Monkeypox Toolkit for Healthcare Providers

Resources from the Centers for Disease Control, the Ohio Department of Health, and Cincinnati Health Department for Cincinnati Area Healthcare Providers

city of CINCINNATI HEALTH DEPARTMENT

August 1, 2022

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Contact Information

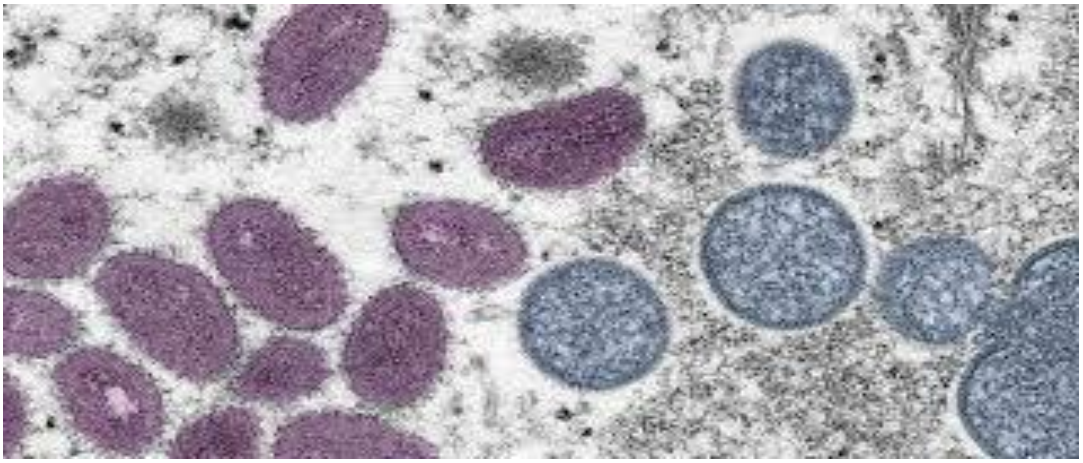
Cincinnati Health Department Communicable Disease	(513) 357-7462
Confidential Fax Line	(513) 357-7396
Disease Reporting Form	cdms.fax@cincinnati-oh.gov
Ohio Department of Health	(614) 995-5599
CDC Monkeypox Provider Hotline	(770) 488-7100

CHD Webpage: https://www.cincinnati-oh.gov/health/monkeypox-virus/

ODH Webpage: https://odh.ohio.gov/know-our-programs/infectious-disease-control-manual/section3/section-3-monkeypox

CDC Webpage: https://www.cdc.gov/poxvirus/monkeypox/index.html

WHO Webpage: https://www.who.int/news-room/fact-sheets/detail/monkeypox



https://www.cdc.gov/poxvirus/monkeypox/index.html

Monkeypox Background Information

What is Monkeypox?

Monkeypox Virus (MPV) is an enveloped double-stranded DNA virus that, like Smallpox, belongs to the *Orthopoxvirus* genus of the *Poxviridae* family. There are two types (or clades) of Monkeypox virus: West African and Congo Basin. The Congo Basin clade has historically caused more severe diseases in endemic areas in Africa and has been thought to be more transmissible.

MPV infection (also referred to as MPX) usually results in a self-limited disease with the symptoms lasting from 2 to 4 weeks. Severe cases occur more commonly among children and have been related to the extent of virus exposure, patient health status, and nature of complications. Underlying immune deficiencies may lead to worse outcomes. The extent to which asymptomatic infection may occur is unknown. Complications of MPV infection can include secondary infections, bronchopneumonia, sepsis, encephalitis, and infection of the cornea with ensuing loss of vision, according to the World Health Organization (WHO).

Although vaccination against Smallpox was protective in the past, today persons younger than 40 to 50 years of age (depending on the country) may be more susceptible to Monkeypox due to the cessation of smallpox vaccination campaigns globally after eradication of the disease.

What are the Symptoms of Monkeypox?

Symptoms of MPV infection can include fever, headache, muscle aches, swollen lymph nodes, chills, exhaustion, and fatigue. The most notable symptom with pox viruses is the rash, Monkeypox rash can look like pimples or blisters that appear on the face, inside the mouth, on the hands, feet, chest, genitals, or anus. This rash can last 2-4 weeks. Some individuals get the rash first, followed by the other symptoms, while others only experience a rash.

How is Monkeypox Transmitted?

MPV infection is primarily spread through contact with an infectious person or in past outbreaks, an infected animal. This can include

- Direct contact with an infectious rash, scabs, or body fluids
- Direct contact with respiratory secretions (for examples: face to face contact, during intimate physical contact, such as kissing, cuddling or sex, or prolonged close contact (>3 hours and <6 foot apart).
- Direct contact with clothing, linens or bandages that previously touched an infectious rash or bodily fluids.
- Pregnant individuals can also spread the virus to their fetus through the placenta.

