Mpox (formerly monkeypox)



THE DISEASE AND ITS EPIDEMIOLOGY

A. Etiologic Agent

Mpox (formerly monkeypox) virus is an enveloped double-stranded DNA virus, a member of the orthopoxvirus genus within the Poxviridae family. Poxviruses cause disease in humans and many other animals; infection typically results in the formation of lesions, skin nodules or disseminated rash. Other orthopoxvirus (OPXV) species pathogenic to humans include cowpox virus, and variola virus (causing smallpox, which has been eradicated). There are two distinct genetic clades of the mpox virus: Clade I (formerly known as the central African (Congo Basin) clade) and Clade II (formerly known as the west African clade). Clade I has historically caused more severe disease. Clade II consists of two subclades, Clade IIa and Clade IIb, with the latter referring primarily to the group of variants largely circulating in the 2022 global outbreak.

B. Clinical Description

Mpox is a rare disease caused by infection with the mpox virus. Mpox virus is part of the same family of viruses as smallpox. Mpox symptoms are similar to smallpox, but milder; mpox is rarely fatal. Mpox is not related to chickenpox.

Presenting symptoms typically include fever, chills, the distinctive rash, or new lymphadenopathy; however, onset of rash, including perianal or genital lesions, in the absence of subjective fever or other symptoms can occur in the current outbreak.

The rash associated with mpox involves vesicles or pustules that are deep-seated, firm or hard, and well-circumscribed; the lesions may umbilicate or become confluent and progress over time to scabs. Lesions progress through specific sequential stages—macules, papules, vesicles, pustules, and scabs. The rash associated with mpox can be confused with other diseases that are encountered in clinical practice (e.g., secondary syphilis, herpes, chancroid, and varicella zoster). Co-infections have occurred in the current outbreak, so patients with a characteristic rash should be considered for testing, even if other tests are positive. CDC has photos of mpox rashes for reference: Signs and Symptoms | Mpox | Poxvirus | CDC

Some individuals associated with the 2022 mpox outbreak have had atypical presentations, including a lack of or delayed prodromal symptoms and lesions that may be few and/or present on only one part of the body.

Mpox illness typically lasts 2-4 weeks and persons are considered infectious until all lesions have resolved and a healthy new layer of skin has formed.

C. Treatment

Tecovirimat (also known as TPOXX or ST-246) is FDA-approved for the treatment of human smallpox disease caused by Variola virus in adults and children. However, its use for other orthopoxvirus infections, including mpox, is not approved by the FDA. There is currently a clinical

trial for tecovirimat for treatment of mpox (STOMP trial). Additional information about the STOMP trial can be found here. Healthcare providers should inform patients about the STOMP trial for patients where TPOXX is indicated for their voluntary participation. The STOMP trial is currently enrolling remotely across the United States. If enrollment in STOMP is not feasible for a patient, tecovirimat use under CDC's expanded access protocol should be in concert with CDC's guidance for treatment.

CDC holds a non-research expanded access Investigational New Drug (EA-IND) protocol that allows for the use of tecovirimat for primary or early empiric treatment of non-variola orthopoxvirus infections, including mpox, in adults and children of all ages.

HCPs should refer to CDC's <u>Guidance for Tecovirimat Use Under Expanded Access Investigational</u>

<u>New Drug Protocol</u> during 2022 U.S. Mpox Cases for additional information about TPOXX, and refer to the Tecovirimat IND.

Tecovirimat may be considered for treatment in people infected with *Mpox virus* who:

- Have severe disease (e.g., hemorrhagic disease, confluent lesions, sepsis, encephalitis, or other conditions requiring hospitalization)
- Are at high risk of severe disease (e.g., immunocompromised, children, pregnant or breastfeeding women, persons with a history or presence of atopic dermatitis or other skin conditions, other co-infections/comorbidities)
- Have involvement of anatomic areas such as the pharynx, genital, or anal regions, which
 may result in serious sequelae that include scarring or strictures

When TPOXX is indicated, early administration is advised.

For up to date information on the TPOXX IND protocol, local health departments and healthcare providers should refer to the following website: <u>Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat) for Treatment of Mpox</u>

CDC now has an Tecovirimat (TPOXX) Online Registry for Providers and Facilities for Electronic Patient Intake and Clinical Outcome Forms. Through the registry, providers can submit:

- 1. Form FDA 1572 (Required)
- 2. Patient Intake Form (Required)
- 3. Clinical Outcome Form (Optional)

A factsheet on the online registry is available here.

Required Documents (Send to CDC)

1. **Informed Consent Form-** Obtain prior to treatment.

