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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

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, >91,000 cases of mpox have been reported in multiple countries worldwide where mpox virus is not endemic, including >31,000 cases in the United States.
- Recent data in New York State (NYS) indicate an uptick in mpox cases during late October and November, 2023, in multiple counties across the state but concentrated in the Central and Western regions.
- Data suggest that individuals who identify as gay, bisexual, and other men who have sex with men comprise the majority of reported cases during this time period.
- Providers should maintain a high level of suspicion of mpox when evaluating patients with symptoms of sexually transmitted infections (STIs), including rash illnesses consistent with mpox, regardless of gender identity, birth sex, sex of sex partner(s), travel history, or other risk factors.
- Providers should take appropriate steps to provide vaccination, testing, and treatment/referral to treatment when appropriate, should strictly adhere to infection control practices, and are required to immediately notify their local health department (LHD) of new cases.
- This advisory provides updates to NYSDOH Health Alert Notice for providers in New York State – June 13, 2023, and supersedes all previous NYSDOH Health Alert Notices on mpox.
- Key updates include:
  - **Notification of recent uptick in reported mpox cases in NYS**
  - **Ongoing recommendation for vaccination for populations disproportionately affected by mpox as a part of routine sexual healthcare**
  - **Reminder of expanded vaccine eligibility**
  - **Information on the STOMP Study of Tecovirimat for Mpox**

Notification of Recent Uptick in Reported Mpox Cases in New York State

During October and November 2023, there was an uptick in the number of reported mpox cases, compared to relatively low case counts throughout the spring and summer of 2023.

This uptick represents cases spanning several counties including but not limited to those listed below, and is concentrated in Central and Western New York State (NYS).

As of the date of this advisory, diagnoses and partner networks have been reported in the following counties: Monroe, Chemung, Seneca, Broome, Oneida, Cayuga, Wyoming, Tompkins, Chenango, Steuben, Schuyler, Wyoming, Onondaga, and Rensselaer.

In addition, recent cases have been identified in the following counties: Bronx, Kings (Brooklyn), New York (Manhattan), and Queens.

Within NYS, the majority of mpox transmission has been documented among individuals who report male-to-male sexual contact, including gay, bisexual, and other men who have sex with men (MSM). However, regardless of gender or sexual identity, providers in NYS are encouraged to maintain a high level of suspicion of mpox when evaluating patients exhibiting symptoms consistent with mpox, as well as provide appropriate testing and referral to treatment options as outlined herein.

Furthermore, individuals who are not exhibiting symptoms of mpox but who are recommended for vaccination, as detailed below, should be offered vaccination if they have not yet completed the two-dose series of JYNNEOS since the beginning of the 2022 mpox outbreak. Providers interested in obtaining a supply of JYNNEOS vaccine should contact their local health department (LHD) or email mpox@health.ny.gov.

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 NYS 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 Disproportionately Affected

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 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

On October 25, 2023, the CDC Advisory Committee on Immunization Practices (ACIP) voted to routinely recommend the JYNNEOS vaccine to those at risk of mpox. This includes vaccination after a known or suspected exposure ***and*** pre-exposure prophylaxis.

NYSDOH highly encourages all providers who care for these populations to offer the JYNNEOS vaccine for prevention of mpox alongside other routine sexual health care services.

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. In addition to adults ages 18 and older, those under 18 are eligible for vaccination for mpox as a part of overall sexual health care as appropriate.

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.

The JYNNEOS vaccine is available to anyone who is at risk for recent or future exposure to mpox, in accordance with NYSDOH and CDC guidance.

Specifically, absent contraindication, vaccination is recommended for persons who:

- Have a known or suspected exposure to someone with mpox
- Have a sex partner in the previous two weeks who was diagnosed with mpox
- Identify as part of a community disproportionately affected by sexually

transmitted infections (STIs)* and who in the last six months have had either:
    - A new diagnosis of one or more STIs
    - More than one sex partner
- Have had any of the following in the past six months:
    - Sex at a commercial sex venue (e.g., sex club or bathhouse) or sex party
    - Sex related to a large commercial event or in a geographic area (e.g., city or county) where mpox transmission is occurring
    - Engage in transactional sex
- Have a sex partner with any of the above risks
- 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
- 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

* While mpox can affect anyone, the majority of mpox transmission in NYS has been documented among individuals who report male-to-male sexual contact, including gay, bisexual, and other MSM; as well as transgender, non-binary and other gender-diverse individuals, and those in their sexual networks.

