



Maine Center for Disease Control and Prevention
11 State House Station
Augusta, Maine 04333-0011
Phone: (800) 821-5821 / Fax: (207) 287-7443

Maine Health Alert Network (HAN) System

PUBLIC HEALTH ALERT

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From: Dr. Isaac Benowitz, State Epidemiologist
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Updates on Monkeypox Testing, Vaccination, and Treatment in Maine

Summary

The global outbreak of monkeypox continues to grow in Maine and across the United States. Most cases have been identified in urban areas in other states. More cases are expected in Maine. Nationwide, the outbreak remains largely confined to [gay, bisexual, or other men who have sex with men and transgender, gender non-conforming, or non-binary individuals who have sex with men](#), although some infections have been identified in other people.

This health advisory provides updates on three key areas for clinicians: testing, vaccination, and treatment. In short,

- Patients with possible monkeypox infection should be tested for monkeypox for clinical and public health purposes. Proper specimen collection is crucial to correct identification. Patients who are for monkeypox who have multiple partners should also be tested for HIV, syphilis, gonorrhea, and chlamydia, as well as other infections if clinically indicated, and might be eligible for HIV PrEP.
- [The Jynneos vaccine is available at several locations in Maine](#) for people who have on-going risk factors for exposure to monkeypox (currently defined as gay, bisexual, or other men who have sex with men and transgender, gender non-conforming, or non-binary individuals who have sex with men) and for post-exposure prophylaxis for people with known exposure to monkeypox.
- The antiviral medication tecovirimat may be beneficial in patients with severe disease, including painful, invasive, or other severe manifestation, and in patients at risk for severe disease due to immunocompromise, altered skin integrity, pregnancy, or young age. A positive test is **not** needed prior to initiating therapy. Informed consent is required prior to treatment. Additional regulatory requirements apply for all clinicians prescribing tecovirimat. [Several health care locations in Maine](#) have tecovirimat; any clinician can write a prescription for a patient to fill at certain pharmacies.

Introduction

As of September 6, 2022, there were 20,733 reported monkeypox cases in the U.S., including 7 in Maine. It is likely that many other monkeypox infections are occurring without any report to public health authorities, and it is likely that there is a spectrum of clinical illness and possibly asymptomatic transmission, as many people with monkeypox infection cannot identify prior contact with someone with monkeypox or a compatible rash. Several elements of the public health response continue to evolve, including who to test for monkeypox, how to conduct testing, vaccine supply and eligibility, who to treat, how to prescribe antiviral therapy, and where to access antivirals in Maine.

Identification

Recent [case data](#) indicate that most case patients identify as men, with a much smaller proportion who identify as women, transgender men, transgender women, or other gender identity. The most common [signs and symptoms](#) include rash (97.5%), fever (66.4%), malaise (63.7%), chills (61.4%), headache (57.5%), lymphadenopathy (57.1%), myalgias (55.6%), pruritis (55.4%), and rectal pain (43.3%). U.S. CDC's [Monkeypox Clinical Recognition](#) page contains more information on the clinical presentation of monkeypox, including photos of monkeypox lesions and other lesions that could be confused with these.

Several individuals who tested positive for monkeypox infection in the State of Maine report having visited several other healthcare facilities with rash-like illness prior to getting tested for monkeypox at a different facility. Clinicians should keep monkeypox in mind when evaluating patients with rash-like illness, particularly for those patients who identify as gay, bisexual, or other men who have sex with men, and transgender, gender non-conforming, or non-binary individuals who have sex with men, who have multiple or anonymous partners, or have recently been in contact with someone with monkeypox.

Clinicians should also ensure the use of proper infection control practices when evaluating patients with monkeypox or other rash illness to prevent transmission to healthcare personnel or other patients. Further information is available from U.S. CDC's [Infection Prevention and Control of Monkeypox in Healthcare Settings](#) and from Maine CDC's [Healthcare Associated Infection Resources](#) page.

Testing

Monkeypox infection can be confirmed by a PCR test run on a swab of a lesion. Multiple lesions should be tested because of the possibility of concurrent rash illnesses. Testing is available at several commercial laboratories and is also available at Maine's Health and Environmental Testing Laboratory. Maine CDC strongly encourages healthcare providers to use commercial laboratories for monkeypox testing. There are no commercially-available tests available for people without any visible lesions.

Proper specimen collection is crucial to correct identification of monkeypox cases. Vigorous swabbing is often needed. Lesions do **not** need to be unroofed. Collection methods such as swab type, transport medium, and shipping temperature may vary by the laboratory used. U.S. CDC has developed resources for specimen collection addressing [Testing Patients for Monkeypox](#) and [Tips for Adequate Collection of a Lesion Specimen from a Suspect Monkeypox Virus Case](#).

The rash of monkeypox overlaps in appearance with other conditions; patients have presented with monkeypox concurrently with other rash illnesses. Additionally, monkeypox is currently circulating predominantly among gay, bisexual, and other men who have sex with men who have multiple or anonymous partners, a group at risk for other STIs. Clinicians evaluating patients with possible monkeypox infection should strongly consider testing for **HIV, syphilis, gonorrhea, and chlamydia**. Other testing might be clinically indicated for lymphogranuloma venereum, herpes simplex virus, or other bacterial, viral, or fungal infections based on a patient's presenting symptoms and exam.

Vaccination

[Jynneos](#) is a live, non-replicating viral vaccine for prevention of smallpox and monkeypox. On August 9, 2022, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) [allowing intradermal administration](#), which uses a smaller dose with the same expected immunological response. A vial of Jynneos could be used for one subcutaneous dose or 4–5 intradermal doses, greatly extending the vaccine supply and allowing access to a larger population.