- Multiple languages and versions of the Informed Consent Form can be found on CDC's website: <u>Information for Healthcare Providers: Tecovirimat (TPOXX) for Treatment of</u> <u>Mpox | Mpox | Poxvirus | CDC</u>
- 2. Patient Intake Form [338 KB, 2 pages]: Baseline assessment.
- 3. <u>FDA Form 1572</u> [1 MB, 2 pages]: One signed 1572 per facility suffices for all TPOXX treatments administered under the EA-IND at the same facility.
- 4. Serious Adverse Events: Per FDA requirement, report life-threatening or serious adverse events associated with TPOXX by completing a <u>PDF MedWatch Form</u> [956 KB, 5 pages] and returning it to CDC via email (<u>regaffairs@cdc.gov</u>) or uploading to <u>ShareFile</u> within 72 hours of awareness or sooner, if possible. The PDF MedWatch Form can also be downloaded from <u>the FDA website</u>. (Note: The MedWatch Form can only be viewed on the Adobe desktop app. Please save or download the form for viewing.)

HCP Requests for TPOXX in New Jersey

NJDOH has received doses of oral TPOXX through the Strategic National Stockpile. In order to request oral TPOXX for a patient that meets criteria for TPOXX use, healthcare providers should send a secure email to DOH-MPOX@doh.nj.gov and copy cds.mpxepi@doh.nj.gov with the following information:

- Verification that FDA Form 1572, Informed Consent Form, and Patient Intake form has been submitted to CDC
- Dosage Requested (Please note: any request for IV TPOXX must go through CDC approval process)
- Requestor Name/Contact Information (Phone, email if different from sender)
- Address for Delivery (provider only, no direct deliveries to patients)
- Point of Contact for Delivery: name, email, direct dial number
- Secondary Point of Contact for Delivery (if applicable): name, email, direct dial number
- Office Hours for Delivery/Special Instructions

The NJDOH Medical Counter Measures Team will work with the HCP to coordinate delivery and provide the requisite forms. HCPs should contact NJDOH at DOH-MPOX@doh.nj.gov and cds.mpxepi@doh.nj.gov if they need to request the intravenous (IV) administration formulation of TPOXX- NJ does not have the IV formulation pre-positioned in state, but the IV formulation is available through the SNS.

Additional Information on Medical Countermeasures for the treatment of Mpox

The CDC has additional information on medical countermeasures available for the treatment of mpox here: <u>Treatment Information for Healthcare Professionals | Mpox | Poxvirus | CDC</u>

D. Reservoirs

Mpox is a zoonotic disease, meaning that it can spread between animals and people, and is caused by Mpox virus, an Orthopoxvirus. While the animal reservoir is unknown, small mammals (rope and sun squirrels, giant-pouched rats, African dormice) are thought to maintain the virus in the environments of West and Central Africa. People can get infected with the virus through direct contact with infected animals, often while hunting, trapping, and processing infected animals or the infected body parts and fluids of animals. Small mammals can carry the virus, sometimes without apparent symptoms, while non-human primates can get sick with mpox and have signs of disease like humans. In 2003, an outbreak of mpox in domesticated prairie dogs occurred after they shared bedding and caging with a shipment of infected small mammals from West Africa. This led to 47 human cases in 6 states in the U.S.

E. Modes of Transmission

Mpox can spread from person-to-person through:

- Direct contact with the infectious rash, scabs, or body fluids
- Respiratory secretions during prolonged, face-to-face contact, or during intimate physical contact, such as kissing, cuddling, or sex
- Touching items (such as clothing or linens) that previously touched the infectious rash or body fluids

Pregnant people can spread the virus to their fetus through the placenta. It's also possible for people to get mpox from infected animals, either by being scratched or bitten by the animal or by preparing or eating meat or using products from an infected animal. At this time, although virus has been detected in semen and vaginal fluids, it is not known what role that plays in transmission.

F. Incubation Period (time from exposure to symptom onset)

After infection, there is an incubation period of roughly 1-2 weeks. Previously, persons were considered not infectious during this time prior to symptom onset, however incorporated findings from a growing body of scientific evidence that show some people can spread mpox virus to others from one to four days before symptoms of mpox appear.

G. Infectious Period

Persons with mpox should be considered infectious one to four days prior to the time symptoms start until the rash has fully healed and a fresh layer of skin has formed. The illness typically lasts 2-4 weeks. Infectiousness is considered greater once the rash has developed. There is currently no evidence showing that people who never develop symptoms have spread mpox virus to someone else.

H. Epidemiology

Mpox was discovered in 1958 when two outbreaks of a pox-like disease occurred in colonies of monkeys kept for research. African rodents and non-human primates (like monkeys) might harbor the virus and infect people.

The first human case of mpox was recorded in 1970. Prior to the 2022 outbreak, mpox had been reported in people in several central and western African countries. Previously, almost all mpox cases in people outside of Africa were linked to international travel to countries where the disease commonly occurs or through imported animals. These cases occurred on multiple continents.

2022 Mpox Outbreak:

Since May 14, 2022, multiple people diagnosed with mpox have been reported in countries outside of Africa, including the United States. The mpox virus is spreading mostly through close, intimate contact with someone who has mpox. Although anyone can get mpox, many—though not all—of the reported cases associated with the 2022 outbreak have been among gay, bisexual, and other men who have sex with men. Current case counts associated with this outbreak are posted online, US, NJ, and globally.