2022 Public Health Emergency of International Concern

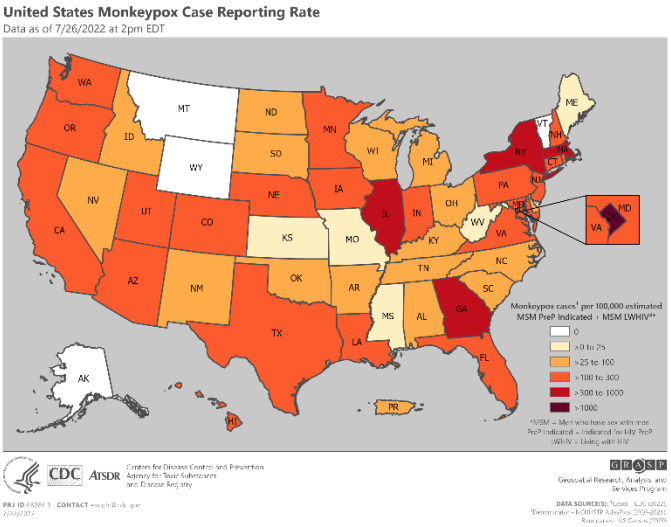
According to the WHO, physicians treating patients with MPV infection, remark, "… it is important to point out that MSM are currently at higher risk of contracting Monkeypox because of the social and sexual networks in which the disease has been spreading the fastest. However, Monkeypox cases are also being detected in women and children, and clinicians must be alert to the possibility of monkeypox in their assessment of any patient."

Also noted about the PHEIC by WHO, "the clinical presentation of Monkeypox cases associated with this outbreak has been atypical as compared to previously documented reports: many cases in newly-affected areas are not presenting with the classically described clinical picture for Monkeypox (fever, swollen lymph nodes, followed by centrifugal rash). Atypical features described include:

- presentation of only a few or even just a single lesion
- absence of skin lesions in some cases, with anal pain and bleeding
- lesions in the genital or perineal/perianal area which do not spread further
- lesions appearing at different (asynchronous) stages of development
- the appearance of lesions before the onset of fever, malaise and other constitutional symptoms (absence of prodromal period)."

2022 US Outbreak: CDC Situation Report

CDC Technical Report



The current MPV infection spreading in the United States is the milder West African strain, which is rarely fatal. Over 99% of people who get this from of the disease are likely to survive. However, symptoms can be extremely painful and permanent scarring may result from the rash.

Preliminary data revealed the median age of patients is 35 years (range 18 to 76). Of the 1,383 patients with information on sex assigned at birth, 99.1% were assigned male sex (13 assigned female sex). Of the 870 patients with information on gender identity, 1 self-reported as transgender male (July 25, 2022).

Many of the initial patients reported international travel in the 21 days prior to symptom onset, visiting countries not known to experience endemic MPV infection and participating in large festivals and other activities where close, personal, skin-to-skin contact likely occurred. Recent travel history does not confirm the person acquired their infection while traveling. Since late June, however, an increasing number of reported cases have been linked to local community transmission.

CDC offers community engagement and communication recommendations to reach people at greatest risk for exposure to MPV infection.

MPV Infection in Ohio

On July 28, 2022, the Ohio Director of Health declared MPV infection a disease of significant public concern akin to the diseases listed in Ohio Adm. Code 3701-3-02(B) after 23 cases were reported. Providers and laboratories are required to report infections or suspected infections to the local health department by the end of the next business day. ODH also added a Monkeypox (MPX) Chapter to the Infectious Disease Control Manual

MPV Infection in Cincinnati

On Tuesday, July 26, 2022, the Cincinnati Board of Health was informed that 2 cases of MPV infection had been reported to the Cincinnati Health Department (CHD). CHD added a MPX web page to the CHD website to provide information and resources for the community. Prevention and early detection messages have also been shared on CHD Social Media accounts. CHD is facilitating access to vaccine and treatment for local providers who have identified patients meeting the current CDC recommendations for vaccine and/or treatment. This toolkit is provided for Cincinnati healthcare providers to better explain the processes involved.

Clinical Considerations

What should prompt clinical suspicion for monkeypox? Clinician FAQs

Clinicians should be alert to patients presenting with a new characteristic rash or if the patient meets one of the epidemiological criteria below and there is a high clinical suspicion for monkeypox. Especially people reporting travel history to a country where Monkeypox has been identified within a month before illness onset, people reporting contact with people who have a similar rash or have received a diagnosis of suspected or confirmed monkeypox, or men who report sexual contact with other men and who present with lesions in the genital/perianal area.

- The Monkeypox rash involves vesicles or pustules that are deep-seated, firm, or hard, and well-circumscribed. Lesions can occur on the palms and soles or be generalized affecting other areas; they may progress over time to scabs. Presenting symptoms typically include fever, chills, the distinctive rash, or new lymphadenopathy; however, onset of perianal or genital lesions in the absence of fever has been reported in recent cases.
- The rash associated with Monkeypox can be confused with other rashes encountered in clinical practice including herpes, syphilis, and varicella. Patients co-infected with Monkeypox virus and other infectious agents (e.g., varicella zoster, herpes, syphilis) have been reported. Clinicians should therefore have Monkeypox on their differential diagnosis when presented with an associated sexually transmitted infection (STI) or STI-like rash, even if it is localized and not (yet) diffuse.

Epidemiological Criteria to Consider

Within 21 days of illness onset:

- Residence in or travel to a country where Monkeypox is endemic; OR
- Contact with a dead or live wild or exotic pet animal of an African species, or used or consumed a product derived from such animals (e.g., game meat, powders, etc.); OR
- Contact with a person or persons, animal or animals, with a suspected or known orthopoxvirus or Monkeypox infection; OR
- Contact with items that could serve as fomites that have been in contact with a person or persons, animal or animals, with suspected or known orthopoxvirus or Monkeypox infection, OR
- Work in a non-clinical laboratory that handles MPV; OR
- Member of a cohort (as defined by public health authorities) experiencing Monkeypox activity.

What is the Expected Course of Illness?

