



COUNTY OF SAN LUIS OBISPO HEALTH AGENCY  
PUBLIC HEALTH DEPARTMENT  
**PROVIDER HEALTH ADVISORY**

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## PROVIDER HEALTH ADVISORY

**Date:** August 1, 2022

**Contact:** Kristin Edler, 805-781-5500, [kedler@co.slo.ca.us](mailto:kedler@co.slo.ca.us)

### Monkeypox Updates for Clinicians

Please see the attached updates from the Centers for Disease Control and Prevention (CDC) regarding monkeypox care and treatment:

- **Update for Clinicians on Testing and Treatment for Monkeypox.** Available at <https://emergency.cdc.gov/han/2022/han00471.asp>
- **Update for Clinicians on Monkeypox in People with HIV, Children and Adolescents, and People who are Pregnant or Breastfeeding.** Available at <https://emergency.cdc.gov/han/2022/han00472.asp>

### Local vaccine update:

The Public Health Department has received 20 doses of the JYNNEOS vaccine, which provides protection against monkeypox and smallpox. This small allocation of vaccine reflects an extremely limited national supply. In accordance with state and national guidance, SLO County's initial small allocation of vaccine will be prioritized for people who have had close contact with someone who tested positive for monkeypox (PEP), and for laboratory workers who regularly handle the virus. We expect to receive a second smaller allocation in late summer, and a third allocation later in the fall as the vaccine supply gradually increases.

While there is not a waiting list for vaccine, local residents may sign up to receive updates on monkeypox, including announcements when vaccine access expands, at [slocounty.ca.gov/monkeypox](http://slocounty.ca.gov/monkeypox). In addition, health care providers will continue to receive updates via advisories like this one.

### To report suspected cases:

**Call the San Luis Obispo County Public Health Department as soon as possible.** Call 805-781-5500 (M-F, 8 a.m.–5 p.m.) or 805-781-4553 (weekends and after hours).

### For more information on monkeypox:

- SLO County Public Health Monkeypox Information: [https://slocounty.ca.gov/monkeypox](http://slocounty.ca.gov/monkeypox)
- CDPH Monkeypox page: [www.cdph.ca.gov/Programs/CID/DCDC/Pages/monkeypox.aspx](http://www.cdph.ca.gov/Programs/CID/DCDC/Pages/monkeypox.aspx)
- CDC Monkeypox Information for Healthcare Professionals: [www.cdc.gov/poxvirus/monkeypox/clinicians/index.html](http://www.cdc.gov/poxvirus/monkeypox/clinicians/index.html)

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#### Public Health Department

2191 Johnson Avenue | San Luis Obispo, CA 93401 | (P) 805-781-5500 | (F) 805-781-5543

[www.slopublichealth.org](http://www.slopublichealth.org)

# Update for Clinicians on Testing and Treatment for Monkeypox



Distributed via the CDC Health Alert Network

July 28, 2022, 9:00 PM ET

CDCHAN-00471

## Summary

As of July 28, 2022, the Centers for Disease Control and Prevention (CDC) and state and local public health partners are reporting 4,907 cases of monkeypox in the United States across 46 states, Washington, D.C., and Puerto Rico. CDC is also tracking multiple clusters of monkeypox that have been reported globally, including in 71 countries that normally do not report monkeypox.

This Health Alert Network (HAN) Health Update serves to alert clinicians on commercial testing capability, collecting clinical specimens for testing, and using TPOXX® (tecovirimat) for treating monkeypox.

## Background

Since May 2022, CDC has been urging healthcare providers in the United States to be on alert for patients who have rash illnesses [consistent with monkeypox](#). Distinguishing features of the rash include papules, vesicles, pustules, or scabs that are deep-seated, firm or rubbery, and have well-defined round borders. Vesicular or pustular [stages of the lesions](#) are often umbilicated (i.e., have a dent in the middle of them). They may be painful, painless, or itchy. People with monkeypox may develop [symptoms](#) including fever, headache, muscle aches, exhaustion or swollen lymph nodes during the prodromal period preceding the rash or with the rash.

## Recommendations for Healthcare Providers on Diagnostic Testing

The public health response to monkeypox depends on timely and comprehensive laboratory testing and reporting of those results. Tests should be performed on persons for whom monkeypox is suspected based on clinical presentation and [epidemiologic criteria](#). Positive diagnostic results from testing of skin lesion material for *Orthopoxvirus* or *Monkeypox virus* DNA in persons without epidemiologic criteria or known risk factors should be verified through repeat testing and/or confirmatory testing.

If there are no identified epidemiologic risk criteria for monkeypox infection, other possible causes of rash in adults should be considered, including secondary syphilis, herpes, and varicella zoster. In children without identified epidemiologic risk criteria for monkeypox, varicella zoster and molluscum contagiosum (MC) should be considered in the differential diagnosis. MC is an infection caused by a poxvirus (molluscum contagiosum virus) that is diagnosed more often in children than in adults. [MC infection](#) is usually a benign, mild skin disease characterized by lesions that may appear anywhere on the body. CDC's FDA-cleared non-variola virus test used within the Laboratory Response Network laboratories and most commercial laboratories, does not cross-react with molluscum contagiosum virus. In children and adolescents, as in adults, other potential etiologies of illness should be tested for in parallel with or before *Monkeypox virus* testing, based on clinical presentation and epidemiologic criteria.