2 CASE DEFINITION

NJDOH is following the interim case definition posted by CDC in the context of the 2022 outbreak: https://ndc.services.cdc.gov/conditions/mpox-virus-infection/

Case definitions enable public health to classify and count cases consistently across reporting jurisdictions and should not be used by healthcare providers to determine how to meet an individual patient's health needs.

A. Epidemiologic Criteria. Within 21 days of illness onset:

- Contact with a person or people with a similar appearing rash or who received a diagnosis of confirmed or probable mpox, OR
- Close or intimate contact with individuals in a social network experiencing mpox activity, this includes men who have sex with men (MSM) who meet partners through an online website, digital application ("app"), or social event (e.g., a bar or party), OR
- Traveled outside the US to a country with confirmed cases of mpox or where mpox virus is endemic, OR
- Had contact with a dead or live wild animal or exotic pet that is an African endemic species or used a product derived from such animals (e.g., game meat, lotions, etc.).
- **B.** Exclusion Criteria. A case may be excluded as a suspect, probable, or confirmed case if:
 - An alternative diagnosis can fully explain the illness, OR
 - An individual with symptoms consistent with mpox does not develop a rash within 5 days of illness onset, OR
 - A case where high-quality specimens do not demonstrate the presence of *Orthopoxvirus* or *Mpox virus* or antibodies to orthopoxvirus.

C. Case classification

CONFIRMED

- Demonstration of the presence of *Mpox virus* DNA by polymerase chain reaction testing,
 OR
- Next-Generation sequencing of a clinical specimen, OR
- Isolation of *Mpox virus* in culture from a clinical specimen

PROBABLE

- No suspicion of other recent *Orthopoxvirus* exposure (e.g., *Vaccinia virus* in ACAM2000 vaccination) AND demonstration of the presence of
 - Orthopoxvirus DNA by polymerase chain reaction of a clinical specimen, OR
 - o *Orthopoxvirus* using immunohistochemical or electron microscopy, OR
 - Demonstration of detectable levels of anti-orthopoxvirus IgM antibody during the period of 4 to 56 days after rash onset

POSSIBLE

- New characteristic rash, OR
- Meets one of the epidemiologic criteria and has a high clinical suspicion for mpox

3 LABORATORY TESTING

The U.S. Food and Drug Administration (FDA) advises swab samples taken directly from a lesion (rash or growth) when testing for the *mpox virus*. The FDA is not aware of clinical data supporting the use of other sample types, such as blood or saliva, for *mpox virus* testing. Testing samples not taken from a lesion may lead to false test results. Personnel who collect specimens should use personal protective equipment (PPE) in accordance with <u>recommendations for healthcare settings</u> (gown, gloves, eye protection [i.e., goggles or a face shield that covers the front and sides of the face], NIOSH-approved particulate respirator equipped with N95 filters or higher).

Laboratory testing has indicated that the current 2022 mpox outbreak is associated with Clade IIb of *mpox virus*. The U.S. government does not consider Clade IIb of *mpox virus* as meeting the definition of Category A infectious substance under the Hazardous Materials Regulations (HMR). Therefore, specimens and material suspected or confirmed to contain Clade IIb of *mpox virus* can be shipped as UN 3373 Biological Substance, Category B.

Depending on the laboratory, testing for mpox is performed with an orthopoxvirus Real-Time PCR Assay, Non-variola Orthopoxvirus Real-Time PCR Assay, and/or Mpox virus Real-Time PCR Assays. In the context of the 2022 mpox outbreak, an orthopoxvirus positive PCR test is diagnostic for mpox. Antibody testing (performed at CDC) may be considered on a case-by-case basis in individuals suspected of having had mpox but in whom the lesions have resolved. LHDs should consult with NJDOH CDS to discuss these scenarios.

Commercial Testing

PCR testing for Orthopoxvirus is available at several commercial/reference laboratories (including ARUP, LabCorp, Quest, Aegis, Mayo Clinics, Sonic Healthcare). Healthcare providers are encouraged to check with their laboratory provider to determine if orthopoxvirus testing is available and pursue commercial testing for suspect mpox cases when feasible. Public health approval for commercial testing is not required.

<u>Equivocal and Inconclusive results</u>: In most cases, if a test result is inconclusive or equivocal and the healthcare provider suspects mpox, additional specimens should be submitted for testing. CDC recommends collecting duplicate swabs from the part of the body being swabbed. If a commercial laboratory test result is inconclusive and if there are swabs left over, they can be sent to PHEL for testing (extracted nucleic acid is not acceptable). If LHDs are interested in sending additional swabs to PHEL for re-testing, consult with CDS.

Public Health Testing

PCR testing is also available at PHEL with pre-approval by the LHD. Specimens submitted to PHEL by clinical laboratories or healthcare facilities without prior approval will be rejected. Public health testing should be considered if commercial testing is not feasible, e.g., if patients are uninsured or underinsured, for patients with severe clinical disease, or in patients where a prompt turn-around time for results is necessary (such as a suspect case in a congregate setting where multiple exposures may have occurred).

