Monkeypox



THE DISEASE AND ITS EPIDEMIOLOGY

A. Etiologic Agent

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 monkeypox virus: the central African (Congo Basin) clade and the west African clade- the Congo Basin clade has historically caused more severe disease.

B. Clinical Description

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

Presenting symptoms typically include fever, chills, the distinctive rash, or new lymphadenopathy; however, onset of perianal or genital lesions in the absence of subjective fever has been reported.

The rash associated with monkeypox 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 monkeypox can be confused with other diseases that are encountered in clinical practice (e.g., secondary syphilis, herpes, chancroid, and varicella zoster). Co-infections have been reported, so patients with a characteristic rash should be considered for testing, even if other tests are positive. CDC has photos of monkeypox rashes for reference: https://www.cdc.gov/poxvirus/monkeypox/symptoms.html

Some individuals associated with the 2022 monkeypox 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.

Monkeypox 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 monkeypox, is not approved by the FDA. Therefore, 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 monkeypox, 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. Monkeypox Cases for additional information about TPOXX.

Tecovirimat may be considered for treatment in people infected with *Monkeypox 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 aberrant infections involving accidental implantation in eyes, mouth, or other anatomic areas where *Monkeypox virus* infection might constitute a special hazard (e.g., the genitals or anus)

On July 21, 2022, CDC IRB approved an <u>amendment [123KB, 1 page]</u> and <u>continuation [105KB, 1 page]</u> of <u>Protocol 6402 [430KB, 21 pages]</u>.

Required Documents (Send to CDC)

- 1. Informed Consent Form [214KB, 5 pages]: Obtain prior to treatment.
- 2. Patient Intake Form [321KB, 3 pages]: Baseline assessment.
- 3. **FDA Form 1572 [1MB, 2 pages]:** One signed 1572 per facility suffices for all TPOXX treatments administered under the EA-IND at the same facility.
- 4. <u>Clinical Outcome Form [279KB, 4 pages]</u>: Progress information during and post treatment.
- Serious Adverse Events : Report life-threatening or serious adverse events associated with TPOXX by completing a <u>PDF MedWatch Form [226KB, 3 pages]</u> 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.

Completed IND protocol forms can be returned to the CDC using one of the following methods:

- Secure Share File for lesion photos and large file sizes : <u>https://centersfordiseasecontrol.sharefile.com/share/upload/r3941801ebcbd4002b4df</u> <u>e98e314ec697</u>
- Email: <u>regaffairs@cdc.gov</u>
- Fax: 404-902-5921

HCP Requests for TPOXX in New Jersey

NJDOH has received a limited number of doses of oral TPOXX through the Strategic National Stockpile (SNS). To request oral TPOXX for a patient that meets criteria for TPOXX use, HCPs should email <u>DOH-MPOX@doh.nj.gov</u> and copy <u>CDSVectorTeam@doh.nj.gov</u>. In the email, include:

• Provider name and contact information

- Address where TPOXX needs to be delivered
- A point of contact (name and phone number) to receive doses at address provided
- Requested doses

The NJDOH Medical Counter Measures Team will work with the HCP to coordinate delivery and provide the requisite forms. HCPs should contact NJDOH at <u>CDSVectorTeam@doh.nj.gov</u> if they need to request the intravenous (IV) administration formulation of TPOXX.

Additional Information on Medical Countermeasures for the treatment of Monkeypox

The CDC has additional information on medical countermeasures available for the treatment of monkeypox here: <u>https://www.cdc.gov/poxvirus/monkeypox/clinicians/treatment.html</u>

D. Reservoirs

Monkeypox is a zoonotic disease, meaning that it can spread between animals and people, and is caused by Monkeypox 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 monkeypox and have signs of disease like humans. In 2003, an outbreak of monkeypox 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

Monkeypox 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 monkeypox 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.

G. Infectious Period

Monkeypox can spread from 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. It is thought that people who do not have monkeypox symptoms cannot spread the virus to others.

