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**TO:** Massachusetts Healthcare Providers, Hospitals, Community Health Centers and EMS  
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**SUBJECT:** Clinical and Laboratory Testing Guidance for Monkeypox

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#### Key Messages and Updates

- Massachusetts has now expanded eligibility for vaccination with JYNNEOS to include pre-exposure vaccination for those at increased risk for monkeypox. JYNNEOS vaccine has been widely deployed for expanded postexposure prophylaxis (PEP and PEP++).
- Cases of monkeypox in Massachusetts have declined substantially since the peak in late July and early August, but transmission is ongoing and providers need to maintain vigilance to identify new cases. Clinicians should be alert to the possibility of monkeypox virus infection in patients with a new onset, clinically compatible skin rash, particularly in those at risk for exposure.
- Patients that meet specific criteria can be tested through the State Public Health Laboratory without calling for pre-approval; testing through commercial laboratories is available for patients that do not meet criteria.
- Patients undergoing testing should isolate until monkeypox virus infection is ruled out.
- Treatment with Tecovirimat (TPOXX) under an IND protocol is available for patients with, or at risk for, severe disease. CDC has updated guidance for treatment of monkeypox with tecovirimat (TPOXX) and has provided additional guidance for treatment of those with severe disease. Guidance on how to obtain and dispense TPOXX in Massachusetts is included.

#### [ABOUT MONKEYPOX](#)

#### [RECOMMENDATIONS FOR CLINICIANS](#)

#### [LABORATORY TESTING AND SPECIMEN COLLECTION](#)

##### [Laboratory testing at SPHL](#)

##### [Laboratory testing at commercial/reference laboratories](#)

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**PUBLIC HEALTH RECOMMENDATIONS PENDING TEST RESULTS**  
**TREATMENT FOR MONKEYPOX**  
**POST-EXPOSURE VACCINATION FOR HIGH RISK MONKEYPOX CONTACTS**

**ABOUT MONKEYPOX:**

On May 18, the Massachusetts Department of Public Health (MDPH) reported the first case of monkeypox virus infection in a Massachusetts resident. Additional cases have been identified in Massachusetts since then with thousands of cases nationally and globally. Cases of monkeypox in Massachusetts peaked in late July to early August and currently continue to occur at a lower rate. **While many of the identified cases are within networks of self-identified gay and bisexual men, other men who have sex with men, and transgender individuals who have sex with men, people of any sexual orientation or gender identity can become infected and spread monkeypox.**

Monkeypox is a viral illness with an incubation period of up to 21 days (typically 1 -2 weeks). Illness may begin with flu-like signs and symptoms (fever, chills, malaise, headache, muscle aches/back aches) and swelling of the lymph nodes and progresses to a rash that can look like pimples or blisters that appears on the face, inside the mouth, and on other parts of the body, like the hands, feet, chest, genitals, or anus. Cases identified during this current outbreak may present only with rash illness without any other symptoms or may also develop mucosal lesions or proctitis. Most infections last 2-to-4 weeks and people are considered infectious throughout duration of symptoms.

The virus does not spread easily between people; transmission most frequently occurs through direct contact with monkeypox rash lesions, scabs, or body fluids. The virus can also be spread through contact with fomites (items that touched the rash lesions or body fluids (clothing, bedding, etc.)), or through large respiratory droplets following prolonged face-to-face contact.

Monkeypox lesions typically progress through specific stages—macules, papules, vesicles, and pustules—before scabbing and falling off. The characteristic lesions are deep-seated and well-circumscribed, often with central umbilication. More information supporting clinical recognition of the disease is available through the Centers for Disease Control and Prevention website at: <https://www.cdc.gov/poxvirus/monkeypox/clinicians/clinical-recognition.html>. Monkeypox can occur concurrently with other illnesses, including other rash illnesses such as varicella-zoster virus, herpes simplex virus or syphilis.

**RECOMMENDATIONS FOR CLINICIANS:**

**Monkeypox considerations**

Clinicians should consider testing for monkeypox virus in patients with a new onset, clinically compatible skin rash (exhibiting macular, papular, vesicular, or pustular lesions; generalized or localized; discrete or confluent; mucosal lesions; or proctitis). Known risk factors that increase the likelihood of monkeypox virus infection include individuals who in the previous 21 days:

- 1) report close contact with a person or people with confirmed or suspected monkeypox; OR
- 2) report close contact with a person or people who have a similar rash; OR

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- 3) report they are a man (individual assigned male sex at birth) who has sex with men, or a transgender man who has sex with men, who regularly has proximate physical, sexual, or other close contact with other men, including encounters with individuals met through online dating applications or in social venues; OR
- 4) report residence in or travel to endemic areas of Africa and had contact with wild animals, especially small rodents.