LHD Approval of Testing at PHEL: Upon receiving a HCP request for mpox testing

- 1) Provide CDC infection control recommendations
- 2) Collect information using the Mpox Investigation Form
- 3) Testing should be approved if individuals meet one of the following criteria (LHDs should contact their CDS Regional Epidemiologist with questions):
 - a. Epidemiologic risk factor identified and rash consistent with mpox. Risk factors include:
 - i. Persons who identify as gay, bisexual, or men who have sex with other men (MSM)
 - ii. Contact with a confirmed orthopoxvirus or mpox case, or with someone who has lesions consistent with mpox
 - iii. Multiple or anonymous sexual partners in the past 14 days
 - iv. Recent travel to an area with mpox cases, OR
 - Clinical criteria met (i.e., characteristic rash and at least one other compatible clinical sign, such as fever or lymphadenopathy), even if no epidemiologic risk factors are present, OR
 - c. Strong clinical suspicion, even in the absence of (a) and (b) above
- 4) If testing criteria is met (providers can consider commercial testing if PHEL testing is not approved),
 - a. Provide specimen collection instructions:
 - i. All recommended PPE should be worn when collecting a specimen from a person with suspected or confirmed mpox.
 - ii. Vigorously swab or brush lesion with two separate sterile **dry** nylon, polyester, or Dacron swab to ensure that adequate viral DNA is collected. Do not use

cotton or other types of swabs. Swabs in viral transport medium (VTM) are also acceptable for testing. Unroofing or aspiration of lesions (or otherwise using sharp instruments for mpox testing) is not necessary, nor recommended, due to the risk for sharps injury. It is recommended to swab multiple lesions - duplicate swabs should be taken for each lesion sampled. Please do not sanitize the patient's skin with an alcohol wipe before swabbing or brushing the lesion.

iii. Break off end of applicator of each swab into a 1.5- or 2-mL screw-capped tube with O-ring or place each entire swab in a separate sterile container.

DRY SWABS ARE PREFERRED BUT PHEL WILL ACCEPT SWABS STORED IN VIRAL TRANSPORT MEDIA (VTM) ONLY, SWABS STORED IN UNIVERSAL TRANSPORT (UTM) WILL NOT BE ACCEPTED.

iv. Refrigerate (2-8°C) or freeze (-20°C or lower) specimens within an hour after collection. Store refrigerated specimens for up to 7 days and frozen specimens for up to 60 days. Refrigerated specimens should be sent within 7 days of collection; frozen specimens should be shipped within 60 days of collection. Shipping on dry ice is strongly recommended.

SWABS IN VTM MUST BE RECEIVED WITHIN 7 DAYS OF COLLECTION. SPECIMENS RECEIVED OUTSIDE OF ACCEPTABLE TEMPERATURE RANGES WILL BE REJECTED.

- v. One swab will be tested at PHEL for orthopoxviruses. CDC can provide Mpox virus-specific testing on the second dry swab specimen if the first dry swab is presumptive positive at PHEL.
- vi. After specimen collection is completed, all protective materials worn by the specimen collector (gloves, mask, gown, etc.) and all used sample collection materials (alcohol wipes, holders, etc.) must be placed in red biohazard bags and autoclaved or incinerated prior to disposal. Thorough handwashing using soap should be done immediately after specimen collection and following removal of personal protective equipment (PPE).
- b. Enter the suspect case into CDRSS (case status = RUI), including symptoms, risk factors and in Comments "Approved for mpox testing at PHEL. CDS notified to coordinate specimen delivery." Enter in CDRSS and e-mail the following information to the CDS regional epidemiologist, who will then contact PHEL to coordinate specimen delivery and testing:
 - i. CDRSS Case ID
 - ii. Lab Contact (name, email, and phone number)

- iii. Hospital and contact info of IP or physician (name, email, phone number)
- c. Instruct the patient to <u>isolate at home</u> until test results are received.

PHEL will coordinate specimen receiving and testing with sending laboratories Monday through Friday, unless pre-approval is obtained for weekend testing in emergent situations.

4

PURPOSE OF SURVEILLANCE AND REPORTING

- To determine the source of exposure to prevent further transmission
- To quickly detect persons with mpox and implement isolation recommendations
- To quickly identify close contacts and offer post-exposure prophylaxis when indicated
- To identify at-risk populations that would benefit from expanded post-exposure prophylaxis and from information on prevention of mpox
- To increase healthcare provider awareness of mpox

5

CASE INVESTIGATION

A. Investigation

Orthopoxvirus test results are received electronically into CDRSS, although if some are received via fax or other means, LHDs should enter these into CDRSS. HCPs should immediately report all laboratory positive orthopoxvirus test results to the LHD, as well as highly suspicious suspect cases while commercial test results are pending.

