2022 Outbreak

The Centers for Disease Control and Prevention is tracking daily case rates for the U.S. by state and globally. International data collected on people with mpox during the current outbreak indicate that 31% to 50% of people with mpox had HIV. Mpox can be transmitted to anyone through close physical contact. The majority of cases in the U.S. and globally to date have occurred among gay, bisexual and other men who have sex with men and are suspected to have occurred through close physical and sexual contact. Based on the case data reported to the CDC, Black/African American and Hispanic/Latino individuals have been disproportionately affected by mpox in the U.S. On Aug. 4, U.S. Department of Human Services Secretary Xavier Becerra declared mpox a national public health emergency. CDC releases periodic technical reports on the mpox response that include the latest data and analysis of the current outbreak. Given the low number of mpox cases in the U.S. today, HHS does not anticipate renewing the public health emergency past Jan. 31, 2023.

#### <u>Infection Prevention and Control in Health Care Settings</u>

CDC has <u>developed guidance</u> for health care settings to prevent the spread of mpox that includes patient isolation, personal protective equipment, waste management and environmental infection control. Recommendations include:

- Placing patients in a private room with a dedicated bathroom. Special air handling is not required.
- Ensuring health care workers wear a gown, gloves, eye protection and a NIOSH-approved particulate respirator with N95 filters or higher.
- Performing standard cleaning and disinfection using an EPA-registered hospital-grade disinfectant with an emerging viral pathogen claim.
- Handling soiled laundry with standard procedures, avoiding contact with any lesion material. Laundry should be gently contained in a bag without dispersing any infectious material.
- Avoiding dry dusting, sweeping or vacuuming in the room.

- Monitoring health care personnel and patients with an exposure to mpox and providing postexposure management according to the CDC Monitoring People Who Have Been Exposed guidance.
- Discontinuing patient isolation in consultation with your state or local health department.

# **Diagnosis & Testing**

- CDC <u>recommends</u> that providers consider testing for all rashes with clinical suspicion of having mpox in addition to testing for sexually transmitted infections and other potential causes of the rash. (See also <u>What to Do If You Suspect Mpox.</u>)
- HIV has been identified as a risk factor for severe manifestations of mpox. CDC <u>recommends</u> conducting HIV testing (including for acute HIV) for all patient with confirmed or suspected mpox in addition to testing for other STIs.
- The clinical presentation of Mpox during the current outbreak is different than the manifestations
  during previous outbreaks. CDC has <u>developed guidance</u> with photos to help with recognizing mpox
  (see below).
- Also see <u>A Web-Scraped Image Database of Mpox, Chickenpox, Smallpox, Cowpox and Measles</u>, Islam et al., *Nature* 2022.

# Key Characteristics for Identifying Mpox From the CDC Clinical Recognition Webpage

- Lesions are well circumscribed, deep seated, and often develop umbilication (resembles a dot on the top of the lesion)
- Lesions are relatively the same size and same stage of development on a single site of the body (ex: pustules on face or vesicles on legs)
- Fever before rash
- Lymphadenopathy common
- Disseminated rash is centrifugal (more lesions on extremities, face)
- Lesions on palms, soles
- Lesions are often described as painful until the healing phase when they become itchy (crusts)

# **Examples of Mpox Rashes**

Photo credit: UK Health Security Agency



- Testing is available from your <u>health department</u> through the public health Laboratory Response Network or through the following commercial laboratories:
  - o Aegis Sciences;
  - o Mayo Laboratories;
  - Labcorp;
  - Quest Diagnostics;
  - o Sonic Healthcare USA.
- CDC recommends collecting two swabs from two to three lesions (See <a href="CDC collection guidance">CDC collection guidance</a>). State and commercial laboratory protocols and swab requirements vary. Check with your state health department for its protocols.
- Testing conducted by health departments is available at no cost. Patients will be charged for testing conducted by the commercial laboratories and the fees will vary. For insured patients, their health insurer will be billed, but they may be subject to their health plan's cost sharing requirement. Uninsured patients will be required to pay out of pocket for testing.