H. Epidemiology

Monkeypox was discovered in 1958 when two outbreaks of a pox-like disease occurred in colonies of monkeys kept for research. Despite being named "monkeypox," the source of the disease remains unknown. However, African rodents and non-human primates (like monkeys) might harbor the virus and infect people.

The first human case of monkeypox was recorded in 1970. Prior to the 2022 outbreak, monkeypox had been reported in people in several central and western African countries. Previously, almost all monkeypox 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 Monkeypox Outbreak:

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

2 CASE DEFINITION

NJDOH is following the interim case definition posted by CDC in the context of the 2022 outbreak: <u>https://www.cdc.gov/poxvirus/monkeypox/clinicians/case-definition.html</u>

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 monkeypox, OR
- Close or intimate contact with individuals in a social network experiencing monkeypox 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 monkeypox or where *monkeypox 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 monkeypox 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 *Monkeypox virus* or antibodies to orthopoxvirus.

C. Case classification

CONFIRMED

- Demonstration of the presence of *Monkeypox virus* DNA by polymerase chain reaction testing, OR
- Next-Generation sequencing of a clinical specimen, OR
- Isolation of *Monkeypox 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 monkeypox

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 *monkeypox virus*. The FDA is not aware of clinical data supporting the use of other sample types, such as blood or saliva, for *monkeypox 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</u> for healthcare settings (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 monkeypox outbreak is associated with the West African clade of *monkeypox virus*. The U.S. government does not consider the West African clade of *monkeypox 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 the West African clade of *monkeypox virus* can be shipped as UN 3373 Biological Substance, Category B.

Depending on the laboratory, testing for monkeypox is performed with an orthopoxvirus Real-Time PCR Assay and/or Non-variola Orthopoxvirus Real-Time PCR Assay. In the context of the 2022 monkeypox outbreak, an orthopoxvirus positive PCR test is diagnostic for monkeypox. CDC has a monkeypox-specific PCR test, but that is not needed to confirm monkeypox infection. Antibody testing (performed at CDC) may be considered on a case-by-case basis in individuals suspected of having had monkeypox but in whom the lesions have resolved. LHDs should consult with CDS to discuss these scenarios.

Commercial Testing

PCR testing for Orthopoxvirus is available at 5 commercial laboratories (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 monkeypox cases when feasible. Public health approval for commercial testing is not required.

<u>Inconclusive results</u>: In most cases, if a test result is inconclusive and the healthcare provider suspects monkeypox, 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.

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 or for patients with severe clinical disease.

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

- 1) Provide <u>CDC infection control recommendations</u>
- 2) Collect information using the <u>Monkeypox Investigation Form</u> and request photos of lesions, if available
- 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 monkeypox. 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 monkeypox case, or with someone who has lesions consistent with monkeypox
 - iii. Multiple or anonymous sexual partners in the past 14 days
 - iv. Recent travel to an area with monkeypox cases, OR
 - b. 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. Sanitize the patient's skin with an alcohol wipe and allow skin to dry.
 - ii. Vigorously swab or brush lesion with two separate sterile dry polyester or Dacron swabs. It is recommended to swab multiple lesions- duplicate swabs should be taken for each lesion sampled.

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. 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.

- b. Enter the suspect case into CDRSS (case status = RUI), including symptoms, risk factors and in Comments "Approved for MPX 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 isolate at home 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.

PURPOSE OF SURVEILLANCE AND REPORTING

- To determine the source of exposure so to prevent further transmission
- To quickly detect persons with monkeypox 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 monkeypox
- To increase healthcare provider awareness of monkeypox

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.

Monkeypox 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 <u>Monkeypox Investigation Worksheet</u> 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 https://www.cdc.gov/poxvirus/monkeypox/clinicians/infection-control-home.html; 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 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-contactmonitoring.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, concerns with non-compliance with isolation, past or future air/cruise travel; difficulties in obtaining vaccine for PEP, pediatric contacts who want vaccine (FDA-IND approval needed for pediatric vaccination) high-concern contacts/settings, e.g., healthcare worker, teacher, etc.