Mpox cases should be immediately investigated by LHDs to ensure appropriate isolation, contact identification and monitoring, and provision of PEP when indicated. Some information can be obtained by the patient's healthcare provider, but a patient interview is required to identify exposures and contacts and to ensure understanding of isolation recommendations. The Mpox Investigation Worksheet can help guide the initial investigation, but LHDs also need to collect detailed exposure information as listed below.

When interviewing the patient, LHDs should provide home isolation guidance: <u>Isolation and Infection Control At Home | Mpox | Poxvirus | CDC</u>; isolation should continue until all lesions have healed and new skin has formed; confirm date of symptom onset and note dates of onset of each symptom; and identify close contacts while infectious (from 4 days prior to onset of prodromal symptoms through resolution of the rash). Ask about medical care sought, other potential common exposures such as sexual contacts, household contacts, social gatherings or events, work exposures, etc. LHDs should review NJDOH Contact Monitoring guidance and categorize the level of risk for each contact.

https://www.nj.gov/health/cd/documents/topics/Monkeypox/monkeypox-contact-

monitoring.pdf; enter close contact information in Contact Tracing section and create a new CDRSS case for all contacts under monitoring with a case status of RUI.

LHDs should notify their CDS Regional Epidemiologist for out-of-state case transfers, questions about TPOXX, high-concern events where multiple exposures may have occurred, probable/confirmed cases in a congregate care setting, past or future air/cruise travel, difficulties in obtaining vaccine for PEP, high-concern contacts/settings, e.g., healthcare worker, teacher, etc.

In the event that a case cannot be reached by the LHD, LHD should continue to attempt to reach case through multiple methods (phone call, email, text, home visit and/or letter delivery). LHD should contact provider to get as much clinical information on case as possible and determine if provider has alternative contact methods. If all means of contact have been exhausted, this should be documented in CDRSS and case should be documented as lost to follow up. If case is reached but refuses to provide information, LHD should note this in CDRSS and document any information that is provided.

<u>Detailed Exposure History</u>

LHDs should use the "2022 MPOX OUTBREAK" Questionnaire, which is available under the Outbreak Information tab (linked to I-2022-23921) when investigating cases to document detailed exposure information. LHDs should ensure that all cases with a positive orthopoxvirus or mpox virus laboratory result be assigned to I-2022-23921 and have this Questionnaire completed in CDRSS.

Closing Case

Once all relevant fields have been fully completed in CDRSS (See table below), the LHD can close the case. LHDs should ensure that all available information, including illness onset, signs and symptoms, clinical status, immunization information, treatment, contact tracing, and detailed exposure history are complete before closing the case. Cases do NOT need to be monitored for 21-days (only contacts of someone with mpox need to be monitored for 21 days with information captured in Mpox Monitoring section)

CDRSS Fields with Specific Instructions for Mpox CASES (laboratory-positive).

B. Key CDRSS Fields Specific for Mpox Cases	Required Information
Disease Information	 Cases positive for orthopoxvirus DNA should have a case status of PROBABLE Cases positive for mpox virus DNA (CDC and some other laboratories) should have a case status of CONFIRMED Persons waiting for test results or contacts under monitoring should have a case status of REPORT UNDER INVESTIGATION Out of state cases or contacts should have a case status of OUT OF STATE. Notify the CDS Regional Epidemiologists if it is determined someone lives out of state. Once the case investigation is complete, contacts are identified/linked, treatment is documented, if indicated, clinical status and all signs/symptoms have been documented, close case as LHD CLOSED
Outbreak Information	 Assign <u>orthopoxvirus positive</u> cases to I# 2022-23921; Complete 2022 MONKEYPOX OUTBREAK Questionnaire, which provides case exposure history
Clinical Status	 Illness Onset Date: If not entered in Disease Information Section, ensure date of earliest symptom is entered Was patient hospitalized Pre-existing conditions (particularly if immunocompromised) Did patient die (include cause of death if known and check "died during investigation" if related to mpox).
Immunization Information	 If patient was vaccinated against this disease, enter date of vaccination If patient was vaccinated against a related disease, e.g., if the individual was immunized against smallpox previously, enter the date of vaccination if known

B. Key CDRSS Fields Specific for Mpox Cases	Required Information
Contact Tracing	 Enter names/case IDs of anyone the person may have exposed while infectious under Contact Tracing Section of Index Case. In each CONTACT case, to assist with monitoring, enter the date of last exposure to the case, the type of exposure, and the exposure risk level. If there are healthcare worker contacts being monitored by the health care facility, they do not need to be individually listed in this section. Enter a note in Comments with the total number of HCW contacts. Ensure CDS is aware of these contacts under HC monitoring.
Mpox Monitoring	DO NOT USE this section for mpox cases (only for monitoring contacts of someone with mpox)
Industry/Occupation	Complete industry/occupation section
Treatment	If patient receives TPOXX, add as "ANTIVIRALS" with dates
Signs and Symptoms	Enter onset date for each reported sign/symptom