#### Vaccination

#### **Vaccines**

- CDC <u>recommends</u> vaccination be considered for anyone who may be at risk for mpox or might be exposed in the future.
- Building Healthy Online Communities is maintaining a <u>directory</u> of mpox vaccine sites by zip code.
- The preferred vaccine JYNNEOS is available from state and territorial health departments.
- JYNNEOS is a two-dose vaccine licensed by the U.S. Food and Drug Administration for prevention of smallpox and mpox. The FDA recommendation is for the two doses to be administered 28 days apart.
- The JYNNEOS vaccine has been studied in people with HIV and people with AIDS (CD4 > 100 cells/mm<sup>3</sup>). Available data indicate the vaccine is safe for people with HIV and that people with HIV generated an immune response comparable to people without HIV. (See <u>CDC HIV Mpox guidance</u>).
- Under the public health emergency declaration, FDA granted an <u>emergency use authorization</u> to allow for intradermal administration of JYNNEOS with an injection volume of 0.1 mL for people 18 years and older. (see CDC Interim JYNNEOS Guidance).
- ACAM2000 is a one-dose vaccine that contains live virus. A greater supply of ACAM2000 is available
  through the Strategic National Stockpile. This vaccine may cause severe illness in people with HIV and
  other individuals who are immunocompromised.
- ACAM2000 is a live virus vaccine and should not be given to people with HIV (see <u>CDC HIV Mpox guidance</u>).
- The CDC recommends against delaying mpox vaccination following COVID-19 vaccination.
- After mpox vaccination, a 4-week waiting period <u>could be considered</u> particularly for young men (ages 12 to 39) before receiving a Moderna, Novavax, or Pfizer-BioNTech COVID-19 vaccine because of the risk for myocarditis and pericarditis. This also could be considered for the Moderna and Pfizer-BioNTech COVID-19 bivalent boosters.

#### Access

- State and territorial health departments are determining the allocations and eligibility policies for vaccination within their state/jurisdiction.
- For states and jurisdictions using online or telephone registration programs, we recommend reserving appointments or vaccine doses for safety-net clinics serving populations at higher risk, including sexual and gender minorities, people of color, people with HIV and other populations at risk for severe illness.

#### **Treatment**

- Tecovirimat (TPOXX) is <u>approved</u> by FDA for the treatment of smallpox under the "Animal Rule" because clinical trials were not ethical or feasible since it has a high fatality rate and has been eradicated.
- CDC currently <u>recommends treatment</u> for people with severe disease or people who may be at high
  risk for severe disease, including people with HIV who are immunocompromised or have poorly
  controlled HIV. It is uncertain whether treating mild disease in people who are not
  immunocompromised is beneficial.
- The mpox virus may have a low barrier to <u>developing resistance</u> to tecovirimat; indiscriminate use could promote resistance.
- Adjustments to treatment dosing and duration may be needed for people who are immunocompromised. Clinical consultation is available from the CDC by calling (770) 488-7100 or send an email to eocevent482@cdc.gov.
- The AIDS Clinical Trials Group is conducting the Study of Tecovirimat for Human Mpox Virus (STOMP) Clinical Trial (A5418) to evaluate the effectiveness of TPOXX. See the <a href="STOMP website">STOMP website</a> for trial information, including a list of participating clinical trial sites.
- TPOXX for treatment of mpox is only available through a CDC <u>expanded access investigation new drug</u> <u>protocol</u>.<sup>1</sup>
- TPOXX can be requested through your <u>state or territorial health department</u> or by contacting the CDC Emergency Operations Center (770-488-7100; <u>poxvirus@cdc.gov</u>). Assistance from the CDC Operations Center is available 24/7, including weekends.
- Jurisdictions also can order TPOXX <u>through HHS</u> and pre-position treatment supplies at pharmacies to expedite access.
- CDC and FDA allow for treatment to be started before the paperwork is submitted with the completion of an <u>informed consent form</u> (<u>Spanish version</u>) and before confirmatory testing results are available. State policies may vary.
- Jurisdictions are encouraged to allow treating facilities to preposition a limited supply of TPOXX inventory to expedite access and prevent delays after hours or on weekends.
- TPOXX has been purchased by the federal government for the Strategic National Stockpile so it is available at no charge to clinics, institutions and patients.
- Severe pain has been a common morbidity with this outbreak. Pain management should be prioritized
  as part of the treatment plan, and CDC has developed <u>guidance for managing pain in patients with
  mpox.</u>

#### Considerations for Treating People With HIV From CDC:

- According to <u>CDC data</u>, 38% of people diagnosed with mpox during the current outbreak are coinfected with HIV.
- Patients with HIV who have low CD4 cell count or who are not on HIV treatment are at increased risk for severe illness from mpox.
- Medication, treatment and close monitoring <u>are recommended</u> for patients with HIV who are exposed to or suspected to have mpox.
- Patients with HIV on treatment for mpox should continue their antiretroviral treatment without interruption.
- Patients with HIV and mpox who are not on HIV treatment should initiate antiretroviral treatment as soon as possible. The HHS Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents

<sup>&</sup>lt;sup>1</sup> See Sherwat, A., et al. <u>Tecovirimat and the Treatment of Monkeypox – Past, Present and Future Considerations</u>, *NEJM*, Aug 3, 2022.