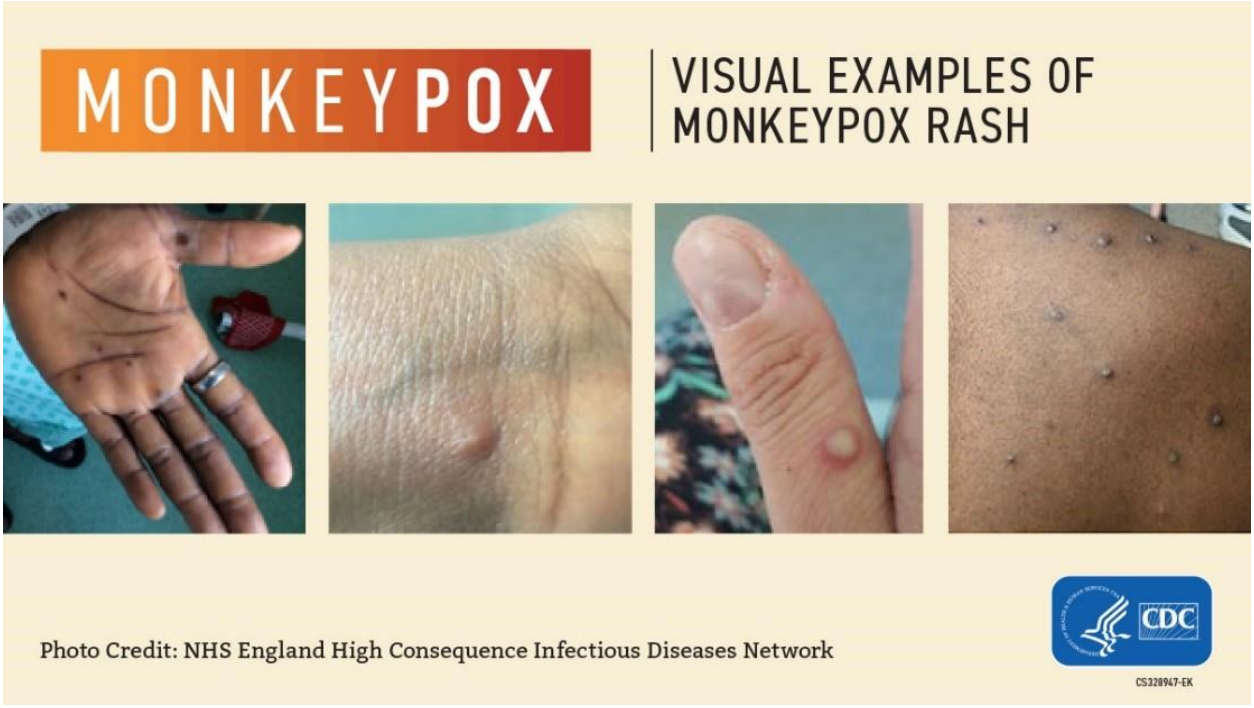
MPX is characterized by an incubation period, prodrome, and rash.

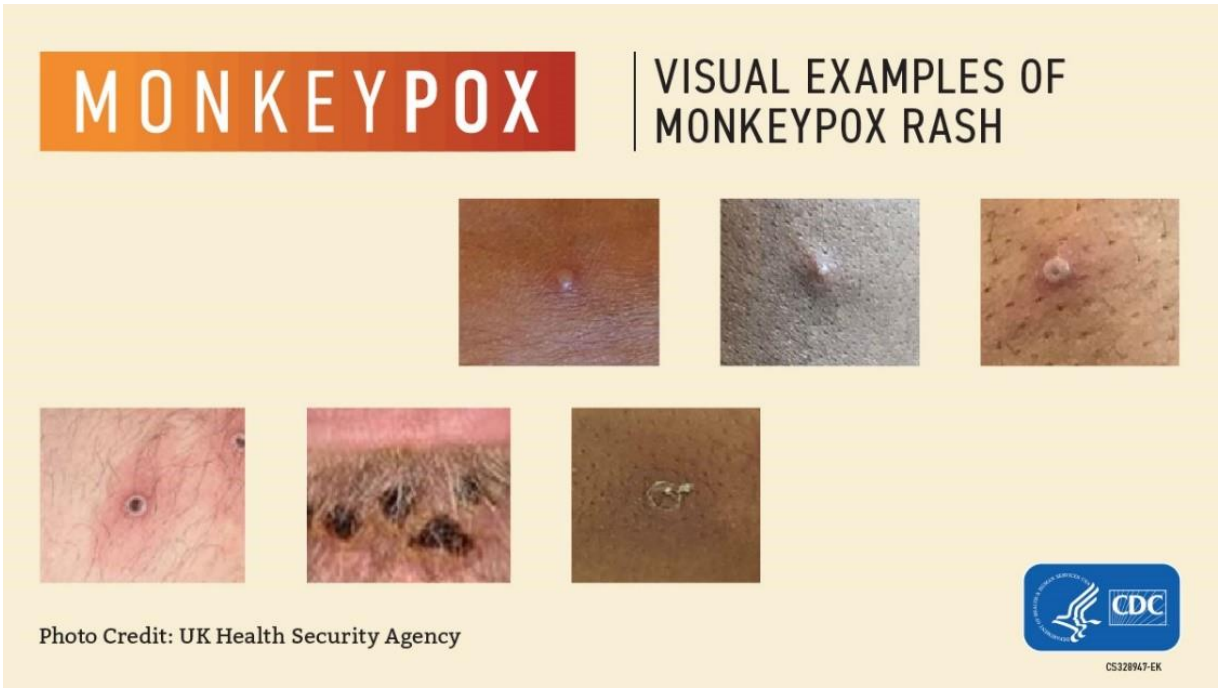
- **Incubation Period:** Infection with Monkeypox virus begins with an incubation period where the person does not have symptoms and may feel fine. The incubation period can be from 5 to 21 days, but usually 6-13 days, according to the WHO. The patient should be careful not to potentially expose other people while monitoring for symptoms, although they are not considered to be infectious before symptoms begin.