6 CONTROLLING FURTHER SPREAD

A. Isolation

Patients with confirmed or suspected mpox infection should be isolated. Patients who do not require hospitalization, but remain potentially infectious to others, should be isolated at home. For individuals with mpox, isolation precautions should be continued until all lesions have resolved, the scabs have fallen off, and a fresh layer of intact skin has formed. LHDs should share CDC guidance for isolating at home with mpox cases: Isolation Control At Home | Mpox | Poxvirus | CDC

People with mpox should remain in isolation for the duration of illness, which typically lasts two to four weeks. However, if a person with mpox says they are unable to remain fully isolated throughout the illness, the following recommendations can help prevent the spread of infection:

While symptomatic with a fever or any respiratory symptoms, including sore throat, nasal congestion, or cough,

- Remain isolated in the home and away from others unless it is necessary to see a
 healthcare provider or for an emergency. This includes avoiding close or physical contact
 with other people and animals.
- Cover the lesions, wear a well-fitting mask (more information below), and avoid public transportation when leaving the home as required for medical care or an emergency.

While a rash persists but in the absence of a fever or respiratory symptoms,

- o Cover all parts of the rash with clothing, gloves, and/or bandages.
- Wear a well-fitting mask to prevent the wearer from spreading oral and respiratory secretions when interacting with others until the rash and all other symptoms have resolved. Masks should fit closely on the face without any gaps along the edges or around the nose and be comfortable when worn properly over the nose and mouth.

Until all signs and symptoms of mpox illness have fully resolved,

- Do not share items that have been worn or handled with other people or animals.
 Launder or disinfect items that have been worn or handled and surfaces that have been touched by a lesion.
- Avoid close physical contact, including sexual and/or close intimate contact, with other people.
- Avoid sharing utensils or cups. Items should be cleaned and disinfected before use by others.

- Avoid crowds and congregate settings.
- Wash hands often with soap and water or use an alcohol-based hand sanitizer, especially after direct contact with the rash.

Administrators of congregate care settings should refer to Congregate Living Settings | Mpox | Poxvirus | CDC if a staff member, volunteer, or resident of a congregate living setting has a mpox infection. Congregate living settings are facilities or other housing where people who are not related reside in proximity and share at least one common room (e.g., sleeping room, kitchen, bathroom, living room). Congregate living settings can include correctional and detention facilities, homeless shelters, group homes, dormitories at institutes of higher education, seasonal worker housing, residential substance use treatment facilities, and other similar settings.

B. Quarantine

Asymptomatic close contacts do not need to quarantine but should be monitored for 21 days from the last exposure to someone with mpox. High-risk close contacts should consider not traveling internationally while under monitoring, because contact monitoring is difficult and adequate medical care may be lacking.

C. Contact Monitoring

Close contacts should monitor for symptoms for 21 days from the last exposure to someone with mpox. Close contacts may be identified through LHD investigation, notification by another state health department (entered CDRSS by CDS), or through DGMQ traveler notifications (entered CDRSS by CDS). Refer to NJDOH Contact Monitoring Guidance https://www.nj.gov/health/cd/documents/topics/Monkeypox/monkeypox-contact-monitoring.pdf to determine the exposure risk level and establish procedures for 21-day symptom monitoring. Close contacts should be listed under the contact tracing section of the index case if they are a contact of a NJ mpox case.

If contact is high or intermediate risk, or if risk level is unknown, provide recommendations for PEP (see Vaccine section of this document). PEP is recommended for high-risk contacts and may be indicated for intermediate risk contacts. LHDs should coordinate PEP for close contacts through the LINCS Vaccine HUB.

Symptom monitoring can be conducted by phone, video conferencing, other electronic means (e.g., text message, email, app, web form), or in-person. Provide individual with a 24/7 LHD contact number to call if compatible symptoms develop and advise individual that if symptoms develop, they should isolate immediately, notify the LHD, and if they need medical care to call the healthcare provider in advance to tell them about their travel and/or exposure history.

If a contact has symptoms that could be consistent with mpox (such as fever, lymphadenopathy, chills, malaise) but no rash, they should isolate at home if medical care is not needed. If rash develops in the next 1-3 days, testing for mpox should be coordinated.

If a contact will be traveling out of state, the LHD should discuss continued symptom monitoring while on travel. If the LHD cannot continue monitoring and the case needs to be transferred out of state for continued monitoring, document travel information in CDRSS (destination address, contact information if different, dates).

The LHD should update temperature and symptoms each day in the Mpox Monitoring Section. Should symptoms develop or if the individual plans on leaving NJ to continue their self-monitoring out of state, contact the CDS Regional Epidemiologist. Once 21-day monitoring period has concluded, enter a "final outcome" in the Mpox Monitoring section and close the case as NOT A CASE / LHD CLOSED.

The LHD should try to reach the individual at least three times through various means of communication (i.e. phone call, text, email if available). If after at least three attempts, contact cannot be reached, attempts should be documented in CDRSS, the "final outcome" in the Mpox Monitoring Section should be listed as "lost to follow up," and case can be closed.

CDRSS Fields with Specific Instructions for Mpox CONTACTS (not laboratory-positive).

