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TO: Healthcare Providers, Hospitals, Local Health Departments, Laboratories, Sexual Health Providers, Family Planning Providers, Emergency Rooms, Community Health Centers, College Health Centers, Community-Based Organizations, and Internal Medicine, Family Medicine, Pediatric, Adolescent Medicine, Dermatology, Infectious Disease, and Primary Care Providers

FROM: New York State Department of Health (NYSDOH) Bureaus of Communicable Disease Control (BCDC) and Healthcare Associated Infections (BHAI)

HEALTH ADVISORY: MONKEYPOX CASES NOT ASSOCIATED WITH TRAVEL TO AREAS WHERE MONKEYPOX IS ENZOOTIC

## **SUMMARY**

Governor

- Historically, monkeypox was considered an uncommon zoonotic viral disease rarely found in the United States.
- Since May 14, 2022, numerous people diagnosed with monkeypox have been reported in several countries that do not normally have monkeypox, including the United States, United Kingdom, Spain, Portugal, and Canada.
- Regardless of gender identity, birth sex, sex of sex partner(s), travel, and/or specific risk factors, providers should be alert for patients who have rash illnesses consistent with monkeypox.
- Clinicians suspecting monkeypox infection should strictly adhere to infection control
  practices and must immediately notify their local health department (LHD).
- This health advisory replaces prior NYSDOH monkeypox health advisories.
- Key updates include, but are not limited to:
  - Testing at Commercial and Public Health Laboratories
  - NYS Vaccine Strategy (outside of NYC)
  - Infection Control Guidelines
  - Packaging and Treatment of Monkeypox Medical Waste
  - Monkeypox Treatment Options

# **Background and Clinical Presentation of Monkeypox**

Monkeypox is a rare disease of the orthopoxvirus family that is caused by infection with the monkeypox virus.

Symptoms of monkeypox can include a flu-like prodrome followed by a rash. In some cases, the rash may start first followed by other symptoms, while others only experience a rash. These rashes can appear like pimples or blisters often in mucosal areas such as the mouth and anogenital or rectal areas which may remain limited to these areas or even spread to the face, torso, or extremities. Lesions go through different stages of healing and typically lasts 2-4 weeks. The progression of these lesions can be seen here: <a href="Centers for Disease Control and Prevention">Centers for Disease Control and Prevention</a> (CDC) Monkeypox Clinical Recognition webpage).

There can be a significant amount of pain associated with symptoms. Pain may interfere with basic functions such as eating, urination, and defecation which can cause distress and compound problems for the patient. Co-infections with sexually transmitted infections, group A strep infection, and other viruses have also been reported. With the presentation of symptoms, it is important to evaluate for and treat other potential infections as deemed appropriate.

# **Spread and At-Risk Populations**

Monkeypox can be spread in a variety of ways. This virus is historically zoonotic in nature from infected animals that either scratch/bite an individual or by eating meat/products that are infected. The most common way individuals spread monkeypox is through direct contact with infectious rash, scabs, and/or body fluids. It is possible to also contract monkeypox through respiratory secretions during face-to-face contact, or during intimate physical contact. Spread can also happen by touching clothing or linens that have been contaminated with infectious rash or body fluids.

Although this is NOT considered a sexually transmitted infection, as described above, monkeypox can spread during intimate physical contact between individuals. People who can get pregnant are also at risk since this virus can spread to their fetus through the placenta.

## **REPORTING**

Healthcare providers must immediately report suspect cases of monkeypox to their LHD.

Reporting should be to the LHD in the county in which the patient resides.

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

If you are unable to reach the LHD where the patient resides, please contact the NYSDOH Bureau of Communicable Disease Control at: 518-473-4439 during business hours or 866-881-2809 evenings, weekends, and holidays.

# **TESTING AT COMMERCIAL LABORATORIES**

Testing for Orthopoxvirus is now available at LabCorp (PFI 2502) using dry swab specimens and will be available shortly at four other national laboratories including: Aegis Sciences Corporation (PFI 9512); Mayo Clinic (PFI 3263 and PFI 8221); Quest Diagnostics Nichols Institute (PFI 2478); and Sonic Healthcare (PFI 8922). Questions about testing at these facilities should be directed to the appropriate

laboratory. Contact information for laboratories can be found by searching the laboratory PFI number at: https://www.wadsworth.org/regulatory/clep/approved-labs.