## Specimen Type and Collection



1. The recommended specimen type is material collected from the surface of a lesion or crust from a healing lesion. CDC recommends that three lesions per patient be swabbed. Swab the surface of the lesion vigorously to collect adequate DNA. It is not necessary to de-roof or lance the lesion before swabbing. For some individuals, the lesions may not be

overtly visible (such as within the oral cavity or within the rectum), therefore clinicians should perform a thorough evaluation including a full body skin, oral, genital, and rectal examination to identify appropriate lesions for sampling.

2. Different laboratories may vary in their specimen preparation requirements. Please contact the appropriate public health department or commercial laboratory to determine acceptable specimens.

### ***Specimen Shipment***

Specimen collection, storage, and shipping of human specimens is subject to the Clinical Laboratory Improvements Amendment (CLIA) restrictions.

- The clinician or facility collecting a specimen for laboratory testing should confirm collection, storage, and shipment instructions with the specific laboratory to which it will be submitted prior to specimen collection. Specimens should be shipped as [Category B](#)  .

### ***Reporting of Test Results***

Any laboratory that performs diagnostic testing for *Orthopoxvirus*, non-variola *Orthopoxvirus*, or *Monkeypox virus* should report test results (positive, negative, equivocal) to state, tribal, local, or territorial health departments. The results should be [reported](#) to the health department in the patient's jurisdiction of residence within 24 hours of testing. These data will inform prevention measures, contribute to the understanding of this outbreak, and can assist in predicting increases in testing demand and planning for potential supply chain issues for reagents and other test materials.


### ***Orthopoxvirus Results Interpretation***





Once results are received from the laboratory, a positive *Orthopoxvirus* test is considered to meet the case definition for probable *Monkeypox virus* infection since there are no other circulating *Orthopoxviruses* within the United States that cause systemic disease. Clinical care and prevention precautions should begin based on the *Orthopoxvirus* test result and should not wait for any additional viral characterization testing that may be performed.

### ***Testing Capacity and Costs***

To build upon CDC's and the Laboratory Response Network's testing capacity, CDC recently worked to bring testing online at five commercial laboratory companies. All five commercial laboratories are now online and, combined with the CDC's Laboratory Response Network, have increased national *Monkeypox virus* testing capacity from 6,000 to up to 80,000 specimens per week.<sup>†</sup> It is not necessary to first consult with state or federal health officials prior to initiating diagnostic testing.

### ***Information for Healthcare Providers on Tecovirimat Treatment***

Tecovirimat (also known as TPOXX or ST-246) is approved by the Food and Drug Administration (FDA) for treating human smallpox disease caused by *Variola virus* in adults and children. Its use for other *Orthopoxvirus* infections, including monkeypox, is not approved by the FDA. However, CDC has an [expanded access Investigational New Drug application](#)  (EA-IND) to allow access to and use of TPOXX to treat monkeypox in adults and children of all ages.

The EA-IND provides an umbrella regulatory coverage so that clinicians and facilities do not need to request and obtain their own INDs. The EA-IND also provides liability protection under the [PREP Act](#)  for healthcare providers prescribing, administering, or dispensing the drug, and ability for patients to seek compensation if they are seriously injured by the medication through the Countermeasures Injury Compensation Program ([CICP](#) ). In the largest safety study of 359 healthy adult volunteers, other than local site reactions the most common adverse reactions among those receiving tecovirimat were headache (12%) and nausea (5%) [[LABEL \(fda.gov\)](#)  ]. The safety of tecovirimat has not yet been studied in people with *Orthopoxvirus* disease.








### ***How to Obtain Tecovirimat (TPOXX)***

- TPOXX is available through the Strategic National Stockpile, and multiple state and territorial health departments are pre-positioning supplies of TPOXX within their jurisdictions. All clinicians and care facility pharmacists requesting TPOXX should contact their state/territorial health department.
- For urgent clinical situations after hours, providers may contact CDC's Emergency Operations Center (770-488-7100) to discuss the case with a clinician but pre-positioned TPOXX may be the fastest route to obtain the therapeutic.
- Treatment with TPOXX can begin upon receiving the medication and after obtaining informed consent. No pre-registration is required for clinicians or facilities to begin treatment.
- Forms requested under the EA-IND can all be returned to CDC **after** treatment begins.

## **TPOXX Expanded Access Investigational New Drug Protocol (IND 116,039/Protocol 6402 )**

CDC, in partnership with FDA, has made it easier for healthcare providers to provide tecovirimat (TPOXX) treatment to patients with monkeypox under the EA-IND protocol. The streamlined process reduces the number of required patient treatment forms from six (21 pages) to two (7 pages); decreases patient visits to three visits that can all be conducted via telemedicine; and makes collecting blood, lesion samples, and lesion photos optional.