**However, clinicians should consider testing clinically compatible patients regardless of whether they have known risk factors for monkeypox and regardless of gender or sexual orientation.**

Although transmission of monkeypox from patients to healthcare workers happens rarely and is primarily associated with needlestick injuries, suspect monkeypox cases should be evaluated clinically using contact and droplet precautions (gloves, eye protection, surgical mask (N95 optional unless aerosol generating procedures are being performed), and a gown or disposable covering).

### **Co-infection considerations**

Patients who are at risk for exposure to monkeypox virus through sexual activity are also at risk for sexually transmitted infections and diagnostic testing should be comprehensive; coinfections are not uncommon. All patients with monkeypox who are not known to have HIV, should be tested for HIV.

Clinicians should also rule out more common causes of rash illness while considering monkeypox. Other diseases that can cause similar appearing rash lesions include:

- herpes
- secondary syphilis
- chancroid
- varicella-zoster virus

### **LABORATORY TESTING AND SPECIMEN COLLECTION:**

Testing for non-variola orthopoxvirus (presumptive monkeypox virus) infection is available from the State Public Health Laboratory (SPHL) and is available from commercial laboratories. Testing turn-around-time is expected to be somewhat shorter through SPHL and is available for:

- Clinically compatible patients with a known risk factor; OR
- Patients for whom there is a strong clinical suspicion of monkeypox who are hospitalized; OR
- Patients for whom there is a strong clinical suspicion of monkeypox and are at high risk of more severe disease<sup>†</sup> (e.g. pregnant people, children under 8 years of age, individuals with immune compromise, or people with concurrent disease/co-morbidities); OR
- Patients for whom there is a strong clinical suspicion of monkeypox in a congregate setting; OR
- Patients for whom cost of commercial testing is a concern.

<sup>†</sup>More information about individuals at high risk for severe disease is available from CDC here:

<https://www.cdc.gov/poxvirus/monkeypox/clinicians/treatment.html>.

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### **Laboratory testing at SPHL**

***Pre-approval for submission of specimens from patients that meet the criteria listed above is not required.*** Submission of specimens to SPHL from patients that do not meet those criteria does require pre-approval through the MDPH Division of Epidemiology at 617-983-6800 (available 24/7).

Acceptable specimen types include dry swabs of crusts and/or fluid from an active, open lesions; dry swabs of an intact vesicle or pustule; or a scab from a lesion. Providers may submit samples from up to 2 sites. Selection of lesions for sampling should focus on identifying lesions that appear different from each other. The rationale for this recommendation is that patients may have multiple diseases and swabs from two different appearing lesions enhances the ability to identify monkeypox virus if it is present. SPHL is not able to test submitted specimens for other pathogens. Note that there are no acceptable specimen types for testing PRIOR to the development of rash lesions.

**Complete specimen collection, labelling and packaging and shipping guidance for specimens sent to the State Public Health Laboratory is available and can be viewed here:**

**<https://www.mass.gov/doc/instructions-for-specimen-collection-for-orthopoxvirus-testing/download>.**

**Please note that duplicate samples are no longer necessary and should not be submitted; however, swabs from up to two different lesions per patient may be submitted. Throat swabs should not be submitted but swabs of oropharyngeal lesions are acceptable.**

### **Laboratory testing at commercial/reference laboratories**

Patients who don't meet the criteria for testing through SPHL can be tested through commercial or reference laboratories. Healthcare providers should consider ordering diagnostic tests for other infections, as clinically indicated, in addition to monkeypox virus. As of the date of this guidance, testing is available through:

- **Labcorp** <https://www.labcorp.com/tests/140230/monkeypox-orthopoxvirus-dna-pcr>
- **Quest Diagnostics** <https://testdirectory.questdiagnostics.com/test/test-detail/12084/monkeypox-virus-dna-qualitative-real-time-pcr?q=monkeypox&cc=MASTER>
- **Aegis Sciences Corporation** <https://www.aegislabs.com/our-services/monkeypox>
- **Sonic Reference Laboratory** [https://directory.sonicreferencelab.com/tests?iframe\\_layout=srl](https://directory.sonicreferencelab.com/tests?iframe_layout=srl)
- **ARUP** <https://ltd.aruplab.com/Tests/Pub/3005716>