They are not currently recommended to quarantine by the CDC. However, exposed patients should be reported to the local health department for monitoring. The local health department will advise patient how to isolate and report symptoms, if any develop and can help arrange for testing if needed.

- **Prodrome:** People with Monkeypox infection may develop an early set of symptoms (prodrome). These symptoms may include fever, malaise, headache, sore throat, or cough, and (in many cases) swollen lymph nodes. Lymphadenopathy is a characteristic feature of monkeypox, and lymph nodes may swell in the neck (submandibular & cervical), armpits (axillary), or groin (inguinal) and can occur on both sides of the body or just one. ***A person may be contagious during this period*** and should be instructed to isolate if they develop any symptoms. There are currently no testing options for this 1-3 day phase.
- **Rash:** In some recent Monkeypox cases, people have presented with a rash without a recognized prodrome. Once a rash appears, a swab of the lesions can be tested to confirm the presence of MPX virus at the state lab or commercial lab. Many of the recent cases have only had localized lesions and have not presented with diffuse rash often seen in figures. People with Monkeypox infection develop lesions that typically progress from papules, macules, vesicles, pustules, and then scabs. ***A person is contagious and required to isolate at home until after all the scabs on the skin have fallen off and a fresh layer of intact skin has formed underneath***.

Clinical Photos of MPX rashes





Infection Control for Healthcare Settings

CDC Full Recommendations can be found here.

Personal Protective Equipment (PPE)

PPE used by healthcare personnel who enter the patient's room should include:

- 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

Exposures

Healthcare personnel and patients in healthcare facilities who have had an exposure to Monkeypox should be monitored and receive postexposure management according to current recommendations. Additionally, if an inpatient is unable to communicate symptom onset (e.g. a newborn, patient with delirium), they should be isolated for 21 days after their last exposure or until they are able to communicate symptom onset (e.g. following delirium resolution) and monitored for the remaining duration of their incubation period. CHD will also be monitoring close contacts in CHD's jurisdiction according to the ODH Infectious Disease Control Manual guidance.

If any symptoms develop during the 21 day monitoring period, the exposed person should isolate at home and be tested as soon as possible. The healthcare provider should report the suspected infection to CHD using the reporting form or by calling 513-357-7462 by the end of the next business day.

CDC provides this guidance to help determine the degree of exposure.

Patient Placement

A patient with suspected or confirmed Monkeypox infection should be placed in a single-person room; special air handling is not required. The door should be kept closed (if safe to do so). The patient should have a dedicated bathroom. Transport and movement of the patient outside of the room should be limited to medically essential purposes. If the patient is transported outside of their room, they should use well-fitting source control (e.g., medical mask) and have any exposed skin lesions covered with a sheet or gown.
Intubation and extubation, and any procedures likely to spread oral secretions should be performed in an airborne infection isolation room.

Testing

If you are a healthcare provider in Cincinnati and you have a patient that you suspect has MPX after clinical evaluation, testing is recommended as soon as possible. It is best if you can obtain the specimens right after the evaluation without having to make a separate appointment. CHD has created an algorithm to help illustrate the specimen submission process. If you are planning to submit your specimens for testing at the ODH Laboratory, please freeze the specimens and use this **ODHL Monkeypox Specimen Submission Form.** You will need to provide an Ohio ID number with the specimens when they are shipped. Specific ODHL collection and submission directions can also be found here.

If you are a healthcare provider in Cincinnati and you have a patient that you plan to test using a commercial laboratory to process your specimens, you *do not* need to submit the ODHL form or include Ohio ID numbers. You will need to notify CHD by the end of the following business day using the Disease Reporting Form. You can also report a suspected MPX case by calling CHD's Communicable Disease line 513-357-7462.

Once a patient is suspected of having MPX *and* specimens have been collected by the healthcare provider for submission to the lab of your choice, the patient's close contacts who have been exposed can be considered for vaccination to prevent infection. Cincinnati healthcare providers can submit a vaccine request form to receive vaccine from CHD to administer or follow the vaccine request guidance below.

Vaccine

Approved MPX Vaccines

The FDA has authorized two vaccines to that may aid in the prevention of MPV infection. Click for the FDA package inserts: JYNNEOS (also known as Imvamune or Imvanex) and ACAM2000.

In the United States, there is currently a limited supply of JYNNEOS, although more is expected in the coming weeks and months. There is a larger supply of ACAM2000, but this vaccine should not be used in people who have certain health conditions, such as a weakened immune system, skin conditions like eczema or other exfoliative skin conditions, or pregnancy. CDC provides additional healthcare provider resources about the proper administration of ACAM2000.

Patients who get vaccinated should still be advised to continue to take steps to protect themselves from infection by avoiding close, skin-to-skin contact, including intimate contact, with someone who has MPX, and continue to monitor themselves for symptoms of MPX if they may have been already exposed.