NYSDOH Wadsworth Center recently released streamlined guidance for the validation of molecular detection assays for Orthopoxvirus and/or monkeypox virus. This guidance is available for clinical laboratories that have a Clinical Laboratory Evaluation Program permit and are interested in building this capability. The guidance can be found at: <a href="https://www.wadsworth.org/monkeypox-testing-guidance">https://www.wadsworth.org/monkeypox-testing-guidance</a>

# **TESTING AT PUBLIC HEALTH LABORATORIES**

Testing for monkeypox is also available at NYSDOH Wadsworth Center and the New York City Public Health Laboratory. **Specimen collection and submission must be coordinated with the LHD and/or NYSDOH.** Within NYC, coordination must be done in consultation with the NYC Department of Health and Mental Hygiene (NYSDOHMH).

NYSDOH Wadsworth Center will accept specimens collected and transported in viral transport media (VTM) OR collected and transported dry. Specimens in VTM can be tested for orthopoxvirus, varicella zoster virus, and herpes simplex viruses I and II. Specimens collected dry can only be tested for orthopoxvirus. Testing for other viruses should be done locally.

The New York City Public Health Laboratory will only accept specimens collected and transported dry. They will only be tested for orthopoxvirus. Testing for other viruses should be done locally.

**Specimen Collection** 

		FOR SPECIMENS COLLECTED FROM NYS RESIDENTS AND TESTED AT THE NYSDOH WADSWORTH CENTER		FOR SPECIMENS COLLECTED FROM NYC RESIDENTS AND TESTED AT THE NYC PUBLIC HEALTH LABORATORY
Specimen Types	1.	Swab in viral transport media (VTM) or dry swab. Collect two samples from each of two lesions, for a total of 4 samples.	1.	<b>Dry</b> Swab ONLY (two for each lesion). Collect two samples from each of two lesions, for a total of 4 samples.
Collection	1.	Identify two (2) lesions per patient to sample, preferably from different locations on the body and/or with differencing appearances. (A total of four swabs should be collected).	1.	Identify two (2) lesions per patient to sample, preferably from different locations on the body and/or with differencing appearances. (A total of four swabs should be collected).
	2.	Collect the sample using the sterile swab, by scrubbing the base of the lesion vigorously enough to ensure that cells from the lesion are collected. Use separate sterile swabs (synthetic-Dacron, nylon, polyester, Rayon).	2.	Collect the sample using the sterile swab, by scrubbing the base of the lesion vigorously enough to ensure that cells from the lesion are collected.
	3.	Storage containers: Place each swab in tubes containing VTM (can be	3.	Storage containers: Place each swab (break off stick if necessary) in its own sterile container (i.e., conical tube or

tested for more viruses) OR place swabs in a dry sterile container (can only be tested for orthopoxvirus). See below for more information. urine cup). (Reminder, do not add or store in viral or universal transport media.)

For additional information on specimen collection refer to the **Specimen** collection, storage, and transport instructions section on the Instructions for Submission of Specimens for Monkeypox Testing to the New York City Public Health Laboratory guidance located here:

https://www1.nyc.gov/assets/doh/downloads/pdf/labs/monkeypox-specimentesting.pdf

# Submission information

A <u>Wadsworth Center Infectious Disease</u>
Request Form must accompany all samples; Remote Order Entry on the Health Commerce System is preferred.

Label all tubes and swab holders with the patient's name, unique identifier, date of collection, source of specimen (vesicle/pustule) and name of person collecting the specimen.

Specimens should be stored and shipped refrigerated or frozen. Should not be shipped at ambient temperature.

Refer to the online test request/requisition page on the Wadsworth Center website for more information on remote ordering: <a href="https://www.wadsworth.org/electronic-test-request-reporting-new">https://www.wadsworth.org/electronic-test-request-reporting-new</a>

A New York City Public Health Test Requisition (available upon request) must accompany each sample/ collection site.