Detailed Exposure History

Until these questions are available in CDRSS via an outbreak questionnaire, LHDs should enter responses in CDRSS Comments. For each question, the case has the option to "prefer not to answer".

- 1. Confirm whether the individual thinks of themselves as: gay, bisexual, straight, a different term, prefers not to answer
- 2. Gender

- 3. Sex assigned at birth
- 4. Any pets in the household? If yes, which type of animal? Are any pets allowed to go outside unsupervised?
- 5. In three weeks prior to illness, what type of dwelling were they in (single family, multifamily, hotel, congregate housing, unsheltered, other)
- 6. First symptom and onset
- 7. In three weeks prior to illness did case:
 - a. Attend any large public/private events (i.e., concerts, weddings, etc.) and if so, what events?
 - b. Interact with anyone with symptoms of monkeypox when case interacted with them
 - a. If yes: date of interaction, sex, and age of person, if they received a lab-confirmed diagnosis of orthopox or monkeypox, did they have recent domestic or international travel, and what type of interaction
 - c. Interact with anyone who has developed signs of monkeypox since the time case interacted with them
 - a. If yes: date of interaction, sex, and age of person, if they received a lab-confirmed diagnosis of orthopox or monkeypox, did they have recent domestic or international travel, and what type of interaction
 - d. Travel domestically or internationally (if so, where, dates of travel, did they wear a mask while in transit)
 - e. Touch any dead animal or animal products
 - $f. \quad \mbox{Engage in sex and/or close intimate contact:} \\$
 - a. How many men? How many women?
 - b. What were the anatomic sites of exposure during sexual or close intimate contact?
 - c. Was it with someone who had recently traveled outside of their city?
 - d. Where did case first meet the sexual contacts?
 - e. Did case participate in any group sex (more than two people) at a festival, group sex event, or sex party?

B. Key CDRSS Fields Specific for MPX Cases	Required Information
Disease Information	 Cases positive for orthopoxvirus should have a case status of PROBABLE Cases positive for monkeypox virus (CDC only, this would be rare) 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, close case as LHD CLOSED
Outbreak Information	 Assign <u>orthopoxvirus positive</u> cases to I# 2022-23921
Clinical Status	 <u>Illness Onset Date</u>: 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 monkeypox).
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, enter the date of vaccination if known

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

B. Key CDRSS Fields Specific for MPX Cases	Required Information
Contact Tracing	 Enter names/case IDs of anyone the person may have exposed while infectious. 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.
Treatment	 If patient receives TPOXX, add as "ANTIVIRALS" with dates
Signs and Symptoms	Enter onset date for each reported sign/symptom
Additional Requirements (Coming Soon – for now see Comments)	o TBD
Case Comments	Enter Detailed Exposure History question responses

6 CONTROLLING FURTHER SPREAD

A. Isolation

Patients with confirmed or suspected monkeypox infection should be isolated. Patients who do not require hospitalization, but remain potentially infectious to others, should be isolated at home. For individuals with monkeypox, 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 MPX cases:

https://www.cdc.gov/poxvirus/monkeypox/clinicians/infection-control-home.html

Administrators of congregate care settings should refer to <u>Preventing Monkeypox Spread in</u> <u>Congregate Settings</u> if a staff member, volunteer, or resident of a congregate living setting has a monkeypox 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 monkeypox. 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 monkeypox. 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.

If contact is high or intermediate risk, or if risk level us 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 monkeypox (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 monkeypox 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 Monkeypox 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 Monkeypox Monitoring section and close the case as NOT A CASE / LHD CLOSED.

B. Key CDRSS Fields Specific for MPX 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 MPX, change case status to PROBABLE
Outbreak Information	 Do NOT assign contacts to the MPX I# (unless they test positive for orthopoxvirus and become a MPX 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, enter the date of vaccination if known
Contact Tracing	 Ensure (or enter) name(s)/case ID(s) of MPX cases (if known and NJ resident)

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

July 2022

B. Key CDRSS Fields Specific for MPX Contacts	Required Information
Monkeypox Monitoring	 Edit questionnaire and complete Days 1-21 from date of last exposure to MPX 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 monkeypox 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. <u>JYNNEOS</u> is a vaccine Indicated for prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection. When administered before or after a recent exposure, vaccines can be effective tools at protecting people against monkeypox illness. JYNNEOS is administered by subcutaneous injection as a 2-dose series delivered 28 days apart. 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 monkeypox.

