Montana Health Alert Network

DPHHS HAN

Information Sheet

DATE

August 25, 2022

SUBJECT

Update to the Protocol for the Investigation of Monkeypox Cases in Montana

BACKGROUND

There are currently two probable cases of monkeypox in Montana. Please visit the Montana Department of Public Health and Human Services (DPHHS) monkeypox webpage for updates on the epidemiology of monkeypox in MT: https://dphhs.mt.gov/publichealth/cdepi/diseases/monkeypox.

The information below is an update to the Protocol for the Investigation of Monkeypox Cases in Montana (DPHHS HAN 2022-19), including updates on testing and who should be considered for vaccination or therapeutic treatment.

INFORMATION

Public health notification for suspect cases

Healthcare providers are required to notify their local health department of high-suspect monkeypox cases and of any positive monkeypox results from reference laboratories, during daytime hours, including weekends (ARM 37.114.201): https://dphhs.mt.gov/publichealth/FCSS/countytribalhealthdepts. Timely communication with your local health department (LHD) will facilitate a coordinated and prompt public health response in the event of a positive result (*i.e.*, contact tracing, vaccination of high-risk close contacts, therapeutics, etc.). Local public health should immediately contact the DPHHS Communicable Disease Epidemiology Program (CDEpi) at 406-444-0273 to notify the program of a high-suspect monkeypox case, and share name and date of birth of the suspect case. For high-suspect monkeypox cases in which vaccination of close contacts or treatment may be needed, LHD and CDEpi are available to discuss suspect monkeypox cases and treatment requests with providers during daytime hours, including weekends. For public health emergencies, providers may contact the afterhours phone numbers. More criteria used to determine if the level of suspicion for a case is high, please refer to our new *Provider Algorithm for MPX Testing* online: https://dphhs.mt.gov/publichealth/cdepi/diseases/monkeypox.

Testing for monkeypox

Given capacity limitations at the Montana Public Health Lab (MTPHL), it is recommended that healthcare facilities designate a reference lab partner to which they can send out specimens for monkeypox testing and communicate this plan with their providers. Providers may send specimens from any suspect monkeypox case to a reference lab, including high-suspect cases; please notify your LHD of high-suspect monkeypox cases. More information on monkeypox testing and reference labs can be found in the *Monkeypox Testing Guidance Document for Healthcare Providers* available online: https://dphhs.mt.gov/publichealth/cdepi/diseases/monkeypox.

Starting August 29, 2022, MTPHL will only perform *orthopoxvirus* testing on Tuesdays and Thursdays, and will begin charging a $55 fee for testing. Only cases that meet both clinical and epidemiologic criteria for testing, determined by consult with CDEpi, may have specimens submitted to the MTPHL for testing. MTPHL will only test

high-suspect specimens that have prior approval by CDEpi. Testing at MTPHL may be conducted other weekdays for high-suspect cases that may have a potential for significant public health impact (*e.g.*, numerous potential close contacts, occurred in a sensitive setting, etc.). Consultation with your LHD or CDEpi to arrange alternate testing days is required.

If specimens arrive at MTPHL without a prior epi approval, they will be sent back to the ordering facility. It is the ordering facility's responsibility to send the specimens to a reference lab. Do not mail specimens (via FedEx or UPS) to MTPHL that will arrive on Saturday or Sunday—the MTPHL does not have staff accepting mail that arrives those days.

If the individual in question has only a low suspicion for monkeypox (*e.g.*, provider is ruling out monkeypox disease, but the clinical index of suspicion is low), please send samples to a reference laboratory. Reference laboratories that can perform monkeypox testing include Quest Diagnostics, LabCorp, Aegis Labs, Sonic Labs, and Mako Medical Laboratories. Please notify your LHD of a positive result.

DPHHS does not supply specimen collection supplies to labs for monkeypox testing. Swabs and sterile tubes can be purchased from almost any medical supply vendor.