Label all tubes and swab holders with the patient's name, unique identifier, date of collection, source of specimen (vesicle/pustule), collection site, and name of person collecting the specimen.

Refer to **Test ordering instructions** on the NYC PHL guidance document at <a href="https://www1.nyc.gov/assets/doh/downloads/pdf/labs/monkeypox-specimentesting.pdf">https://www1.nyc.gov/assets/doh/downloads/pdf/labs/monkeypox-specimentesting.pdf</a>.

Briefly, go to <a href="https://a816-phleorder.nyc.gov/PHLeOrder/">https://a816-phleorder.nyc.gov/PHLeOrder/</a> and perform the following

- 1. Sign in using credentials or register as a new user.
- 2. Fill out required information and add the following to the specified fields: a. Test: Clinical Poxvirus b. Specimen Container: Swab c. Specimen Source: Other d. Specimen Source Other: Skin or Lesion + site of lesion swabbed (e.g., Left arm) e. Fill in both collection date and collection time fields (required). 3. Communicate with your clinical laboratory that specimens are to be delivered to PHL and that an eOrder has been submitted.

Shipping	Dr. Christina Egan	Dr. Scott Hughes
Address	DAI 3021, Biodefense Laboratory,	New York City Public Health Lab
	Wadsworth Center, NYS Dept. of	Biothreat Response Unit
	Health 120 New Scotland Avenue	455 1 <sup>st</sup> Avenue
	Albany, NY 12208	New York, NY 10016
Questions	Call the Wadsworth Center Biodefense	Call the NYC Biothreat Response
	Laboratory at 518-474-4177 (business	Laboratory at 212-671-5834 (business
	hours)	hours) or Poison
	or the duty officer 866-881-2809 (after	Control at 212-764-7667; ask for PHL
	hours).	duty officer (after hours).

# **Specimen Collection**

To collect vesicular and pustular material:

- 1. Perform hand hygiene and don gloves, gown, face, and eye protection.
- 2. Sanitize the patient's skin with an alcohol wipe and allow skin to air dry (do not "wave" the site to facilitate drying).
- 3. For swabs in tubes containing VTM (NYS), label a swab holder and remove swab from the outer sheath. Collect cells from the lesion base by 1) vigorously swabbing or brushing lesion with two separate sterile synthetic swabs (Dacron, nylon, polyester, or Rayon); 2) Place each swab in a separate sterile tube containing VTM. Secure each tube with parafilm.
- 4. For the dry swabs (NYC and NYS) label a swab holder and remove swab from the outer sheath. Collect cells from the lesion base by 1) vigorously swabbing or brushing lesion with two separate sterile dry polyester, nylon, or Dacron swabs; 2) 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. Do not add or store in viral or universal transport media.
- 5. Repeat this process on different lesions.
  - a. For NYS there should be two specimens collected for each lesion: two sets of plastic tubes from each lesion for a total of 4 tubes.
  - b. For NYC there should be two swabs for each lesion
- 6. After specimen collection is completed, all personal protective equipment (PPE) worn by the specimen collector and all waste generated during the specimen collection (e.g., alcohol wipes, holders, etc.) should be discarded according to facility's usual procedures for what is considers regulated medical waste (I.e., there are no changes to what is considered regular waste versus regulated medical waste when caring for someone with suspect or confirmed orthopox/monkeypox). All sharp devices used to open vesicles (e.g., needles, blades, etc.) used to open vesicles should be disposed of in an appropriate sharps container. Hand hygiene should be performed before and immediately after specimen collection and following removal of PPE. Alcohol-based hand sanitizers are preferred unless hands are visibly soiled. If hands are visibly soiled, hand hygiene should be performed using soap and water.
- 7. Other sample types such as serum and whole blood may also be requested.

Please note: Monkeypox virus can be cultivated in several cell culture types routinely used by the viral testing laboratory. Although laboratories should not attempt to isolate this virus, if you become aware that your laboratory has isolated monkeypox using cell culture, you should **immediately** contact the Wadsworth Center or the NYC PHL.

