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SUBJECT: Clinical and Laboratory Testing Guidance for Monkeypox

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Key Messages and Updates

- Given the severely limited national supply of JYNNEOS, beginning August 8, 2022 the Department of Public Health and our vaccine partners are prioritizing first doses for as many eligible people as possible (second dose appointments made before August 8th are to be honored and are not to be cancelled).
- 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.
- Clinicians should be alert to the possibility of monkeypox virus infection in patients with a new onset, clinically compatible skin rash, especially if they report known or suspected exposure to someone else with monkeypox.
- 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, more severe disease.

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ABOUT MONKEYPOX:

Since May 18, when the Massachusetts Department of Public Health (MDPH) reported the first case of monkeypox virus infection in a Massachusetts resident, there have been over 26,000 cases identified globally, over 7,000 in the United States and over 157 cases in Massachusetts. **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 rare 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 and herpes simplex virus infections.

RECOMMENDATIONS FOR CLINICIANS:

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
- 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.

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

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.

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).

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 increasingly available from commercial and reference 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[†] (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.

[†]More information about individuals at high risk for severe disease is available from CDC here:

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

Laboratory testing at SPHL

Pre-approval for submission of specimens from patients that meet the criteria listed above is no longer 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 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 and throat swabs (in the absence of oral lesions)

are no longer necessary and should not be submitted; however, swabs from up to two different lesions per patient may be submitted.

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

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>.

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

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 who may be at high risk of severe disease:
 - People with immunocompromise (e.g., 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 history or presence of atopic dermatitis, persons with other active exfoliative skin conditions (e.g., 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
- People with one or more complications (e.g., secondary bacterial skin infection; gastroenteritis with severe nausea/vomiting, diarrhea, or dehydration; bronchopneumonia; concurrent disease or other comorbidities)
 - People with monkeypox virus aberrant infections that include accidental implantation in eyes, mouth, or other anatomical areas where monkeypox virus infection might constitute a special hazard (e.g., the genitals or anus)

Because tecovirimat is not approved for use for monkeypox virus infection, it is available for use under an EA-IND. However, treatment can be initiated prior to completing the EA-IND process as long as patient consent has been obtained. More information about tecovirimat is available here:

<https://www.cdc.gov/poxvirus/monkeypox/clinicians/Tecovirimat.html> and the process for obtaining the drug is available here: <https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html>.

Providers planning to treat a patient with tecovirimat should contact the MDPH Division of Epidemiology at (617) 983-6800 to arrange for access to the drug.

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 is severely limited.

Given the severely limited national supply of JYNNEOS, beginning August 8, 2022 the Department of Public Health and our vaccine partners are prioritizing first doses for as many eligible people as possible (as of August 8th, second dose appointments that are already scheduled will be honored and not cancelled; no new second dose appointments will be scheduled until additional vaccine is available).

Scientific evidence indicates that a single dose of JYNNEOS provides substantial, rapid protection from monkeypox infection. A second dose given weeks to months after the primary dose will still result in boosting and provide long-term immunity. For individuals with moderate to severe immune compromise (e.g. individuals living with HIV infection who are not virologically suppressed, persons on chemotherapy and individuals who have recently received an organ transplant), second doses should still be administered using the 28 day dosing interval. Second doses for others will be made available as soon as possible when more doses are available from the CDC.

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-information-for-health-care-providers>.