NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

JAMES V. McDONALD, M.D., M.P.H.
Acting Commissioner

MEGAN E. BALDWIN
Acting Executive Deputy Commissioner

May 1, 2023

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

FROM: New York State Department of Health (NYSDOH) AIDS Institute (AI), Bureaus of Communicable Disease Control (BCDC), Immunization (BI), and Healthcare Associated Infections (BHAI)

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

SUMMARY:

- Since May 14, 2022, >86,000 cases of mpox have been reported in multiple countries worldwide where mpox virus is not endemic, including >30,000 cases in the United States.
- Data suggest that individuals who identify as gay, bisexual, and other men who have sex with men comprise the majority of reported cases in the current mpox outbreak.
- Regardless of gender identity, birth sex, sex of sex partner(s), travel, and/or specific or perceived risk factors, providers should be alert for patients who have rash illnesses consistent with mpox.
- Clinicians suspecting mpox infection should strictly adhere to infection control practices and are required to immediately notify their local health department (LHD).
- This advisory provides updates to NYSDOH Health Alert Notice for providers in New York State - July 8, 2022 .
- Key updates include:
    - Background on status of mpox outbreak, including the updated name “mpox” from “monkeypox”
    - Addition of mpox to the list of sexually transmitted infections (STIs) in New York Codes, Rules, and Regulations (NYCRR) Title 10, Section 23.1
    - NYS Vaccine Strategy (outside of NYC)
    - Testing
    - Obtaining tecovirimat (TPOXX) for treatment or postexposure prophylaxis
    - Reporting requirements

Background and Clinical Presentation of Mpox

Mpox (previously known as monkeypox) is an infectious disease caused by the orthopoxvirus: monkeypox virus. In November 2022, the World Health Organization announced that “mpox”

would be used as the preferred term for monkeypox. The New York State Department of Health (NYSDOH), along with the U.S. Centers for Disease Control and Prevention (CDC) have updated their terminology accordingly.

Symptoms of mpox can include a flu-like prodrome followed by a rash. In some cases, the rash may predate other symptoms, while others experience only the rash. These rashes can appear like pimples or blisters most often in mucosal areas such as the mouth, or the anogenital or rectal areas. The rash may remain limited to these regions or spread to the face, torso, or extremities. Lesions proceed through different stages of healing which typically last 2–4 weeks. The lesions remain infectious until new skin formation has occurred. The progression of these lesions can be seen here: Centers for Disease Control and Prevention (CDC) Mpox Clinical Recognition webpage).

Significant pain is commonly associated with the rash and lesions. Pain may interfere with basic functions such as eating, urination, and defecation which can cause distress and compound problems for the patient. Co-infections with STIs, group A streptococcal infection, and other viruses have also been reported. With the presentation of symptoms, it is important to evaluate for and treat other potential infections as deemed appropriate.

While the incidence of mpox is currently low in New York State as well as nationally, projections from the CDC indicate that there is still a present risk of resurgence of new mpox cases due to low immunity among populations most affected. Clinicians should continue to be aware of the risk of mpox and be prepared to provide vaccination, as well as testing and treatment if indicated.

Spread and Populations Considered at Increased Risk

Mpox can be spread in a variety of ways. This virus is historically zoonotic and spread from an infected animal scratching or biting an individual or by someone eating infected meat or meat products. The most common human-to-human spread of mpox is through direct contact with an infectious rash, scabs, and/or body fluids. It is possible to also contract mpox through respiratory secretions during face-to-face contact (i.e., droplet spread), or during intimate physical contact. Fomites can also spread mpox by touching clothing or linens that have been contaminated with drainage from an infectious rash or other body fluids.

Because of the nature of the spread of mpox in the current outbreak, as well as populations disproportionately affected by mpox, the NYSDOH has taken steps to add mpox to the list of diseases recognized as STIs in New York State Codes, Rules, and Regulations Title 10, Section 23.1. The purpose of this designation is to ensure that mpox care, especially vaccination, can be obtained by adolescents under the age of 18 without requiring parental consent, and accessible from LHDs and other providers alongside services for other STIs.

VACCINATION

JYNNEOS (aka: IMVANEX, IMVAMUNE) is licensed by the US FDA as a two-dose series for the prevention of mpox among adults ages 18+. The vaccine is also authorized by the FDA for administration in individuals under 18 at risk for mpox. At present, JYNNEOS is available only via the federal Strategic National Stockpile and is being made available by the federal government. See the FDA's fact sheet for healthcare providers here.

During the summer and fall of 2022, NYSDOH rolled out vaccine in a phased approach as the supply of JYNNEOS increased. As of this writing, New York State has a sufficient supply of JYNNEOS vaccine to make the vaccine available to anyone who is at risk for mpox, in accordance with CDC guidance.

Specifically, absent contraindication, vaccination is recommended for:

- Those with known or suspected exposure to someone with mpox
- Those with a sex partner in the previous two weeks who was diagnosed with mpox
- Those who identify as gay, bisexual, or other men who have sex with men, as well as transgender, nonbinary, or gender-diverse person who in the past six months has had any of the following:
    - A new diagnosis of one or more STIs (e.g., chlamydia, gonorrhea, or syphilis)
    - More than one sex partner
- Those who have had any of the following in the past six months:
    - Sex at a commercial sex venue (e.g., sex club or bathhouse)
    - Sex related to a large commercial event or in a geographic area (e.g., city or country) where mpox transmission is occurring
- Those with a sex partner with any of the above risks
- Those who anticipate experiencing any of the above scenarios
- Persons living with HIV (PLWH) or other causes of immune suppression who had recent or anticipate future risk of mpox exposure from any of the above scenarios
- Those who work in settings where they may be exposed to mpox:
    - Those who work with orthopoxviruses in a laboratory
    - Those who are part of an orthopoxvirus health care worker response team

In addition to the above criteria, New York State recommends that those who fall under the criteria below also receive the vaccine:

- Those who engage in transactional sex
- Those who have or anticipate attending private or public sex parties

Please note: The above criteria should also include those who self-identify as being at risk or acknowledge the possibility of or anticipate engaging in risk behaviors in the near future, without needing to disclose specific identities or risk behaviors.

