NEW YORK STATE OF OPPORTUNITY. Department of Health

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TO: Healthcare Providers, Hospitals, Local Health Departments, Laboratories, Sexual Health Providers, Family Planning Providers, Emergency Rooms, Community Health Centers, College Health Centers, Community-Based Organizations, and Internal Medicine, Family Medicine, Pediatric, Adolescent Medicine, Dermatology, Infectious Disease, and Primary Care Providers, Higher Education Institution Health Clinics, Pharmacies

FROM: New York State Department of Health

**HEALTH ADVISORY: MPOX CASES ASSOCIATED WITH PERSON-TO-PERSON TRANSMISSION**

Recommendations from the U.S. Centers for Disease Control and Prevention on clinical and public health management of clade I mpox in the United States were released August 28, 2024, and are attached here. These recommendations outline the importance of rapid clade-specific testing of individuals exhibiting symptoms of mpox with travel history to the Democratic Republic of the Congo (DRC) or neighboring countries, or those who have had exposure to travelers from these areas; isolation of persons with confirmed clade I mpox, and those with possible clade I mpox pending differentiation testing results; active monitoring of high and intermediate risk exposures; and ongoing coordination between clinicians and health officials to monitor the clinical course of illness.

To date, no cases of clade I mpox have been identified in the United States. However, due to the potential for clade I mpox to continue spreading beyond countries in which it is endemic, all New York State clinicians should be aware of its potential to spread to the United States and to New York State.

The New York State Department of Health (NYSDOH) requests that all New York State providers:

- understand the transmissibility, signs, and symptoms of clade I vs. II mpox,
- be prepared to collect and submit specimens for testing,
- determine the appropriate treatment and therapy, and
- provide vaccination to anyone with risk factors for mpox or those with a recent exposure to mpox (as post-exposure prophylaxis).

Laboratories which have the capability to provide molecular testing for mpox should continue to perform testing using a non-variola orthopoxvirus (NVO) target as well as a clade II target for routine mpox testing. Laboratories that obtain a result indicating a potential clade I result (positive NVO, negative clade II test) should contact their local health department immediately and forward specimens to the Wadsworth Center or New York City Department of Mental Health and Hygiene Public Health Laboratory for analysis. If clade I mpox is suspected, specimens

should be sent to the appropriate public health laboratory for testing. Further guidance on mpox specimen submission is available here: Mpox for Healthcare Providers (ny.gov)

While clade II mpox has spread primarily via sexual contact and has disproportionately affected gay, bisexual, and other men who have sex with men, the transmission patterns of clade I mpox in a global context are not yet known. NYSDOH will continue to update all partners as more is learned about patterns of transmission of clade I mpox and will provide updates to vaccine and other recommendations accordingly.

**Vaccination:**

The JYNNEOS vaccine, which is the principal vaccine currently deployed for use against clade II mpox, is also effective against clade I. The JYNNEOS vaccine is available for commercial ordering in a manner similar to other vaccines and is covered by Medicare and Medicaid, and it is expected that commercial insurance will cover the vaccine as well. New York State continues to take steps to make the JYNNEOS vaccine as accessible as possible, including by permitting pharmacists to administer mpox vaccines.

New York State healthcare providers, especially those who serve New Yorkers disproportionately affected by clade II mpox, are highly encouraged to consider maintaining a supply of JYNNEOS vaccine or identifying available referral pathways for patients who are eligible for and seek vaccination.

Providers seeking to order vaccine can find a list of JYNNEOS distributors on the Bavarian Nordic website.

Providers who have a supply of vaccine on hand should ensure that their site is properly registered to appear on the CDC's mpox vaccine finder.

**Reporting:**

Confirmed or suspected cases of mpox are reportable to the local health department (LHD) of the county in which the patient resides.

- Outside of NYC, contact information for LHDs is available at: https://www.health.ny.gov/contact/contact_information. If unable to reach the LHD where the patient resides, contact the NYSDOH Office of Sexual Health and Epidemiology at: 518-474-3598 during business hours or 866-881- 2809 evenings, weekends, and holidays.
- For NYC residents, report to the NYC Health Department's Provider Access Line at 866-692-3641.