Current Vaccine Recommendations

CDC Recommends post-exposure prophylaxis for people who have been exposed to Monkeypox and pre-exposure prophylaxis for people who are at higher risk for being exposed to monkeypox, including certain laboratorians and healthcare providers who care for people with Orthopoxviruses. CHD is currently facilitating the delivery of Jynneos Vaccine for patients/people meeting that criteria. As more vaccine becomes available, more people will be able to receive it based upon the vaccination strategies recommended by CDC.

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. Benefits may still outweigh risks when giving vaccine more than 14 days after exposure in some clinical situations (e.g., high risk exposure in a person at high risk for severe disease, such as severe immune compromise).

Vaccination given after the onset of signs or symptoms of Monkeypox is not expected to provide benefit.

CDC provides this guidance to help determine the degree of exposure.

How to Request Vaccine

CHD has created an algorithm to better explain the ordering process. *If you are a healthcare provider in Cincinnati*, to process your request to receive and administer Jynneos Vaccine for a specific patient or person, CHD needs to collect certain required information. Please fill out this form and fax it or email it to cdms.fax@cincinnati-oh.gov. You can call 513-357-7462 to make sure that it was received.

Treatment

Current Treatment Recommendations

CDC has updated the Interim Clinical Guidance for the Treatment of Monkeypox. Antivirals, such as tecovirimat (TPOXX), may be recommended for people who are more likely to get severely ill, like patients with weakened immune systems. TPOXX is an antiviral medication that is approved by the United States Food and Drug Administration (FDA) [PDF] for the treatment of Smallpox in adults and children. Data is not available on the effectiveness of tecovirimat in treating Monkeypox infections in people, but studies using a variety of animal species have shown that tecovirimat is effective in treating disease caused by orthopoxviruses. Clinical trials in people showed the drug was safe and had only minor side effects. CDC holds an expanded access protocol (sometimes called "compassionate use") that allows for the use of stockpiled tecovirimat to treat Monkeypox during an outbreak. Tecovirimat is available as a pill or an injection.

If you have questions about treating patients with MPV infection, the CDC has also provided a hotline for healthcare providers with specific questions: (770) 488-7100.

CHD has created an algorithm to better explain the ordering process. *If you are a healthcare provider in Cincinnati*, to process your request to receive and administer TPOXX to a specific patient or person, CHD needs to collect certain required information. Please fill out this form and fax it or email it to cdms.fax@cincinnati-oh.gov. You can call 513-357-7462 to make sure that it was received.

Information For Patients with Monkeypox

Instructions for Isolation at Home

- Do not leave the home except as required for emergencies or follow-up medical care. Rash and lesion areas should be covered with dressings when possible if you must leave the home for care. Wear a well-fitting mask.
- Persons without an essential need to be in the home should not visit.
- Avoid all close contact with others (including hugging, snuggling, massaging, etc.)
- Avoid close contact with pets in the home.
- Abstain from all sexual activity.
- Do not share items that could be contaminated by the lesions (e.g., bed linens, clothing, towels, wash cloths). Do not share drinking glasses or eating utensils.
- Routinely clean and disinfect commonly touched surfaces and items (e.g., counters, light switches) using an EPA-registered disinfectant in accordance with the manufacturer's instructions.
- Wear a well-fitting mask or respirator for source control when in close contact with others at home.
- Avoid use of contact lenses to prevent inadvertent infection of the eye.
- Avoid shaving areas of the body with lesions as this can lead to the spread of the virus.

- Bathroom usage:
  - If possible, use a separate bathroom if there are others who live in the same household.
  - If there is not a separate bathroom in the home, the patient should clean and disinfect surfaces (e.g., counters, toilet seats, faucets) using an EPA-registered household cleaning product after using a shared space if the lesions are exposed (e.g., showering, toileting, changing bandages covering the lesions). Consider disposable glove use while cleaning if lesions are present on the hands.
- Limit exposure to others:
  - Avoid contact with unaffected individuals until lesions have resolved, the scabs have fallen off, and a fresh layer of intact skin has formed, to be evaluated and determined by provider.
  - Isolate in a room or area separate from other household members and pets when possible.
- Limit use of spaces, items, and food that are shared with other household members.
  - Do not share dishes and other eating utensils. It is not necessary for the infected person to use separate utensils if properly washed. Wash soiled dishes and eat utensils in a dishwasher or by hand with warm water and soap.
- Limit contamination within household:
  - Keep lesions covered when in common areas of the home.

- Avoid direct contact with upholstered furniture and porous materials that cannot be laundered by placing coversheets, waterproof mattress covers, thick blankets, or tarps over these surfaces.
- Additional precautions such as steam cleaning can be considered if there is concern about contamination.

Cleaning and Disinfection

Researchers have found that left untouched, the Monkeypox virus can live on surfaces for up to 15 days. Researchers believed that the virus could live even longer on bedding and clothing. Surfaces should be disinfected with an EPA approved disinfectant, for more instruction please go to the EPA Website and look for the EVP Q-list of disinfectants, this will provide a comprehensive list of approved cleaners for monkeypox.

Even if a patient is isolating at home alone, it is important to clean and disinfect services regularly, especially high touch surfaces, to limit household contamination. Wash and disinfect your hands using soap and water, or at least a 60% alcohol-based sanitizer. Any shared spaces, appliances, or items should be disinfected immediately following use.