Ordering of Vaccine

Due to limitations on the number of shipment sites and doses, the Montana Immunization Program will be placing orders for Jynneos and coordinating delivery to facilities. Some facilities may have the vaccine shipped directly while others may be coordinated through redistribution. If you need doses of Jynneos for PEP, PEP++, or PrEP uses, and do not have them at your location, please call the Montana Immunization Program at 406-444-5580 to coordinate delivery.

Prior to transferring any doses to other sites/jurisdictions, notify the Montana Immunization Program.

Vaccine Eligibility Criteria

Post-exposure prophylaxis (PEP)

- Adults 18*years and older who have had exposure to individuals with confirmed *orthopoxvirus/* monkeypox virus infection.

Expanded Post-exposure prophylaxis (PEP++)

- Adults 18* years and older who have had multiple sexual partners in the past 14 days in a jurisdiction with known monkeypox which may include:
    - Known contacts who are identified by public health via case investigation, contact tracing, and risk exposure assessments
    - People who are aware that one of their sexual partners from the past 2 weeks has received a monkeypox diagnosis.
    - Gay, bisexual, other men who have sex with men, and transgender people who report any of the following in the past 2 weeks:
        - Group sex or sex with multiple partners
        - Sex at a commercial sex venue or in association with an event, venue, or defined geographic area where monkeypox transmission has been reported.

Pre-exposure prophylaxis (PrEP)

- Adults 18* years and older who meet one of the following criteria:
    - Gay, bisexual or transgender people who have sex with men and have recently had multiple or anonymous sexual partners; ***OR***

- Partners of gay, bisexual or transgender people who have sex with men who have had multiple or anonymous sexual partners; ***OR***
- Sex workers (of any sex); ***OR***
- Staff (of any sex) at establishments where sexual activity occurs (e.g., bathhouses, saunas, sex clubs); ***OR***
- Were diagnosed with gonorrhea or early syphilis within the past 12 months; ***OR***
- Persons experiencing homelessness with high-risk behaviors; ***OR***
- Are on HIV pre-exposure prophylaxis; ***OR***
- Are part of high-risk cohorts identified by clinical staff in the correctional system.

Note: eligible persons, per the criteria above, who are immunocompromised (e.g., those with advanced or uncontrolled HIV) or those who have underlying medical conditions that confer increased risk for severe disease (e.g., atopic dermatitis, eczema) could be prioritized for vaccination.

- Certain healthcare and public health response team members designated by public health authorities may be vaccinated for preparedness purposes according to ACIP guidance.
  - *At this time, most clinicians in the U.S. and laboratorians not performing the orthopox generic test to diagnose orthopoxviruses, including monkeypox virus, are not advised to receive monkeypox vaccine PrEP.*

* For individuals under the age of 18 years, Jynneos may be administered under the current EUA as a 2-dose 0.5 mL subcutaneous injection given 28 days apart.

Therapeutics

The antiviral drug named tecovirimat was developed and approved to treat human smallpox disease, and the Food and Drug Administration (FDA) allows the Centers for Disease Control and Prevention (CDC) to use it to treat monkeypox during an outbreak. The need for monkeypox treatment will depend on how sick someone gets and whether they are likely to get severely ill, like patients with weakened immune systems.

CDC offers treatment considerations in their *Guidance for Tecovirimat Use Under Expanded Access Investigational New Drug Protocol during 2022 U.S. Monkeypox Cases* https://www.cdc.gov/poxvirus/monkeypox/clinicians/Tecovirimat.html. The *Tecovirimat Investigational New Drug (IND) Protocol* contains important medication information, including dosing, administration, patient monitoring, special populations, and safety at https://www.cdc.gov/poxvirus/monkeypox/pdf/Tecovirimat-IND-Protocol-cdc-irb.pdf. Per the IND protocol, tecovirimat treatment may be initiated for patients with laboratory confirmed non-variola *orthopoxvirus* infection or suspected infection based on known exposure(s) and/or clinical manifestations of disease.

DPHHS has pre-positioned supplies of oral tecovirimat in Helena, Great Falls, Missoula, Billings, Kalispell, Sidney, Butte, and Bozeman for redistribution, when necessary. The state supply of tecovirimat is limited, so DPHHS will review/approve requests before use. The request process is outlined below.