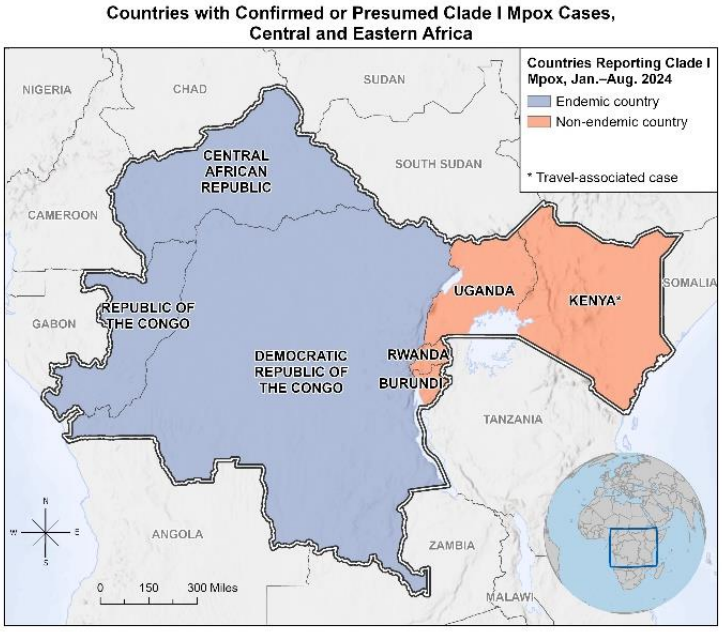
Questions about mpox or mpox vaccine can be directed to NYSDOH at mpox@health.ny.gov.

**Clinical and public health management of clade I mpox in the United States**

**SUMMARY**: This document outlines CDC's current recommendations for the clinical and public health management of clade I monkeypox virus (MPXV) in the United States. Although no cases of clade I mpox have been reported in the United States, the potential for clade I mpox to result in more severe clinical disease and higher mortality, as well as uncertainty around transmission patterns compared to clade II mpox necessitates domestic preparedness efforts. CDC continues to monitor the epidemiology and disease course of clade I, including both sub-clades (clade Ia and clade Ib), in the Democratic Republic of Congo and neighboring countries currently experiencing outbreaks. We will update these recommendations as more information is available.

The recommended clinical management of clade I mpox, consistent with current mpox clinical guidance, calls for a treatment approach based on the severity of mpox at diagnosis and the potential for development of complications because of comorbid conditions. CDC is reinforcing existing diagnostic and clinical recommendations, and suggesting some additional public health measures, to prevent further transmission of clade I mpox in the event that it is diagnosed in the United States. Specifically:

- Rapid clade-specific testing of any mpox patients with travel history to the Democratic Republic of the Congo or its neighboring countries, or of those who have had exposure to travelers from this region;
- Isolation of persons with possible clade I mpox pending and following orthopoxvirus and mpox clade differentiation testing results;
- Active monitoring of all high and some intermediate risk exposure contacts;
- Close clinician, state/local health department, and CDC collaboration to monitor the clinical course of patients with clade I mpox where possible. This monitoring will help increase understanding of the clinical severity and transmission patterns of clade I mpox in the United States.




This guidance may be updated based on experience gained from any initial cases of clade I mpox observed in the United States. The intensity of efforts to contain spread may be scaled up or down depending on the lessons learned from the management of any initial U.S. cases. If multiple clade I cases are detected simultaneously in disparate geographic areas of the United States with evidence of ongoing domestic transmission, this guidance may be updated accordingly.

**Background**

MPXV has two distinct genetic clades, I and II, which are endemic to Central and West Africa respectively. Clade II is responsible for the global mpox outbreak that began in 2022, which was predominantly transmitted through intimate and sexual contact and disproportionately affected gay,

bisexual, and other men who have sex with men (MSM). Clade I MPXV has previously been observed to be more transmissible and to cause a higher proportion of severe infections than clade II MPXV.

Clade I mpox has never been reported in the United States and the risk to the general population in the United States remains very low. However, a sustained increase in clade I mpox cases reported in the Democratic Republic of Congo (DRC) during 2023-24, cases recently reported in neighboring countries, including in urban areas where transmission might accelerate, as well as a case reported in Sweden, emphasizes the need to be prepared for the possibility of introduction of clade I mpox into the United States.

**Diagnosis**

Laboratory diagnosis of mpox is performed by testing lesions using real-time PCR-based tests available at many large commercial laboratories and state public health labs. Mpox specimens regardless of clade have the same biosafety considerations, but specimens identified as clade I MPXV are regulated as a select agent. The CDC-developed, FDA 510(k)-cleared, non-variola orthopoxvirus (NVO) test will detect both clades of MPXV but is unable to distinguish between them. Multiple laboratories in the United States currently perform clade-specific testing (via PCR and/or sequencing), with some of these laboratories using an EUA authorized multi-target PCR test, where specimens that are NVO positive and clade II negative are flagged for additional testing. CDC also provides clade differentiation testing on NVO-positive specimens referred from a large number of U.S. laboratories. In addition, several public health laboratories (PHLs) in the United States have developed or are developing and onboarding MPXV-clade-specific laboratory developed tests (LDT) that will expand this capability. CDC is developing an mpox triplex assay, which includes targets that are clade I- and clade II-specific, as well as an NVO target. CDC has submitted a pre-Emergency Use Authorization (EUA) package to the Food and Drug Administration (FDA) for review that, if approved, would provide this test to public health labs to be used under EUA, further expanding mpox clade differentiation capacity in the United States.