- **Laundry**
  When at all possible, people infected with Monkeypox should do their own laundry, and it should be separated from other in the household. This is to reduce the risk of transmission from the clothing items to others. When handling laundry, avoid contact with your skin, or rashes. Store your dirty laundry items in a solid container (plastic tub/container) or a fabric bag that can be disinfected after the laundry have been removed. Laundry should then be loaded and cleaned per your washing and detergent instructions.
- **Hard Surfaces**
  Routinely clean and disinfect all surfaces uses by the individual infected with monkeypox, using an EPA approved cleaner, according to its manufacturer's directions. Surfaces such as tables, counters, door handles, toilets, sinks. Light switches, floors, and the hard surfaces in cars such all be disinfected.
- **Dishes**
  Wash all dishes, utensils in a dishwasher with hot water, or hand wash with hot water and dish soap.
- **Upholstered furniture, carpet, soft furnishing:**
  If direct contact or excessive drainage has occurred on an upholstered surface, steam cleaning is recommended. If the person with Monkeypox had minimal contact, the surfaces can be disinfected with an appropriate disinfectant based on the surface.

Recovery from MPX

People who have recovered from Monkeypox and whose isolation has ended should conduct a thorough disinfection of all spaces within the home that they had been in contact with. Follow the following steps to minimize risks of infection to others in your home after recovery:

- Protection for persons cleaning after a recovery
  - At minimum disposable gloves and a respiratory or well-fitting mask should be worn.
  - Clothes that full cover the skin should be worn and then immediately taken off and laundered after the cleaning.
- Focus on disinfecting items and surfaces that were directly uses, or touched by the person with monkeypox, if you are unsure, disinfect it.
- After cleaning and disinfect, gloves should be disposed, and hand should be washed with warm water and soap or sanitized using at least 60% alcohol-based hand sanitizer.
- If it can be avoided do not sweep or dust, as this can spread infectious particles.
- Wet cleaning with wipes, sprays and mops are recommended and preferred for disinfecting.
- Vacuuming is acceptable when using a vacuum with a high efficiency air filter, if not, the person vacuuming should wear a well-fitting mask or respirator.
- General waste containment - collect and contain in a sealed bag (or double bag) any soiled waste such as bandages, paper towels, food packaging, and other general trash. Contaminated waste should be contained in a separate container from household waste.
- Laundry - gather contaminated clothing and linen before anything else in the room is cleaned. Do not shake linens out, this could spread infectious material. If using shared laundry facilities or public laundry facilities, *first*, hand wash laundry using OxiClean Laundry and Home Sanitizer (EPA approved) in the sink or bathtub before taking laundry to a shared or public laundry facility.
- Disinfect hard surfaces and household items and appliances.
  Upholstered furniture and carpets - use a vacuum with either an air filter or wear a well-fitting mask or respirator.
- Other types of flooring - avoid sweeping in favor of wet cleaning such as mops, wipes, and sprays.

References & Resources

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Appendix

A. Healthcare Guidance for Monkeypox Testing
B. Healthcare Guidance to Request the Jynneos Vaccine
C. Healthcare Guidance to Request TPOXX Antivirals
D. CHD Jynneos Vaccine Request Form
E. CHD TPOXX Antiviral Request Form

Healthcare Provider Guidance for Monkeypox Testing

An individual that wants to be tested for monkeypox should reach out to a healthcare provider.

Healthcare provider evaluates patient's symptoms, risk factors and determines if they need to be tested.

Yes,they have the clinical signs and symptoms of monkeypox and should be tested.

No, they do not have the clinical signs and symptoms of monkeypox and do not need to be tested at this time.

Provider should test for monkeypox. Follow the instruction of the lab you are planning to send samples to, or use CDC guidance to prepare and collect swabs.

Send to a commercial lab for testing.

Commerical Labs Currently Accepting Monkeypox Specimens.

1. **Aegis Science**
2. **Labcorp**
3. **Mayo Clinic Labrotories**
4. **Quest Diagnostics**
5. **Sonic Healthcare**

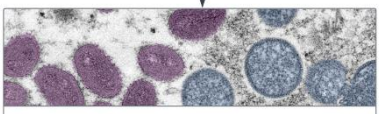
Send to the Ohio Department of Health (ODH) for testing.

If there are questions regarding sending sampes to ODH lab, Please call CHD: (513)-357-7462

If there are no questions regarding sending the sample to ODH. Fill out the linked ODH survey, to receive instructions.