- Provider contacts DPHHS CDEpi (406-444-0273) to initiate request for an eligible patient, per CDC guidance.
- DPHHS will work with the provider's facility to arrange transfer of tecovirimat, when indicated.
- DPHHS will share a summary of the CDC reporting requirements for tecovirimat use with the treating provider when treatment is released.

Treatment with tecovirimat can begin upon receipt of the medication and after obtaining informed consent. Forms requested under the expanded access IND can be returned to CDC after treatment begins. Additional reporting information is available at the CDC Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat) for Treatment of Monkeypox at https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html.

CDC offers specific clinical guidance and treatment considerations for people with HIV (https://www.cdc.gov/poxvirus/monkeypox/clinicians/people-with-HIV.html), people who are pregnant or breastfeeding (https://www.cdc.gov/poxvirus/monkeypox/clinicians/pregnancy.html), and children and adolescents (https://www.cdc.gov/poxvirus/monkeypox/clinicians/pediatric.html).

RECOMMENDATIONS

Recommendations for Healthcare Providers

1. Become familiar with the key clinical characteristics of monkeypox disease and consider testing for other infectious diseases that may have a similar or concurrent clinical presentation: https://www.cdc.gov/poxvirus/monkeypox/clinicians/clinical-recognition.html
2. Healthcare providers may use any reference laboratory offering *orthopoxvirus*/monkeypox testing. Healthcare providers are required to notify their local health department of high-suspect monkeypox cases and of any positive monkeypox results from reference laboratories during daytime hours, including weekends. Providers may also discuss indeterminate monkeypox results with public health to determine if recollection is recommended: https://dphhs.mt.gov/publichealth/FCSS/countytribalhealthdepts.
3. Starting August 29th, MTPHL will only test monkeypox specimens on Tuesdays and Thursdays. Specimens must have been approved for MTPHL testing by a CDEpi consult prior to submission. Additionally, MTPHL will begin charging a $55 testing fee on August 29th.
4. Instruct the patient to isolate themselves and avoid close contact with other people and animals while their monkeypox test result is pending.
5. Refer to the CDC *Preparation and Collection of Specimens* for proper specimen collection guidance: https://www.cdc.gov/poxvirus/monkeypox/clinicians/prep-collection-specimens.html
6. Implement infection prevention measures in the healthcare setting, consistent with CDC guidance for *Infection Prevention and Control of Monkeypox in Healthcare Settings*: https://www.cdc.gov/poxvirus/monkeypox/clinicians/infection-control-healthcare.html
7. Evaluate whether the suspect case meets the criteria for treatment with tecovirimat per CDC *Guidance for Tecovirimat Use Under Expanded Access Investigational New Drug Protocol during 2022 U.S. Monkeypox Cases*: https://www.cdc.gov/poxvirus/monkeypox/clinicians/Tecovirimat.html. If so, contact DPHHS CDEpi at 406-444-0273 to request a course from the state supply.

Recommendations for Local Public Health

1. On notification of a high-suspect monkeypox case, contact the DPHHS Communicable Disease Epidemiology Program (CDEpi) at 406-444-0273, share name and date of birth of the suspect case, and whether the individual meets the criteria for lab testing at the MTPHL or if it will be sent to a reference lab.
2. For high-suspect cases, initiate case investigation for the purposes of identifying contacts eligible for post-exposure prophylaxis with Jynneos vaccine and recommendations to minimize further disease transmission.
3. Vaccine is available for PEP, PEP++, and PrEP at several LHD throughout Montana. If your LHD does not have vaccine and a resident needs vaccine, please contact the Montana Immunization Program at 406-444-5580 to arrange vaccine transfer.
4. Visit the Montana Department of Public Health and Human Services (DPHHS) monkeypox webpage for updates on the epidemiology of monkeypox in MT: https://dphhs.mt.gov/publichealth/cdepi/diseases/monkeypox.