**Questions about testing should be directed to the MDPH Division of Epidemiology at (617) 983-6800 available 24/7.**

### **PUBLIC HEALTH RECOMMENDATIONS PENDING TEST RESULTS:**

Anyone who is being tested for monkeypox is considered a Person Under Investigation (PUI) and should be told to isolate pending test results. Isolation at home is preferred and means staying away from household members to the extent possible. The PUI should cover all lesions and wear a mask at any time they are around anyone else. Household members should also mask if they must be in the same room. The PUI should have their own bedroom and should use a separate bathroom from household members (if possible). Disinfection of high touch surfaces in a shared bathroom and kitchen between uses should be performed. Standard household cleaning/disinfectants may be used in accordance with the manufacturer's instructions. Information about how to safely isolate at home is available from CDC at <https://www.cdc.gov/poxvirus/monkeypox/clinicians/infection-control-home.html>.

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## **TREATMENT FOR MONKEYPOX:**

Most cases associated with the recent outbreak have had self-limiting disease not requiring hospitalization. However, certain conditions are associated with the possibility of more severe disease. Although there is no treatment specifically approved for monkeypox virus infections, the antiviral tecovirimat (TPOXX), developed for use in patients with smallpox, is available for use, including presumptive use prior to laboratory test results.

When considering the use of tecovirimat, clinicians and patients should understand 1) the lack of tecovirimat effectiveness data to date in people with monkeypox, 2) the lack of data indicating which patients might benefit the most from tecovirimat, and 3) the concern for the development of resistance to tecovirimat, which could render the drug ineffective for any treated patients.

Patients who should be considered for treatment include:

- People with severe disease (e.g., hemorrhagic disease, confluent lesions, sepsis, encephalitis, or other conditions requiring hospitalization)
- People with involvement of an anatomic area which might result in serious sequelae that include scarring or strictures
  - Lesions involving pharynx causing dysphagia, inability to control secretions or need for parenteral feeding
  - Lesions involving penile foreskin, vulva, vagina, urethra or rectum with the potential for causing strictures or requiring catheterization
  - Anal lesions interfering with bowel movements
  - Severe infections (including secondary bacterial skin infections), especially those that require surgical intervention such as debridement
- People who may be at high risk of severe disease:
  - People with severe immunocompromise (e.g., advanced or poorly controlled human immunodeficiency virus/acquired immune deficiency syndrome infection, leukemia, lymphoma, generalized malignancy, solid organ transplantation, therapy with alkylating agents, antimetabolites, radiation, tumor necrosis factor inhibitors, high-dose corticosteroids, 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 autoimmune disease with immunodeficiency as a clinical component)
  - Pediatric populations, particularly patients younger than 8 years of age
  - People with a condition affecting skin integrity including atopic dermatitis, eczema, burns, impetigo, varicella zoster virus infection, herpes simplex virus infection, severe acne, severe diaper dermatitis with extensive areas of denuded skin, psoriasis, or Darier disease [keratosis follicularis])
  - Pregnant or breastfeeding people

For patients with severe manifestations of disease, prolongation of treatment length beyond the standard 14-day course may be advisable. Addition of other therapeutics like brincidofovir, cidofovir, or vaccinia immune globulin intravenous (VIGIV) may also be indicated. In these cases, providers should seek consultation with MDPH.

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Because tecovirimat does not have approval from the Food and Drug Administration for use in treating monkeypox virus infection, it is available under an expanded access Investigational New Drug (EA-IND) protocol. More information about tecovirimat is available here:

<https://www.cdc.gov/poxvirus/monkeypox/clinicians/Tecovirimat.html> and the regulatory requirements for treating patients with tecovirimat through the EA-IND are available here:

<https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html>.

Providers planning to treat a patient with tecovirimat can obtain supply of the medication by registering with the MDPH here: <https://survey123.arcgis.com/share/6e41621e8c194ac999d1ab77413a783d>.

MDPH is tracking administration of tecovirimat for individuals with suspected or confirmed monkeypox virus in Massachusetts. Providers should log every person treated with tecovirimat through the EA-IND using the REDCap survey link here: <https://redcap.ehs.mass.gov/redcap/surveys/?s=LYHCNW9YLTY4HPNJ>.