B. Key CDRSS Fields Specific for Mpox Contacts	Required Information
Disease Information	 Contacts under monitoring should have a case status of REPORT UNDER INVESTIGATION If contacts live or are transferring outside of NJ, change case status to OUT OF STATE and notify the CDS Regional Epidemiologist Once the contact completes their 21 days monitoring and vaccine is documented, if indicated (including 2nd dose), change case status to NOT A CASE and close case as LHD CLOSED If contact becomes symptomatic and tests positive for orthopoxvirus or mpox, change case status to PROBABLE or CONFIRMED
Outbreak Information	Do NOT assign contacts to the mpox I# (unless they test positive for orthopoxvirus and become an mpox Case)
Immunization Information	 If patient was vaccinated against this disease, enter date(s) of vaccination If patient was vaccinated against a related disease, e.g., if the individual was immunized against smallpox previously, enter the date of vaccination if known

B. Key CDRSS Fields Specific for Mpox Contacts	Required Information
Contact Tracing	 Ensure (or enter) name(s)/case ID(s) of mpox cases (if known and NJ resident)
Mpox Monitoring	 Edit questionnaire and complete Days 1-21 from date of last exposure to mpox case At end of monitoring period, enter "final outcome"
Case Comments	Enter exposure risk level (high, intermediate, low/uncertain) and describe nature of exposure (e.g., sexual, other skin to skin, close face-to-face)

D. Vaccine

Two vaccines licensed by the U.S. Food and Drug Administration (FDA) are available for preventing mpox infection – JYNNEOS (also known as Imvamune or Imvanex) and ACAM2000. Owing to the method of administration as well as an improved safety profile, JYNNEOS is preferred when available. JYNNEOS is a vaccine Indicated for prevention of smallpox and mpox disease in adults 18 years of age and older determined to be at high risk for smallpox or mpox infection. When administered before or after a recent exposure, vaccines can be effective tools at protecting people against mpox illness. On 8/9/22, the FDA issued an emergency use authorization (EUA) for the JYNNEOS vaccine to allow healthcare providers to use the vaccine by intradermal injection for individuals 18 years of age and older who are determined to be at high risk for mpox infection. This change increases the total number of doses available for use by up to five-fold. The EUA also allows for use of the vaccine in individuals younger than 18 years of age determined to be at high risk of mpox infection; in these individuals JYNNEOS is administered by subcutaneous injection.

The vaccine manufacturer has advised that it is not recommended to give the second dose before the minimum interval of 28 days; however, doses may be given up to 4 days before the minimum interval of 28 days (i.e., 24 days after the first dose) based on ACIP's general best practices. Based on available clinical study data, the second dose may be given up to 7 days after the minimum interval of 28 days (i.e., 35 days after the first dose). If there is a delay in administering the second dose and the interval becomes longer than 35 days, the second dose should be administered as soon as possible based on ACIP's general best practices. There is no need to restart the series.

The CDC hasv vaccination information at the following pages:

Vaccines | Mpox | Poxvirus | CDC

Vaccination Administration Considerations for Specific Populations | Mpox | Poxvirus | CDC

Two doses of JYNNEOS are required, as this is the only FDA-approved dosing regimen.

- Exceptions to the two-dose vaccine series:
 - In the context of the current mpox outbreak, and while the supply of JYNNEOS vaccine is limited:
 - A person who is diagnosed with mpox after their first dose of JYNNEOS is not recommended to receive the second dose at this time, because mpox infection likely confers additional immune protection.
 - A person who would be eligible for vaccination but has been diagnosed with Mpox virus infection during this outbreak, which started in the United States on May 17, 2022, is not recommended to be vaccinated at this time, because Mpox virus infection likely confers immune protection.
 - An immunocompromised person who is diagnosed with Mpox virus infection after their first dose of JYNNEOS may be eligible to receive the second dose of JYNNEOS on a case-by-case shared decision-making basis based on the clinical judgment of the healthcare provider.
 - These recommendations may be revised as data become available and/or as the supply of JYNNEOS increases to meet or exceed outbreak response needs.

People are considered fully vaccinated about 2 weeks after their second shot of JYNNEOS and 4 weeks after receiving ACAM2000. However, people who get vaccinated should continue to take steps to protect themselves from infection by avoiding close, skin-to-skin contact, including intimate contact, with someone who has mpox.

No special precautions are needed for persons administering JYNNEOS vaccine, but the COVID-19 pandemic is ongoing and vaccine administrators should follow COVID-19 vaccine guidelines:

- https://www.cdc.gov/vaccines/pandemic-guidance/index.html
- https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html.
- https://www.cdc.gov/vaccines/hcp/admin/downloads/COVID-19-vaccine-administration-ppe-508.pdf

Pre-Exposure (PrEP)

This approach refers to administering vaccine to someone at high risk for mpox (for example, laboratory workers who handle specimens that might contain mpox virus). At this time, most clinicians in the United States and laboratorians not performing the orthopoxvirus generic test to diagnose orthopox viruses, including mpox virus, are not advised to receive mpox vaccine PrEP. https://www.cdc.gov/mmwr/volumes/71/wr/mm7122e1.htm. LHDs should consult with CDS concerning needs for PrEP.