A standardized national surveillance case definition for mpox has been in place since 2022. Mpox is a national notifiable condition and the Council for State and Territorial Epidemiologists (CSTE) recommends that all states and territories make mpox cases reportable in their jurisdiction. CDC has posted interim case definitions for clade I mpox that are to be applied to the current situation in which clade I outbreaks are limited to known endemic areas in Africa with no evidence of widespread transmission in other continents. To fulfill the criteria for a suspect or probable case of clade I mpox under the interim case definitions, one must be a case of probable or confirmed mpox according to the standardized national case definition for mpox, as well as fulfill interim clade I epidemiologic criteria.

**Clinical and public health management of clade I mpox in the United States**
**Clinical management of clade I mpox in the United States**
In light of the ongoing clade I mpox outbreak in Central and Eastern Africa, CDC recommends clinicians and jurisdictions in the United States maintain a heightened index of suspicion for mpox in patients who have recently been in DRC or to any country sharing a border with DRC (Republic of the Congo, Angola, Zambia, Rwanda, Burundi, Uganda, South Sudan, Central African Republic) and present with signs and symptoms consistent with mpox. If mpox is suspected in a patient with travel history or other epidemiologic link to the current clade I mpox outbreak, clinicians are advised to contact their state/local public health laboratory (PHL) to determine where to obtain clade-specific testing as per CDC clinical testing guidance, noting CDC guidelines for collection and handling specimens for mpox testing.

Regardless of clade, mpox cases in the United States should be managed clinically according to the severity of illness, or the potential for the development of severe mpox illness due to underlying severe immunocompromising (e.g., HIV CD4 <200 or similar severe immunocompromise) or other conditions (e.g., presence of atopic dermatitis or other conditions affecting skin integrity).

- Interim clinical guidance for treatment of mpox can be found here: Treatment Information for Healthcare Professionals | Mpox | Poxvirus | CDC
- Interim clinical treatment considerations for severe manifestations can be found here: https://www.cdc.gov/mmwr/volumes/72/wr/mm7209a4.htm?s_cid=mm7209a4_w

Clinicians evaluating persons with suspected mpox, should be aware of CDC's guidance for infection prevention and control of mpox in healthcare settings, which specifies recommended protective measures, including PPE, that apply to all types of mpox regardless of clade.

*Public health notification*

Clinicians diagnosing mpox, regardless of clade, should follow state and/or local mpox reporting requirements, and are encouraged to collaborate with their state and local health departments to submit case information as per CDC case reporting recommendations for health departments. Clinicians with a patient in whom mpox is diagnosed based on the presence of a compatible clinical presentation, and in whom there is a potential epidemiologic link to clade I mpox as per interim clade I epidemiologic criteria, should contact the state and/or local health department where the patient resides promptly to report the possibility of a clade I mpox case. A CSTE website listing 24/7 Epidemiology on call numbers for states and large cities can be found here: https://www.cste.org/page/EpiOnCall

Although clade-specific test results do not inform clinical management decisions, clinicians should be aware that public health management of patients with possible clade I mpox illness as described in the following section is being recommended to help contain the spread of clade I MPXV. This is true - even pending results of clade-specific testing - for patients in whom clade I mpox is suspected based on their having a compatible clinical presentation and fulfilling interim clade I epidemiologic criteria.

Following notification of the local or state health department (HD) of a case of clade I mpox, the state HD and diagnosing clinician are encouraged to contact the CDC Emergency Operations Center (EOC) at 770-488-7100 and request a clinical mpox consult, regardless of the severity of illness. Such clinical consults are an opportunity to collect detailed information on clinical manifestation and disease progression within the United States in a standardized manner to inform future recommendations for clinical and public health management of clade I mpox in this country.

**Public health management of clade I mpox in the United States**:

These public health management recommendations are intended to be used with the initial suspect, probable, or confirmed case of clade I mpox as per the interim clade I mpox case definition in the United States, or initial group of such cases (if closely clustered in time).

These recommendations are also intended to serve as the foundation for updated public health management recommendations for clade I mpox informed by observations of any initial or initial group of clade I mpox cases in the United States. The following recommendations for public health management of clade I mpox are intentionally cautious to maximize likelihood of preventing further transmission until additional evidence is collected and evaluated.