## VACCINATION

JYNNEOS (aka: IMVANEX, IMVAMUNE) is licensed by the US FDA as a 2-dose series for the prevention of monkeypox among adults ages 18+. If given within 4 days of exposure, this vaccine may reduce likelihood of infection, and within 14 days may reduce severity of symptoms. JYNNEOS is available only via the federal National Strategic Stockpile and is being made available by the federal government for the primary purpose of post-exposure prophylaxis (PEP) among those with a possible recent exposure to monkeypox. PEP may be further divided into two strategies:

- 1) PEP for an exposed contact of a suspected or confirmed monkeypox case, and
- 2) Broader community distribution for persons who are not known to be exposed contacts of a suspected/confirmed case but have behavioral/epidemiological criteria consistent with a possible recent exposure. CDC has called this strategy "PEP++".

In the United States and in New York, there is currently a limited supply of JYNNEOS vaccine, although more vaccine is expected in the coming weeks and months. NYSDOH is rolling out vaccine in a phased approach, as it becomes available, in accordance with CDC guidance. Currently, JYNNEOS for both PEP uses are available through NYSDOH distributions via Local Health Departments.

For #1 above, people who are identified by an LHD as exposed to a suspected or confirmed monkeypox case in the past 14 days will work directly with their LHD and healthcare provider to discuss obtaining the JYNNEOS vaccine.

For #2 above, community-distributed PEP for those with recent qualifying behavioral/epidemiological criteria, NYSDOH's approach is consistent with CDC guidance and limited supply, currently in 2 phases:

- Phase 1 (July 11 through about July 15) offers a limited amount of vaccine doses and is focused on reaching those at high risk of a recent (within the past 14 days) exposure to monkeypox.
  - According to CDC, those at high risk of a recent exposure to monkeypox may include members of the gay, bisexual, transgender and gender non-conforming community and other communities of men who have sex with men who have engaged (in the past 14 days) in intimate or skin-to-skin contact with others in areas where monkeypox is spreading.
  - This includes those who have had skin-to-skin contact with someone in a social network experiencing monkeypox activity, including men who have sex with men who meet partners through an online website, digital application ("app"), or social event (e.g., a bar or party).

The following counties outside of New York City have received doses for Phase 1 distribution: Nassau, Rockland, Saratoga, Suffolk, Sullivan, and Westchester. These doses are being administered through specific points of distribution only. Please refer patients to county webpages to learn more about options for scheduling an appointment.

Phase 2 (after July 15 and through the summer) will offer a modestly expanded supply of vaccine
doses and also focus on those at high risk of a recent exposure (within the past 14 days), where
vaccination can reduce risk of infection and decrease symptoms if infection has occurred.

As the vaccine program evolves, additional information on the program (outside of NYC), dose availability, and clinical guidance will be made available at https://health.ny.gov/monkeypox.

For information on the NYC vaccine program, please visit: <a href="https://www1.nyc.gov/site/doh/health/health-topics/monkeypox.page#vax">https://www1.nyc.gov/site/doh/health/health-topics/monkeypox.page#vax</a>.

## INFECTION CONTROL GUIDELINES

Standard Precautions should be applied for all patient care, including for patients with suspected monkeypox. If a patient seeking care is suspected to have monkeypox, infection prevention and control personnel should be notified immediately. Activities that could resuspend dried material from lesions, e.g., use of portable fans, dry dusting, sweeping, or vacuuming should be avoided.

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, wound dressing, or gown. Intubation and extubation and any procedures likely to spread oral secretions should be performed in an airborne infection isolation room (AIIR).

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), and a NIOSH-approved particulate respirator equipped with N95 filters or higher.

For more information on infection prevention and control of monkeypox, please visit the CDC website at https://www.cdc.gov/poxvirus/monkeypox/clinicians/infection-control-healthcare.html or the monkeypox main information page at <a href="https://www.cdc.gov/poxvirus/monkeypox/index.html">https://www.cdc.gov/poxvirus/monkeypox/index.html</a>.

# Update: PACKAGING AND TREATMENT OF MONKEYPOX MEDICAL WASTE

In June 2022, the U.S. Department of Transportation (USDOT) released additional guidance on the handling of regulated medical waste (RMW) from suspected or confirmed cases of monkeypox. The USDOT June 2022 guidance can be found at: <a href="https://www.phmsa.dot.gov/transporting-infectious-substances/planning-guidance-handling-category-solid-waste">https://www.phmsa.dot.gov/transporting-infectious-substances/planning-guidance-handling-category-solid-waste</a>.