Post-Exposure Prophylaxis (PEP)

Persons who had an intermediate or high-risk contact with someone with mpox can be vaccinated following exposure to help prevent illness. CDC recommends that the vaccine be given within 4 days from the date of exposure for the best chance to prevent onset of the disease. If given between 4 and 14 days after the date of exposure, vaccination may reduce the symptoms of

disease, but may not prevent the disease. Vaccination of close contacts of someone highly suspicious for mpox can also be considered while test results are pending. LHDs should coordinate provision of PEP with their LINCS Mpox Vaccine HUB and document doses received in the contact's CDRSS record (Immunization Information). LHDs should coordinate with healthcare facilities in their jurisdiction to provide vaccine for eligible exposed healthcare workers, regardless of where the individual healthcare worker resides.

<u>Pediatric close contacts:</u> The US Food and Drug Administration (FDA) has also issued an Emergency Use Authorization (EUA) for the emergency use of JYNNEOS for active immunization by subcutaneous injection for prevention of mpox disease in individuals less than 18 years of age determined to be at high risk for mpox infection.

Expanded Vaccination

In the context of the 2022 outbreak, additional individuals are eligible for vaccination through expanded vaccination efforts.

NJDOH recommends vaccination against mpox for:

- People who have known or suspected exposure to someone with mpox in the last two weeks
- People who had a sex partner in the past two weeks who was diagnosed with mpox
- People who are gay, bisexual, or other men who have sex with men, transgender, nonbinary, or gender-diverse people who in the past 6 months have had any of the following:
 - A new diagnosis of one or more sexually transmitted diseases (e.g., chlamydia, gonorrhea, or syphilis)
 - More than one sex partner
- People who have had any of the following in the past 6 months:
 - Sex at a commercial sex venue
 - Sex related to a large commercial event in a geographic area (city or county for example)
 where mpox virus transmission is occurring
 - Sex in exchange for money or other items
- People who have a sex partner with any of the above risks
- People who anticipate experiencing any of the above risks
- People who have HIV or other causes of immune suppression and have had recent or anticipate future risk of mpox exposure from any of the above scenarios
- People who work in settings where they may be exposed to mpox:
 - People who work with orthopoxviruses in a laboratory- Consult with your <u>local health</u> department

Persons with the above risk factors that also have a condition that may increase their risk for severe disease if infected with mpox virus, such as a condition that weakens the immune system, or a history of atopic dermatitis or eczema, should be a high priority for vaccination.

Check the NJDOH website for current vaccine recommendations and locations: https://www.nj.gov/health/monkeypox/vaccines/

E. Air Travel

Flight Exposures

If someone who is positive for orthopoxvirus or mpox traveled by air while infectious and meets the following criteria, notify CDS:

- Air travel must have occurred in previous 21 days and was ≥3 hours long, AND
- The traveler either had
 - o Fever (100.4°F [38°C]) at the time of their flight, OR
 - Respiratory symptom(s) at the time of their flight (including sore throat, nasal congestion, cough), regardless of mask use, OR
 - o Did not wear a mask during their flight (even if no respiratory symptoms), OR
 - Did not cover all lesions during their flight.

Travel Restrictions

CDC advises that persons with mpox not travel, but if they must travel, persons with mpox should be afebrile, not have any respiratory symptoms (sore throat, nasal congestion, cough), and be advised to cover all their lesions and wear a well-fitting mask during travel. LHDs should notify CDS if they are aware of someone with suspected/ probable/ confirmed MPX who they have reason to think may not comply with this guidance.

F. Other Preventive Measures

Take the following steps to prevent getting mpox:

- Avoid close, skin-to-skin contact with people who have a rash that looks like mpox.
- Do not touch the rash or scabs of a person with mpox.
- Do not kiss, hug, cuddle or have sex with someone with mpox.
- Do not share eating utensils or cups with a person with mpox.
- Do not handle or touch the bedding, towels, or clothing of a person with mpox.
- Wash your hands often with soap and water or use an alcohol-based hand sanitizer.
- In Central and West Africa, avoid contact with animals that can spread mpox virus, usually rodents and primates. Also, avoid sick or dead animals, as well as bedding or other materials they have touched.

If you are sick with mpox:

- Isolate at home.
- If you have an active rash or other symptoms, stay in a separate room or area away from people or pets you live with, when possible.

If you have recovered from mpox:

• Safe sex, barrier practices (i.e., wearing condoms) are recommended, but there is little data to support the length of time patients need to wear condoms. Some other countries are recommending 8-12 weeks, but we are still learning about this virus in the context of transmission through sexual contact

Resources

- NJDOH Mpox webpage: Public health testing, requesting antivirals, vaccination
- CDC Mpox webpage: 2022 outbreak and guidance