2022 MPX Testing Approval Form
Ohio

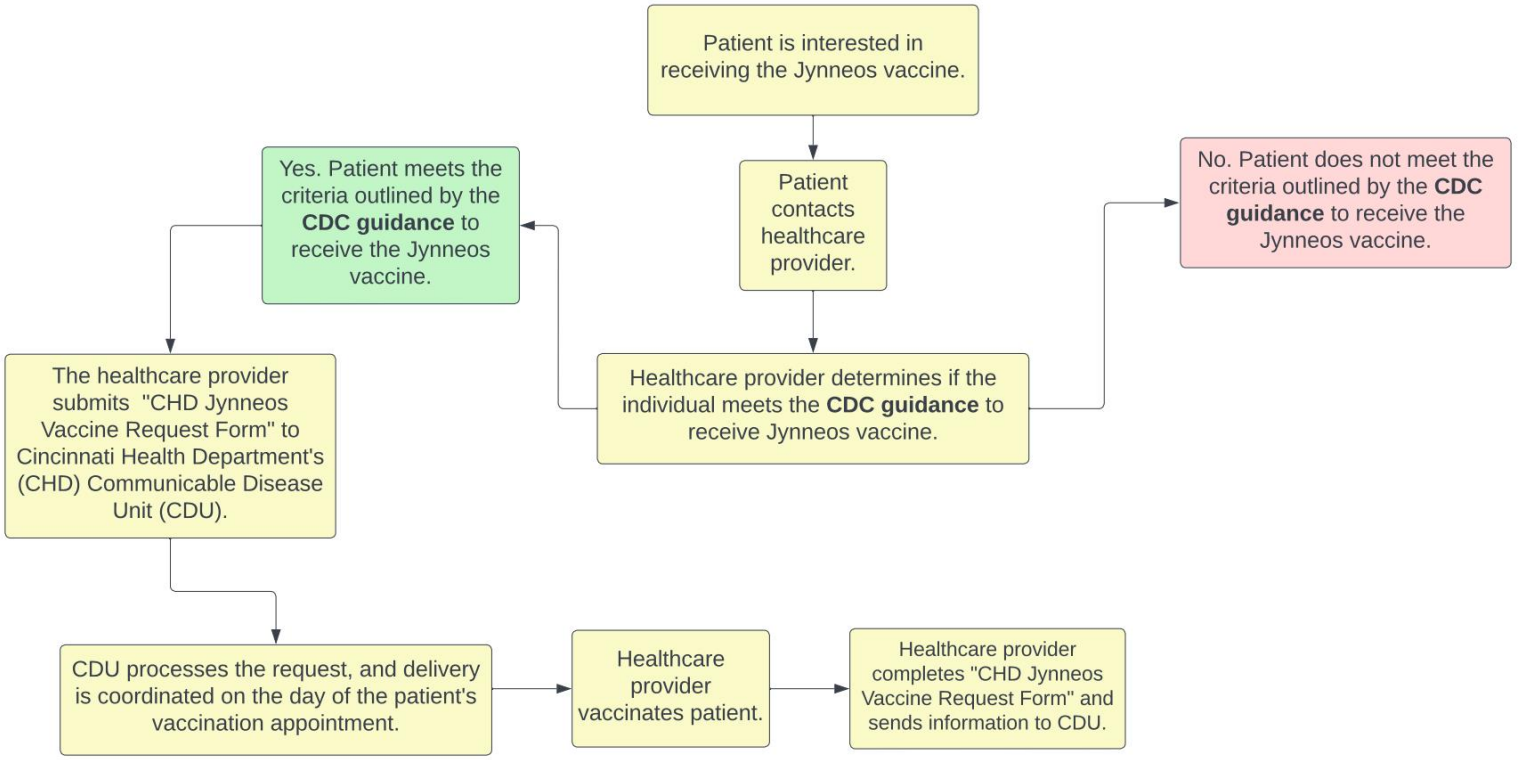
CDC guidance on preparation and collection of swabs.



Monkeypox in the U.S.
Centers for Disease Control and Prevention

CB-7/27/22

Healthcare Provider Guidance to Request the Jynneos Vaccine.



city of CINCINNATI HEALTH DEPARTMENT

For any further questions, please contact CHD at: (513)-357-7462, opt. 2

To review the CDC Guidance click here:

Considerations for Monkeypox Vaccination
Cdc

CB- 08/02/22

Healthcare Provider Guidance to Request TPOXX Antivirals

Healthcare provider considers antiviral options for patient with Monkeypox.

Healthcare provider determines if patient meets **CDC guidance** to receive TPOXX antiviral treatment.

Yes. Patient meets the criteria outlined by the **CDC guidance** to receive TPOXX antiviral treatment.

No. patient does not meet the criteria outlined by the **CDC guidance** to receive TPOXX antiviral treamtment.

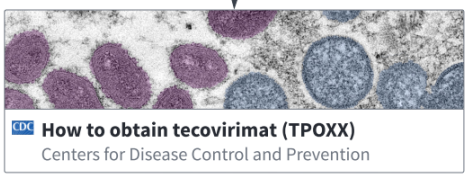
The healthcare provider submits "CHD TPOXX Antiviral Request Forms" to CDU

CDU processes request and delivery is coordinated with the healthcare provider.

Healthcare provider dispenses treatment to patient.

Healthcare provider completes and forwards all required CDC and FDA forms outlined in the "CHD TPOXX Antiviral Request Form", within 3 days of the treatment being adminstered.

To review the CDC Guidance click here:



How to obtain tecovirimat (TPOXX)
Centers for Disease Control and Prevention

city of CINCINNATI
HEALTH DEPARTMENT

For any further questions, please contact CHD at: (513)-357-7462, opt. 2

CB- 08/02/22

city of CINCINNATI HEALTH DEPARTMENT

CHD JYNNEOS Vaccine Request Form

If you are a healthcare provider in Cincinnati, to process your request to receive and administer Jynneos Vaccine for a specific patient or person, CHD needs to collect certain required information. Please fill out this form and fax it or email it to cdms.fax@cincinnati-oh.gov. You can call 513-357-7462 to make sure that it was received.

Please provide the following information:

Only one dose will be provided per patient. A second dose will have to be requested when needed.