The previous position of the USDOT was that facilities should hold untreated RMW generated from suspected cases of monkeypox and wait until testing confirms the diagnosis and identifies the clade before disposing of the waste.

However, the USDOT, in conjunction with other Federal partners, has issued new guidance indicating that during the ongoing 2022 multi-national outbreak of West African clade monkeypox, if clinician teams determine that a patient does not have known epidemiological risk for the Congo Basin clade of monkeypox (e.g. history of travel to the Democratic Republic of the Congo, the Republic of Congo, the Central African Republic, Cameroon, Gabon, or South Sudan in the prior 21 days) it is appropriate to manage waste from suspected monkeypox patients as RMW. If the Congo Basin clade of monkeypox is excluded, medical waste does not have to be held pending clade confirmation and medical waste needs to be packaged, transported, and treated as RMW. The waste must be packaged in accordance with 49 CFR § 173.197, labelled as United Nations (UN) 3291, Regulated medical waste (Monkeypox waste), and treated by incineration or by autoclaving at 121°C/250°F for at least 30 minutes.

Additional information can be found on the Centers for Disease Control and Prevention (CDC) web site at: <a href="https://www.cdc.gov/csels/dls/locs/2022/06-21-2022-lab-advisory-interagency partners update planning guidance disposal shipment material suspected contain monkeypox virus.html">https://www.cdc.gov/csels/dls/locs/2022/06-21-2022-lab-advisory-interagency partners update planning guidance disposal shipment material suspected contain monkeypox virus.html</a>

However, if epidemiological risk factors indicate a risk for Congo Basin clade, waste should be managed as a Category A infectious substance pending clade confirmation. If testing shows any clades except the West African clade, it needs to be packaged, transported, and treated as Category A waste. The waste must be packaged in accordance with 49 CFR § 173.196, labelled as United Nations (UN) 2814, Infectious substances, affecting humans (Monkeypox waste), and managed as Category A waste.

## TREATMENT OPTIONS

## Mild to Moderate Disease-Low risk for severe disease

- Supportive care including fluids and wound hygiene/care
- Analgesics as needed
- Topical or aerosolized diphenhydramine (Benadryl) or lidocaine for lesion associated pruritus and pain respectively

# **Supportive Care**

This first level of care includes the maintenance of fluids, pain management, treatment of bacterial superinfections of skin lesions, and treatment of any possible co-occurring sexually transmitted or superimposed bacterial skin infections.

Skin lesions should be kept clean and dry to prevent further secondary infection. Pruritus can be treated with an oral antihistamines and topical agents such as calamine lotion, cortisone 10, or petroleum jelly. For oral lesions, prescription medicated mouthwashes can be used to manage pain. Oral antiseptics are helpful in keeping lesions clean. Topical gels such as benzocaine/lidocaine can be used for temporary relief, while eating and drinking.

Proctitis can occur with or without lesions and is often manageable with supportive care, stool softeners may be beneficial. Topical gels such as benzocaine/lidocaine can be used for temporary relief as well. Sitz baths can also be used for proctitis. Pain management may be beneficial utilizing over-the-counter medication such as acetaminophen or prescription medications (narcotics risk constipation). Additionally, proctitis may cause rectal bleeding, which should be evaluated by a healthcare provider.

Nausea and vomiting can be controlled with the use of anti-emetic as deemed appropriate. Diarrhea should be managed through proper hydration and electrolyte replacement.