The above criteria should also include anyone who requests vaccination, 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

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.

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

Vaccination After Mpox Infection

As of the date of this HAN, the CDC does not recommend that individuals who receive a medical diagnosis of mpox since May 2022 receive the JYNNEOS vaccine. However,

individuals who believe they may have been infected with mpox (i.e. were self-diagnosed) during the 2022 mpox outbreak began but did ***not*** receive a diagnosis from a healthcare provider may receive the vaccine on a case-by-case, shared decision-making basis based on the clinical judgment of a healthcare provider.

Additionally, immunocompromised persons who were diagnosed with mpox after receiving their first dose of JYNNEOS may be eligible to receive their second dose on a case-by-case, shared decision-making basis based on the clinical judgement of a healthcare provider. For more information, visit the CDC's vaccination administration considerations for special populations.

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

Patients with rashes initially considered characteristic of more common infections (e.g., varicella zoster or STIs) should be carefully evaluated for a characteristic mpox rash (see main page for images). Submissions of specimens of lesions should be considered, especially if the person has epidemiologic risk factors for mpox infection.

Testing for mpox is currently available at numerous laboratories, including but not limited to commercial and public health laboratories (Erie County Public Health Laboratory, NYSDOH Wadsworth Center Laboratory, the New York City Public Health Laboratory, and the Westchester County Department of Laboratories and Research). The process for testing is in accordance with CDC guidance and based on the testing process that CDC has laid out nationwide. Additional directions for ensuring adequate collection of a lesion specimen are available from CDC here.

Providers are encouraged to contact their routine reference laboratory for specific specimen submission procedures for mpox testing, or to contact their LHD for further guidance.

Wadsworth Center testing guidance can be found here. Questions related to mpox testing can be directed to the Wadsworth Center at wcid@health.ny.gov.

TREATMENT WITH TECOVIRIMAT

Obtaining Tecovirimat in NYS

Providers caring for a patient diagnosed with mpox have the following options to refer them for treatment with tecovirimat/TPOXX:

STOMP – Study of Tecovirimat for Mpox: STOMP is a Phase 3 clinical trial evaluating the efficacy of Tecovirimat in treating mpox. Providers may inform patients of the STOMP trial for their voluntary participation. The trial is open to all participants with diagnosed or suspected mpox, not just those who meet the Expanded Access IND Protocol referenced below.

- Individuals are randomized 2:1 to receive tecovirimat
- Individuals with severe mpox are eligible for an open-label arm where they receive tecovirimat

There are currently 10 participating sites in NYS, some of which accept remote enrollment for individuals not in close proximity.

More information about the STOMP trial can be found here.

New York State provider treatment network: NYSDOH 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 three calendar days by the responsible clinician/healthcare provider along with a CV of the treating physician
- Patient intake form to provide patient's baseline condition at time of treatment
- Serious adverse events 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.

PARTNER SERVICES

Partner Services is a free and confidential NYSDOH program that assists in linking persons diagnosed with STIs and/or HIV and their partners to testing, treatment, medical care, prevention interventions and/or other appropriate support services in order to improve their health outcomes and reduce the risk of transmission to others. Partner Services Specialists help diagnosed individuals in planning the best way to notify their partners who have been exposed to an STI or HIV.

For more information on Partner Services, visit health.ny.gov/partnerservices and to learn more about how Partner Services can extend the continuum of care to your patients, their partners, and others who may have been exposed, please view this video.

AIDS INSTITUTE PROVIDER DIRECTORY REGISTRATION

Register the clinical services (e.g., HIV, HCV, PrEP, PEP, Buprenorphine, STI services – including mpox testing) provided at your facility/practice on the AIDS Institute Provider Directory at https://providerdirectory.aidsinstituteny.org/Register/RegisterCreate.

Update the clinical services (e.g., HIV, HCV, PrEP, PEP, Buprenorphine, STI services – including mpox testing) provided at your facility/practice on the AIDS Institute Provider Directory at https://providerdirectory.aidsinstituteny.org/Register/RegisterEditList.

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