### **POST-EXPOSURE VACCINATION FOR HIGH RISK MONKEYPOX CONTACTS:**

People who are known or presumed to have been exposed to monkeypox are eligible to receive post-exposure vaccination with JYNNEOS. Vaccine is recommended to be administered within 4 days after exposure to prevent onset of disease but may be administered up to 14 days after exposure to help reduce disease severity. In the United States, the vaccine is being distributed only from the CDC and the national supply remains severely limited.

On August 9, CDC and FDA released an EUA (Emergency Use Authorization) allowing an alternative dose vaccination regimen in people 18 years and over and allowing the use of the JYNNEOS vaccine in individuals younger than 18 years. The original JYNNEOS approval included the use of two 0.5 mL doses administered subcutaneously 28 days apart. The alternative regimen allows the use of two lower doses, 0.1 mL of vaccine administered intradermally 28 days apart. Scientific evidence indicates that antibody levels following the 0.1 mL intradermal regimen are equivalent to levels following the 0.5 mL subcutaneous regimen. This equivalence exists after both the first and second doses.

**Beginning August 18, 2022, the Department of Public Health and our vaccine partners are administering JYNNEOS vaccine intradermally in most people aged 18 years and older. People less than 18 years of age and people of any age who have a history of developing keloid scars will still be vaccinated using the standard regimen administered subcutaneously.**

Some considerations for JYNNEOS vaccination include:

- People 18 years of age and older who received their first JYNNEOS dose administered subcutaneously should receive their second dose using the alternative regimen (0.1 mL administered intradermally);
- Once the JYNNEOS vial has been punctured, the vial should be kept refrigerated and the contents used within 8 hours, any remaining content should be discarded at that point;
- Healthcare providers administering JYNNEOS under the EUA are required to report the following adverse events to VAERS (<https://vaers.hhs.gov>):
  - Vaccine administration errors whether or not associated with an adverse event;
  - Serious adverse events (irrespective of attribution to vaccination);
  - Cases of cardiac events including myocarditis and pericarditis;
  - Cases of thromboembolic events and neurovascular events.

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## **Vaccine is also available for prevention of monkeypox in individuals at risk:**

As of October 3, 2022, vaccination will be available to individuals who live or work in Massachusetts and meet the CDC's current eligibility criteria, which have recently expanded to include individuals at potential risk for monkeypox in addition to those with possible recent exposure to an individual with monkeypox: Persons eligible for post-exposure vaccination (PEP) includes:

- Known contacts identified by public health via case investigation, contact tracing, and risk exposure assessments (this may include sexual partners, household contacts, and healthcare workers); as well as
- Presumed contacts who meet the following criteria:
  - Know that a sexual partner in the past 14 days was diagnosed with monkeypox
  - Had multiple sexual partners in the past 14 days in a jurisdiction with known monkeypox

In addition, CDC now allows for pre-exposure vaccination (PrEP) of persons at risk for monkeypox which includes:

- Gay, bisexual, and other men who have sex with men, transgender, gender non-conforming, or nonbinary people who
  - Have had a diagnosis of or have sought testing for one or more sexually transmitted diseases (i.e., chancroid, chlamydia, gonorrhea, or syphilis) in the past year
  - Are living with HIV infection
  - Are on or are eligible to be on HIV PrEP
  - Have recently had more than one sex partner
- People who:
  - Have had sex at a private or commercial sex venue (e.g., sex party, bathhouse)
  - Have had sex in association with a large public event (e.g., rave, circuit party) in a geographic area where monkeypox transmission is occurring
- Sexual partners of people with the above risks
- People who anticipate experiencing the above risks

When you request vaccine, you will not be asked which of these criteria applies to you. It is sufficient to say that you consider yourself to be at risk for monkeypox.

While many of the identified cases are within networks of self-identified gay and bisexual men, other men who have sex with men, and transgender individuals who have sex with men, people of any sexual orientation or gender identity can become infected and spread monkeypox.

Current information about who is eligible to receive vaccine and where to access it is available on the DPH website here: <https://www.mass.gov/info-details/monkeypox-vaccination>

## **Additional information is available on the CDC website:**

- [Interim Clinical Considerations for Use of JYNNEOS](#)
- [Video on Administering JYNNEOS Intradermally](#)
- [Intradermal Vaccine Preparation and Administration Summary](#)
- [Vaccine Administration Errors and Deviations](#)
- [Vaccine Administration Considerations for Specific Populations](#)
- [FDA EUA Fact Sheet for Providers](#)
- [FDA EUA Fact Sheet for Patients and Caregivers](#)
- [JYNNEOS Vaccine Information Statement](#)

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