# Moderate to Severe Disease – or people at high risk for development of severe disease

- Currently no treatments are approved specifically for monkeypox, however multiple agents have been developed for smallpox which may be beneficial in treating monkeypox
- Four agents available for treatment
  - o Tecovirimat (TPOXX)
  - o Vaccinia Immune Globulin Intravenous (VIGIV)
  - o Cidofovir (Vistide)
  - o Brincidofovir (CMX001 or Tembexa)

# **Tecovirimat (TPOXX)**

Tecovirimat (TPOXX) is a renally excreted antiviral targeting the Orthopoxvirus envelope wrapping protein. TPOXX is FDA approved for the treatment of smallpox in children and adults and available in oral and intravenous formulations. There is no data for the effectiveness of TPOXX in treating monkeypox infections in people. Since the monkeypox virus is of the same genus as the smallpox, it is believed that the similarities in morphology will allow TPOXX to be effective against monkeypox. In animal studies, TPOXX was found to reduce the risk of death. In people, efficacy was limited to drug levels in blood and a few case studies, while a case series of individuals infected with Monkeypox virus included on patient treat with TPOXX showed that the medication may shorten the duration of illness and viral shedding (Adler et al., 2022).

TPOXX can only be obtained from the Centers for Disease Control and Prevention, which holds a non-research Expanded Access Investigational New Drug (EA-IND) Protocol for tecovirimat to be used on presumed and confirmed cases of monkeypox. Informed consent from the patient is necessary to receive tecovirimat. (See here for more information.

www.accessdata.fda.gov/drugsatfda docs/label/2022/214518s000lbl.pdf)

## Who Should Receive Tecovirimat

This course of treatment may be considered in people infected with monkeypox virus that meet the following:

- With severe disease
- At high risk of severe disease
  - Immunocompromised
  - Pediatric populations
  - o Pregnant or breastfeeding individuals
  - o People with history or presence of skin conditions
  - o People with one or more complication from infection
- With infections deviating from normal involving implantation in eyes, mouth, or other anatomic areas where infection might become a special hazard

## Who should not receive Tecovirimat

Under the EA-IND, people who are ineligible for tecovirimat treatment are those who are unwilling to signed informed consent documentation as well as those with a known allergy to the drug or its components

# **Absorption and Adverse Effects of Tecovirimat**

**Oral tecovirimat**: Absorption of this drug is dependent on adequate intake of a full, fatty meal. For adults, the standard dosing is 600mg every 12 to 14 hours. This will require taking 3 pills every 12 hours, for most adults. Therefore, it is important for the adult to tolerate consistent intake of meals twice a day. Reported adverse effects include headache (12%), nausea (5%), abdominal pain (2%), and vomiting (2%). Neutropenia was found in one study participant.

**IV tecovirimat**: IV tecovirimat should not be administered to those with severe renal impairment (CrCL <30 mL/min). For this population, the oral formulation is still an option. IV tecrovirimat should also be used with caution for those with moderate (CrCL 30-49 mL/min) or mild (CrCL 50-80 mL/min) renal impairment as well as those less than 2 years of age given immature renal tubular function. Reported adverse effects of IV tecovirimat include infusion site pain (19%), infusion site swelling (39%), infusion site erythema (23%), infusion site extravasation (19%), and headache (15%).

## What is Required from Clinicians/Healthcare Providers

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

- Informed consent prior to treatment initiation
- FDA Form 1572
  - Complete within 3 calendar days by the responsible clinician/healthcare provider along with a CV of the treating physician
- Patient intake form to provide patients baseline condition at time of treatment
- Adverse event form
- Clinical outcomes form
  - To report treatment duration and patient's clinical outcome upon completion
- Photos of lesions
  - 1 prior and 1 during treatment (between days 7 and 14) with dates indicated

# **Requesting Tecovirimat**

Tecovirimat is only available through the federal Strategic National Stockpile. For facilities that are interested in prescribing tecovirimat for patients eligible under the EA-IND criteria, medication must be requested through the Centers for Disease Control State and territorial health authorities can direct their requests for medical countermeasures for the treatment of monkeypox to the CDC Emergency Operations Center (770-488-7100).