- with HIV Drug-Drug Interactions tables have been updated to include an Antivirals Orthopoxviruses (Mpox, Smallpox) section. Dose adjustments are not recommended for any of the antiretrovirals when treating people with HIV with TPOXX.
- The <u>HHS Guidelines</u> recommend delaying initiation of cabotegravir/rilpivirine (Cabenuva) during tecovirimat treatment and for two weeks after completing treatment.
- Clinicians also can consult the <u>Liverpool HIV drug interactions page</u> for clinically relevant drug
  interactions and may offer additional considerations to the HHS Guidelines as more information is
  learned.
- Patients taking pre-exposure prophylaxis or postexposure prophylaxis should continue without interruption.

### **Isolation and Prevention Measures for Patients**

- CDC has developed <u>guidance</u> for safer sex to prevent the spread of mpox, such as limiting the number of sex partners, covering and avoiding contact with any rashes and avoiding anonymous partners, and for large gatherings, such as avoiding skin-to-skin contact and dark places such as back rooms, saunas or sex clubs.
- CDC <u>recommends</u> that people with mpox isolate until all symptoms resolve, which typically is between two and four weeks after onset of symptoms.
- CDC also <u>offers guidance</u> for people with mpox who may not be able to isolate for the duration of the illness.
- For the 2022 global outbreak, in the United States, the primary type of exposure and transmission has been skin-to-skin contact and/or close intimate and sexual contact with individuals with mpox.
- It is not yet known how often, or at what point during infection, the virus may be spread from respiratory secretions or whether the virus can be spread through bodily fluids, such as semen and vaginal fluids.

### **Guidance for Key Populations**

CDC has developed the guidance documents below for people with HIV, children and adolescents and people who are pregnant or breastfeeding.

# Clinical Considerations for Treatment and Prophylaxis of Mpox Virus Infection in People With HIV

• Special considerations for treating and vaccinating people with HIV developed because people with HIV with advanced disease may be at increased risk for severe disease.

# Clinical Considerations for Mpox in Children and Adolescents (CDC)

 Guidance based on available data and information on conditions that may put children and adolescents less than 18 years of age at greater risk for severe illness in addition to considerations for treating and vaccinating them.

# Clinical Considerations for Mpox in People Who Are Pregnant or Breastfeeding (CDC)

 Guidance based on available data and information on risks for pregnant and breastfeeding people and vaccination, treatment and diagnosis of people who are pregnant and breastfeeding.

# **Access to Services and Coverage**

CDC-recommended vaccinations and antiviral treatments are available for people exposed to mpox or diagnosed with mpox. Mpox vaccines and treatment are currently being provided by the U.S. federal

government without any charge to providers or patients.

# **Ryan White HIV/AIDS Program**

HRSA's HIV/AIDS Bureau Associate Administrator Laura Cheever, MD, MPH, issued a "<u>Dear Colleague</u>" letter with guidance for Ryan White program providers on mpox. Key points are highlighted below.

- Mpox testing is available through public health laboratories and commercial laboratories. Testing done through public health laboratories is free of charge, while commercial laboratories bill health care coverage for the cost of the test. If a RWHAP provider does not have access to public health laboratory testing, RWHAP funds can be used to cover co-pays and deductibles for testing for clients with health insurance and for the cost of testing for clients without insurance.
- RWHAP funds may be used to pay for fees associated with vaccine administration and treatment of
  mpox for eligible clients, such as medical visit costs, including personal protective equipment for staff,
  and vaccination supplies, including co-pays and deductibles for insured clients, in accordance with Policy
  Clarification Notice #16-02 Ryan White HIV/AIDS Program Services: Eligible Individuals & Allowable Uses of
  Funds.
- The mpox-related services available at Ryan White clinics will vary depending on the resources available locally. A directory of Ryan White providers is <u>available online</u>.

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