1. What is the date it is required? _____ or asap*(see end of form for more information)
2. Name of receiving site: _____
3. Shipping address: _____
4. Receiving POC #1 at shipping address (name, email, 24/7 monitored phone #)

   _____
5. Receiving POC #2 at shipping address (name, email, 24/7 monitored phone #)

   _____
6. Hours available to receive shipment:
   a. Monday-Friday hours to receive SNS shipments: _____
7. Notes (i.e., special delivery instructions):

   _____
8. Received by Provider _____
   a. NDC #: _____
   b. Manufacturer: _____
   c. Lot #(s): _____
   d. Sub-Q Injection Site: _____
   e. Expiration Date: _____
   f. Date(s) Administered: _____
   g. Time of Injection: _____

9. CHD CDU Contact: _____
10. Does the Provider have access to the ODH Impact Statewide Immunization System Vaccine Ordering Management System /Impact SIIS/VOMS?

    (Y/N)_____
11. If yes, please provide Account #_____
    a. Pin_____
12. Patient Name/DOB: _____
13. Patient's Address: _____

City, State, Zip: _____

_____

14. Patient Phone Number: _____
15. Local Health Department Jurisdiction: _____
16. Date PT. was evaluated by HCP: _____
17. PT. Exposure Date (if known): _____
18. Reason for Request: High Risk? Exposure? _____

_____

Physician Name/Date: _____

*Transporting the vaccine while frozen is **not** recommended. The Healthcare facility administering the vaccine should prepare to store at 2-8 degree Celsius until administered, within 12 hours of **departure from** CHD facility.

city of CINCINNATI HEALTH DEPARTMENT

CHD TPOXX Antiviral Request Form

If you are a healthcare provider in Cincinnati, to process your request to receive and administer TPOXX antiviral for a specific patient or person, CHD needs to collect certain required information. Please fill out this form and fax it or email it to cdms.fax@cincinnati-oh.gov. You can call 513-357-7462 to make sure that it was received.

1. Shipping address of provider requesting TPOXX: _____

   _____

2. Receiving POC #1 at shipping address (Name, email, 24/7 monitored phone #): _____

   _____

3. Receiving POC #2 at shipping address (Name, email, 24/7 monitored phone #): _____

   _____

4. Cincinnati Health Department's POC (Name, email, 24/7 monitored phone #): _____

   _____

5. Number of bottles of PO Tecovirimat (1 full course=2 bottles for people weighing 40-120kg):

   _____

6. If IV is requested, please specify the number of days of therapy (for many patients, 14 vials [=7 days] of IV tecovirimat will be enough and the patient can be converted to PO tecovirimat; if the clinical picture does not improve after 7 days, additional IV doses can be ordered):_____

7. Days/time the shipping address is NOT available to receive shipment: _____

_____

8. Other notes or comments on delivery: _____

9. Patient Name/DOB: _____

10. Patient's Address: _____

City, State, Zip: _____

_____

11. Patient Phone Number: _____

12. Local Health Department Jurisdiction: _____

13. Date PT. was evaluated by HCP: _____

14. PT. Exposure Date (if known): _____

15. Reason for Request: High Risk? Exposure? _____

_____

Physician Name/Date: _____

****Please see next page for CDC and FDA required forms for patient to receive TPOXX****

Treating clinicians or their designees will be responsible for patient follow-up, monitoring, and reporting collected information to CDC. The following report forms are required to be completed, retained, and/or returned to CDC:

- Obtain Informed Consent: **PRIOR** to initiating tecovirimat treatment; provide a copy to the patient and retain a copy at the treating facility/institution. A copy does **NOT** need to be returned to CDC. Only if the signed informed consent forms cannot be maintained at the treating facility/institution, then they can be sent to CDC within 3 working days of tecovirimat initiation.

- Complete Form FDA 1572 and return to CDC within 3 working days of tecovirimat initiation.

- Patient Intake Form (Attachment 2- Form A) Please return to CDC within 3 working days of tecovirimat initiation. The form includes fields for:

    - Medical history, baseline signs/symptoms, vital signs, concomitant medications.
    - Clinical laboratory parameters, if performed per treating clinician's clinical judgment depending on patient's underlying condition, then attach a copy of clinical laboratory results (e.g., hematology, chemistry, urinalysis).
- Clinical Outcome Form (Attachment 2 – Form B). Please return to CDC within 3 working days of last patient follow-up. The form includes fields for:
    - Progress of tecovirimat therapy and clinical outcomes, clinical labs (if performed based on clinical judgment depending on patient's underlying condition), and lesion/scab and serum samples *(if collected)*.
    - Occurrence of SAEs – if yes, reported by completing a fillable-PDF MedWatch Form (Attachment 6) and returning to CDC via email (regaffairs@cdc.gov) within 72 hours of awareness or sooner if possible. A fillable-PDF MedWatch Form can also be downloaded from MedWatch Forms for FDA Safety Reporting | FDA.

Optional Lesion photos: If feasible, take lesion photos at baseline prior to tecovirimat treatment, and post-treatment to follow lesion progression and healing during treatment. When submitting photos, please indicate date the photo was taken, the corresponding tecovirimat treatment day, patient name or MRN, and treating facility.

Methods of returning the above information are:

- Secure Share File for lesion photos and large file sizes (please zip multiple files and use usernames with patient identifier, hospital name, and date: https://centersfordiseasecontrol.sharefile.com/rr3941801ebcbd4002b4dfe98e314ec697
- Encrypted email: reaffairs@cdc.gov (personally identifiable information should **not** be emailed without encryption)
- Fax: 404-902-5921

Please See the revised IND protocol: (https://www.cdc.gov/poxvirus/monkeypox/pdf/Tecovirimat-IND-Protocol-CDC-IRB.pdf)

Please also see the link to CDC's protocol site:(https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html) this may answer any questions that may come up.