In patients in whom there is a high degree of suspicion for clade I mpox based on a compatible clinical presentation and an epidemiologic link to clade I mpox, and in any patient who meets the interim case definition for clade I mpox, the following infection prevention measures are recommended:

1. Isolation / activity restrictions:
    a. The patient should isolate at home or in an alternative location pending results of clinical testing for mpox if their clinical status enables outpatient management. If mpox result is negative through diagnostic testing, only those infection prevention measures applicable to diagnoses remaining under consideration need to be followed. If there is laboratory confirmation of mpox, CDC-recommended mpox activity restrictions should be followed until mpox has resolved.
    b. Health care providers managing patients with suspected mpox should review and follow CDC recommendations for infection prevention and control of mpox in healthcare settings.
    c. Health care facility discharge considerations should include assessment of the ability of the patient to carry out isolation and infection control recommendations in their home or other setting prior to discharge, and in situations where this may not be possible, alternative isolation locations should be considered[1].

2. Contact tracing:
    a. A public health interview should be conducted to elicit names and contact information for all high and intermediate risk contacts going back 4 days prior to illness onset, and ending with the resolution of the illness (or the time of the interview, if illness is not resolved).

Isolation of the possible clade I mpox case-patient and contact tracing should proceed, even while laboratory confirmation of clade I mpox is pending. Any probable or confirmed case of mpox, regardless of clade, should be reported promptly (within 24 hours) to the state/local health department.

**Management of contacts of clade I mpox cases:**
Health departments are encouraged to support and assist with the notification of contacts of any clade I mpox cases promptly, consistent with applicable state and local laws and policies, given uncertainty about transmission patterns and severity of illness in the U.S. context. Exposed contacts who are symptomatic at the time of notification and have not yet been evaluated by a doctor or other qualified clinician should have a prompt in-person clinical evaluation, and clade-specific mpox diagnostic laboratory testing if indicated. Symptomatic contacts should isolate as per CDC recommended mpox activity restrictions, pending results of diagnostic testing.

Eliciting and notifying contacts of those persons identified as contacts of mpox cases ("contacts of contacts", or secondary contact tracing), is not expected to be useful, and will not be recommended unless observations of unusual transmission patterns suggest potential utility.

1. [1]Isolation and Infection Control At Home | Mpox | Poxvirus | CDC
2. Cleaning and Disinfecting Your Home, Workplace, and Other Community Settings | Mpox | Poxvirus | CDC

The approach to contact monitoring for mpox is based on exposure risk. Criteria for risk assessment for mpox exposures, which applies to mpox caused by any MPXV clade, can be found on the CDC webpage Mpox Monitoring and Risk Assessment for Persons Exposed in the Community. The recommended approach to monitoring contacts of possible clade I mpox cases pending results of clade-specific testing, and suspected, probable or confirmed clade I mpox cases is the following:

High-risk exposure

- Active monitoring by health department with daily phone calls, texts, or emails for 21 days. Any mpox symptoms or skin lesion requires timely in-person evaluation by a clinician, and clade-specific mpox diagnostic testing if indicated.
- Activity restriction as per current CDC guidance
- Curtail travel during the monitoring period if their travel plans would not allow for isolation and access to prompt medical evaluation if symptoms develop as per the guidance for exposed contacts who become symptomatic below.
- Mpox vaccine (if not already fully vaccinated) may be offered as post-exposure prophylaxis if within acceptable post-exposure timeframe. Fully vaccinated is defined as receipt of 2 doses of JYNNEOS or 1 dose of ACAM 2000).

Intermediate exposure risk

- Self-monitoring for 21 days, in most cases, with the exceptions being immunocompromised patients and children, who should have active monitoring. Any exposed contact who has or develops mpox symptoms should be promptly evaluated by a qualified clinician, and clade-specific mpox diagnostic laboratory testing if indicated.
- Activity restriction as per current CDC guidance
- Curtail travel during the monitoring period if their travel plans would not allow for isolation and access to prompt medical evaluation if symptoms develop as per the guidance for exposed contacts who become symptomatic below.
- Mpox vaccine (if not already fully vaccinated) may be offered as post-exposure prophylaxis if within acceptable post-exposure timeframe. Fully vaccinated is defined as receipt of 2 doses of JYNNEOS or 1 dose of ACAM 2000)

Low exposure risk

- Self-monitoring as per current CDC recommendations

**Considerations for pediatric patients:**

Historical observations of clade I mpox transmission in the DRC note that a substantial portion of mpox transmission occurs within households and many cases are reported in children under 15 years of age. Household transmission is not anticipated to be a major driver of U.S. clade I spread. However, if pediatric cases are among the initial clade I mpox cases diagnosed in the United States, aggressive clinical management may be warranted, pending further information. **Preventing transmission from pediatric cases and the monitoring of exposed pediatric contacts will have different operational challenges that should be proactively considered by state and local health departments**. CDC and relevant public health will consider appropriate recommendations in the event warranted for pediatric cases.

If you have questions on these recommendations please direct them to poxvirus@cdc.gov (during regular business hours) or call the CDC Emergency Operations Center (770-488-7100).