Contacts of suspected or confirmed cases of mpox (i.e. PEP) who have not yet received the JYNNEOS vaccine should be prioritized for receipt of their first dose as soon as possible. If given within 4 days of exposure, the vaccine may reduce the likelihood of infection, and within 14 days may reduce severity of symptoms.

Second doses, vaccination after mpox

JYNNEOS is offered as a two-dose vaccine series, with doses administered four weeks (28 days or 4 weeks) apart. Based on ACIP best practices, a second dose may be administered up to four days before the minimum 28-day interval. Please see the CDC's JYNNEOS vaccine clinical considerations for more information on dosing. Two doses of the vaccine are recommended to provide stronger protection compared with one dose alone. However, vaccination coverage data show that many have received one dose but not two. **Providers offering JYNNEOS vaccine should make efforts to schedule second dose appointments for individuals upon receipt of the first dose, or as soon as possible after the first dose.**

Individuals who previously received one dose of JYNNEOS but not their second should be encouraged to do so as soon as is feasible, in accordance with CDC guidelines.

Additionally, while a previous diagnosis of mpox is thought to provide some protection against future infection with mpox, it is currently unknown how long this immunity will last. Therefore, those who received a previous diagnosis of mpox, absent contraindication, should be offered the JYNNEOS vaccine or a second dose.

At this time, individuals who have completed the two-dose JYNNEOS vaccine series do not need additional doses of JYNNEOS.

Route of administration
As of December 2022, subcutaneous administration is now recommended as the primary route of administration, though intradermal administration (previously recommended for adults ages 18 and older) is still allowed as an alternate regimen. Please see the CDC JYNNEOS Provider Agreement for more information. (Subcutaneous administration continues to be the only route of administration recommended for those under the age of 18.)

As the vaccine program evolves, additional information on the program (outside of NYC), dose availability, and clinical guidance will be made available at https://www.health.ny.gov/diseases/communicable/zoonoses/mpox/. Questions about vaccination may be directed to mpox@health.ny.gov.

TESTING

On August 9, 2022, the FDA issued an emergency use authorization for the detection and/or diagnosis of mpox virus. CLIA-certified clinical laboratories that perform high complexity testing were allowed to test through FDA enforcement discretion. Many commercial and clinical laboratories can provide testing. A list of laboratories that can perform testing can be found at: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/monkeypox-mpox-and-medical-devices#Laboratories. Questions about specimen collection and submission to these facilities should be directed to the appropriate laboratory.

If there are any questions regarding mpox testing, please contact the Wadsworth Center wcid@health.ny.gov.

TREATMENT WITH TECOVIRIMAT

Obtaining Tecovirimat in New York State

New York State has established a network of providers throughout the state to provide evaluation for tecovirimat/TPOXX. Providers outside of NYC who diagnose a patient with mpox may refer them to one of these sites to be evaluated for potential treatment. More information about obtaining and using TPOXX for treatment of mpox can be found here.

NYC-based providers can refer to the Department of Health and Mental Hygiene's mpox treatment webpage for more information about obtaining tecovirimat in NYC.

CDC's Expanded Access IND Protocol: Use of Tecovirimat (TPOXX®) for Treatment of Human Non-Variola Orthopoxvirus Infections in Adults and Children

www.cdc.gov/poxvirus/mpox/pdf/Tecovirimat-IND-Protocol-CDC-IRB.pdf

Additional information about supportive care for mild to moderate disease can be found on the NYSDOH mpox provider webpage.

What is Required from Clinicians/Healthcare Providers

When administering tecovirimat there are certain documentation requirements under an EA-IND that must be met. Providers may be contacted for further follow-up if necessary. These requirements include:

- Informed consent prior to treatment initiation
- FDA Form 1572
    - Complete within 3 calendar days by the responsible clinician/healthcare provider along with a CV of the treating physician
- Patient intake form to provide patients baseline condition at time of treatment
- Serious adverse event form

As of October 28, 2022, new providers and affiliated medical facilities providing tecovirimat under the EUA-IND protocol must register with the tecovirimat IND online registry.

REPORTING

Healthcare providers **must immediately report suspect cases of mpox to their LHD.** Reporting should be to the LHD in the county where the patient resides.

If you are unable to reach the LHD where the patient resides, please contact the NYSDOH Office of Sexual Health and Epidemiology at: 518-474-3598 during business hours or 866-881-2809 evenings, weekends, and holidays.

New York City residents suspected of mpox infection should be reported to the NYC Health Department Provider Access Line (PAL) at 866-692-3641. Outside of New York City, contact information is available at: https://www.health.ny.gov/contact/contact_information.

MPOX RESOURCES

NYSDOH Mpox for Healthcare Providers
https://www.health.ny.gov/diseases/communicable/zoonoses/mpox/providers/

CDC. Treatment Information for Healthcare Professionals.
https://www.cdc.gov/poxvirus/mpox/clinicians/treatment.html

CDC. Guidance for Tecovirimat Use
https://www.cdc.gov/poxvirus/mpox/clinicians/Tecovirimat.html

Food and Drug Administration. Tecovirimat package insert.
https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/214518s000lbl.pdf

CDC. Infection Control for Healthcare Settings.
https://www.cdc.gov/poxvirus/mpox/clinicians/infection-control-healthcare.html