Pre-Exposure (PrEP)

This approach refers to administering vaccine to someone at high risk for monkeypox (for example, laboratory workers who handle specimens that might contain monkeypox virus). At this time, most clinicians in the United States and laboratorians not performing the orthopoxvirus generic test to diagnose orthopox viruses, including monkeypox virus, are not advised to receive monkeypox vaccine PrEP. <u>https://www.cdc.gov/mmwr/volumes/71/wr/mm7122e1.htm</u>. 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 MPX 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 monkeypox can also be considered while test results are pending. LHDs should coordinate provision of PEP with their LINCS MPX Vaccine HUB and document doses received in the contact's CDRSS record (Immunization Information).

<u>Pediatric close contacts:</u> JYNNEOS is licensed by the FDA for use in the prevention of smallpox or monkeypox in people ages 18 years and older. Use in younger populations requires submission of a single patient Expanded Access Investigational New Drug (IND) application. If a child has had an intermediate or high-risk exposure to someone with MPX and the child's pediatrician and parent/guardian are interested in PEP, email <u>CDSVectorTeam@doh.nj.gov</u> and provide contact information for the treating physician, the contact, a description of the exposure type/date, and any underlying conditions. CDS will coordinate necessary CDC/FDA approvals and provide requisite paperwork.

HCPs should monitor the patient for a minimum of 30 minutes post each vaccination for immediate adverse reactions. The patient will need to be periodically followed-up by phone or in person to assess for serious adverse events, medically attended adverse events and adverse events of special interest (e.g., cardiac related events, symptoms consistent with monkeypox) occurring immediately after the 1st vaccination through at least 30 days after the 2nd vaccine dose. The patient should be instructed to report any adverse events to the treating clinician as well as to report to <u>https://vaers.hhs.gov/</u>.

Expanded Post-Exposure Prophylaxis (a.k.a. PEP++)

In the context of the current 2022 MPX outbreak, people with certain risk factors are more likely to have been recently exposed to monkeypox. The "PEP plus-plus" or "PEP++" vaccination strategy aims to reach these people for post-exposure prophylaxis, even if they have not had documented exposure to someone with confirmed monkeypox. Under this strategy, the following residents are eligible for vaccination (check the NJDOH MPX website for current eligibility criteria and locations: https://www.state.nj.us/health/cd/topics/monkeypox.shtml

- Individuals that attended an event where known monkeypox exposure occurred within the past 14 days
- Individuals that identify as gay, bisexual, or men who have sex with men (MSM), and/or transgender, gender non-conforming, or gender non-binary and who have a history of multiple or anonymous sexual partners within the past 14 days

Persons that have a condition that may increase their risk for severe disease if infected with monkeypox 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 if they have exposure risk as listed above. When coupled with self-isolation and other prevention measures when symptoms first occur, PEP++ may help slow the spread of the disease in areas with large numbers of monkeypox cases—which would suggest a higher level of monkeypox virus transmission.

LHDs should refer residents meeting criteria for PEP++ to one of the vaccination locations specified at: <u>https://www.state.nj.us/health/cd/topics/monkeypox.shtml</u>

Take the following steps to prevent getting monkeypox:

- Avoid close, skin-to-skin contact with people who have a rash that looks like monkeypox.
- Do not touch the rash or scabs of a person with monkeypox.
- Do not kiss, hug, cuddle or have sex with someone with monkeypox.
- Do not share eating utensils or cups with a person with monkeypox.
- Do not handle or touch the bedding, towels, or clothing of a person with monkeypox.
- 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 monkeypox 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 monkeypox:

- 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

Resources

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