# Other medications and treatment options:

Vaccina Immune Globulin Intravenous (VIGIV): Vaccinia Immune Globulin Intravenous (VIGIV) is an FDA approved treatment for the complications following vaccinia vaccination. The CDC's expanded access protocol allows for the use of VIGIV for the treatment of Orthopoxviruses (including monkeypox) in an outbreak. Effectiveness data is not available of VIG in treatment of monkeypox virus infection. There is no known benefit in treatment of monkeypox and is also unknown if a person with severe monkeypox infection will benefit from treatment with VIG. However, VIGIV use may be considered in severe cases. VIVIG may also be considered for prophylactic use in exposed individuals with severe T-cell dysfunction for which smallpox vaccination following exposure to monkeypox virus is contraindicated. VIGIV is not commercially available but can be made available through the Strategic National Stockpile (SNS) for the treatment of smallpox vaccine complications in patients with serious clinical manifestations. (See <a href="https://www.fda.gov/media/78174/download">www.fda.gov/media/78174/download</a> for full dosing, administration, reactions, and contraindications)

Cidofovir (Vistide): Cidofovir (Vistide) is an intravenous, renally excreted antiviral targeting the cytomegalovirus (CMV) DNA polymerase. Cidofovir is FDA approved for the treatment of CMV retinitis in patients with Acquired Immunodeficiency Syndrome (AIDS). The CDC's expanded access protocol allows for the use of Cidofovir for the treatment of orthopoxviruses (including monkeypox) in an outbreak. Effectiveness data is not available for Cidofovir in treating human cases of monkeypox. However, it has shown to be effective against Orthopoxvirus in *in vitro* and animal studies. It is unknown if a person with severe monkeypox infection will benefit from treatment with Cidofovir, its use may be considered in such instances. Brincidofovir may be a safer option over Cidofovir. Serious renal toxicity or other adverse events have not been observed during treatment of cytomegalovirus infections with Brincidofovir as compared to treatment using Cidofovir. Given Cidofovir's use in CMV disease, it may be also available outside the CDC's access protocol. Currently, cidofovir is stockpiled by the SNS and would be made available under the appropriate regulatory mechanism.

(See <a href="https://www.accessdata.fda.gov/drugsatfda">www.accessdata.fda.gov/drugsatfda</a> docs/label/1999/020638s003lbl.pdf for full dosing, administration, reactions and contraindications)

Brincidofovir (CMX001 or Tembexa): Brincidofovir (CMX001 or Tembexa) is an oral, hepatically excreted antiviral targeting the smallpox DNA polymerase. Brincidofovir is FDA approved for the treatment of human smallpox disease in adult and pediatric patients, including neonates. Effectiveness data is not available for Brincidofovir in treating cases of monkeypox in people. However, it has shown effectiveness against orthopoxviruses in *in vitro* and animal studies. The CDC is currently developing an Expanded Access for an Investigational New Drug (EA-IND) for Brincidofovir use for treatment for monkeypox. (Brincidofovir is currently unavailable from the United States' Strategic National Stockpile (SNS)).

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World Health Organization. Clinical Management and Infection Prevention and Control for Monkeypox – Interim Rapid Response Guidance. June 10, 2022. <a href="https://www.who.int/publications/i/item/WHO-MPX-Clinical-and-IPC-2022.1">https://www.who.int/publications/i/item/WHO-MPX-Clinical-and-IPC-2022.1</a>

# **ENVIRONTMENTAL INFECTION CONTROL - FOR HEALTHCARE SETTINGS**

Standard cleaning and disinfection procedures should be performed using an EPA- and DEC-registered hospital-grade disinfectant with an emerging viral pathogen claim. Products with <a href="Emerging Viral">Emerging Viral</a> <a href="Pathogens claims">Pathogens claims</a> may be found on EPA's <a href="List Q">List Q</a>. Follow the manufacturer's directions for concentration, contact time, and care and handling.

Soiled laundry (e.g., bedding, towels, personal clothing) should be handled in accordance with <u>recommended [PDF – 241 pages]</u> standard practices, avoiding contact with lesion material that may be present on the laundry. Soiled laundry should be gently and promptly contained in an appropriate laundry bag and never be shaken or handled in manner that may disperse infectious material.

Activities such as dry dusting, sweeping, or vacuuming should be avoided. Wet cleaning methods are preferred.

Management of food service items should also be performed in accordance with routine procedures.

Detailed information on environmental infection control in healthcare settings can be found in CDC's <u>Guidelines for Environmental Infection Control in Health-Care Facilities</u> and <u>Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings</u> [section IV.F. Care of the environment].

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