The route of access to be used depends on the person’s age and underlying medical conditions:

- **Jynneos must be given via the intradermal route for people 18 years and older.**
- **If the patient has a history of keloid formation, the subcutaneous route should be used.**
- **For people under 18 years old, the subcutaneous route must be used for all patients.**

The vaccine ships frozen; thawed vaccine can be held for 8 weeks in a refrigerator. Each vial should be discarded within 8 hours after the first puncture. Further information on dosing, storage, and handling is available in at [FDA’s EUA](#) and the attached [fact sheet for providers](#). U.S. CDC’s [Jynneos](#) webpage has educational resources for intradermal administration, including figures and a short video tutorial.

Vaccination is available to individuals of all ages who meet at least one of the criteria below:

- Gay, bisexual, or other men who have sex with men
- Transgender, gender non-conforming, or non-binary individuals who have sex with men
- Individuals exposed to someone with monkeypox in the past 14 days who were notified of the exposure by a public health agency OR by a person with monkeypox

Additional groups may be added as vaccine supply increases. These criteria, along with a list of locations offering vaccine, are available on [Maine CDC’s Monkeypox website](#).

Vaccination is also available to laboratory workers who work with specimens that could contain monkeypox: [Orthopox Vaccine Guidance for Persons at Risk of Occupational Exposure](#). At this time, vaccination is not yet available to all healthcare workers or to other groups in the general community.

Treatment

Monkeypox infections can be painful, debilitating, and life-threatening. Moderate to severe illness might benefit from targeted therapy. Patients may also benefit from a collaborative approach to care including pain management, dermatology, gastroenterology, urology, and other medical specialties.

Currently, most monkeypox infections are being identified in men who have multiple sexual partners, and who might be at risk for other STIs and other infections. People with multiple sexual partners might be candidates for **HIV pre-exposure prophylaxis (PrEP)**. If they are not infected with monkeypox, they might be candidates for **monkeypox vaccine**. For further information, see [U.S. CDC’s Sexually Transmitted Infection Treatment Guidelines](#).

[Tecovirimat](#) (TPOXX) is an antiviral with excellent activity against smallpox and monkeypox. It is available in oral and intravenous (IV) formulation. It is indicated for treatment of smallpox, and it is available under an Expanded Access Investigational New Drug (EA-IND, also called compassionate use) regulatory framework, including for treatment of certain manifestations of monkeypox infection, and for post-exposure prophylaxis in narrow circumstances. **Patients do not need a positive test for monkeypox prior to initiating therapy. The only requirement prior to initiating treatment is informed consent. Additional steps, listed below, can be completed after initiating treatment.**

All patients with monkeypox should be tested for monkeypox and many of these patients should be tested for other STIs. All clinical care can be delivered via telemedicine, including obtaining informed consent. However, it might be necessary to see a patient in person at least once to perform a thorough exam of the skin and mucosal areas, test for other STIs, and obtain any desired screening lab testing prior to initiation of therapy, however this is not required and should not be a barrier to treatment.

The State of Maine has placed supplies of oral and IV TPOXX with hospitals, urgent care and walk-in care sites, STI clinics, and pharmacies to provide access for hospitalized patients and non-hospitalized patients. Maine CDC's [Monkeypox](#) webpage lists locations where patients can be treated with TPOXX and also lists pharmacies that can dispense TPOXX to patients with a valid prescription.

[Clinicians prescribing tecovirimat](#) for the treatment of monkeypox must:

- File an [FDA Form 1572](#) to provide liability coverage for this medication under the PREP Act. **This form should be submitted to RegAffairs@cdc.gov. It should not be sent to Maine CDC.**
- Obtain **informed consent** ([English](#), [Spanish](#), or use the [Short Form Consent](#) and [Written Summary](#))
- Complete a **clinical assessment**, using the [Patient Intake Form](#), prior to initiating treatment.
- Report **adverse events** with the [FDA MedWatch form](#) to U.S. CDC at RegAffairs@cdc.gov or via [ShareFile](#).
- *Optionally*, complete the [Clinical Outcome Form](#) during and after treatment, [patient diary](#), photos of lesions, and collect [lesion samples for resistance testing](#) and [pharmacokinetic samples for testing](#).

Maine CDC clinician updates

Please join Maine CDC for a monthly call with updates for clinicians on monkeypox and other areas. This monthly call, on the 2nd Tuesday of the month from 12–1pm, also includes COVID-19 updates, and slides are posted afterward to the [Monkeypox Information for Healthcare Providers](#) webpage.

Maine CDC Clinician Informational Session: COVID-19 and monkeypox

Held on the 2nd Tuesday of every month at 12pm

Upcoming sessions: September 13, October 11, November 8, December 13

<https://mainestate.zoom.us/j/83384535429>

Meeting ID: 833 8453 5429

Mobile: +13017158592,,83384535429# (DC) or +13126266799,,83384535429# (Chicago)

Find your local number: <https://mainestate.zoom.us/u/keev9ZGoew>

For More Information

- [Maine CDC: Monkeypox](#)
- [Maine CDC: Monkeypox Information for Healthcare Providers](#)
- [U.S. CDC: JYNNEOS Vaccine](#) (includes videos and images for intradermal administration)
- [U.S. CDC: Information for Healthcare Providers on Obtaining and Using TPOXX \(Tecovirimat\) for Treatment of Monkeypox](#)
- [U.S. CDC's Sexually Transmitted Infection Treatment Guidelines](#)