Healthcare providers should perform the following:

1. Obtain [informed consent](#)  prior to treatment.
2. Conduct a baseline assessment and complete the [Patient Intake Form](#) . If feasible, give the patient the [diary form](#)  to complete at home and encourage the patient to return it directly to CDC. The top of the diary form provides the patient with instructions on how to return it to CDC.
3. Sign the [FDA Form 1572](#) . One signed 1572 form per facility suffices for all (including future) TPOXX treatments administered under the EA-IND at the same facility.
4. Document progress during and after treatment on the [Clinical Outcome Form](#) .
5. Report life-threatening or serious adverse events associated with TPOXX by completing a [PDF MedWatch Form](#)  [226KB, 3 pages] and returning it to CDC via email ([regaffairs@cdc.gov](mailto:regaffairs@cdc.gov)) or uploading to [ShareFile](#)  within 72 hours of awareness or sooner, if possible.
6. Comply with FDA requirements for IRB review described here: [Information for Healthcare Providers on Obtaining and Using TPOXX \(Tecovirimat\) for Treatment of Monkeypox | Monkeypox | Poxvirus | CDC](#).

It is important to note that clinicians can start the patient's treatment upon obtaining informed consent. All forms can be completed and submitted after treatment initiation to facilitate timely care of the patient. Timely return of patient intake and clinical outcome forms by providers and healthcare facilities enables CDC to monitor clinically appropriate and safe use of TPOXX.

### **For More Information**

- [Considerations for Monkeypox Vaccination | Monkeypox | Poxvirus | CDC](#)
- [How to Report Test Results](#)
- [Preparation and Collection of Specimens](#)
- [Obtaining and Using TPOXX \(Tecovirimat\)](#)
- [Treatment Information for Healthcare Professionals | Monkeypox | Poxvirus | CDC](#)
- Visit [CDC-INFO](#) or call CDC-INFO at 1-800-232-4636
- CDC 24/7 Emergency Operations Center (EOC) 770-488-7100

### **Footnote**

†Testing at public health laboratories remains free. Commercial laboratory companies will bill private insurance, Medicaid or Medicare for all testing performed. Those who are underinsured or uninsured will receive a bill for that testing. The Administration continues to work to identify funding that would cover the cost of monkeypox testing regardless of the individual's coverage. Clinicians may find the relevant CPT code for *Monkeypox virus* testing on each commercial laboratory's website.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

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### HAN Message Types

- **Health Alert:** Conveys the highest level of importance; warrants immediate action or attention.
- **Health Advisory:** Provides important information for a specific incident or situation; may not require immediate action.
- **Health Update:** Provides updated information regarding an incident or situation; unlikely to require immediate action.

- **Info Service:** Provides general information that is not necessarily considered to be of an emergent nature.

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This message was distributed to state and local health officers, state and local epidemiologists, state and local laboratory directors, public information officers, HAN coordinators, and clinician organizations.

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# Update for Clinicians on Monkeypox in People with HIV, Children and Adolescents, and People who are Pregnant or Breastfeeding



Distributed via the CDC Health Alert Network

July 30, 2022, 1:15 PM ET


CDCHAN-00472

## Summary

As of July 29, 2022, the Centers for Disease Control and Prevention (CDC) and state and local public health partners are reporting 5,189 cases of *Monkeypox virus* infections in the United States across 47 states, Washington, D.C., and Puerto Rico. CDC is also reporting multiple outbreaks of monkeypox that have been reported globally in 71 countries that do not normally report monkeypox activity. On Friday, July 22, CDC reported the first two cases of monkeypox in children in the United States during the current outbreak.

This Health Alert Network (HAN) Health Update serves to alert clinicians to clinical considerations for preventing, diagnosing, and managing monkeypox in people with HIV, children, adolescents, and people who are pregnant or breastfeeding.

## Background

Since May 2022, CDC has been urging healthcare providers in the United States to be on alert for patients who have rash illnesses [consistent with monkeypox](#). People with HIV, individuals who are immunocompromised, children, adolescents, and people who are pregnant or breastfeeding may be at risk for increased disease severity and adverse health outcomes associated with monkeypox infection. Clinicians should be familiar with unique clinical considerations for monkeypox in these patient populations. A broad diagnostic approach is encouraged to distinguish *Monkeypox virus* infection from other causes of fever and rash illness. Testing should be performed on persons for whom monkeypox is suspected based on clinical presentation or [epidemiologic criteria](#). Clinicians should consult their state or territorial health department ([State Contacts](#)  [↗](#)) or CDC through the CDC Emergency Operations Center (770-488-7100) as soon as monkeypox is suspected.

CDC has issued clinical considerations for monkeypox infection in multiple populations including: [people with HIV](#), [children and adolescents](#), and [people who are pregnant or breastfeeding](#). These newly released clinical considerations complement existing clinical guidance for managing monkeypox and provide information on signs and symptoms of *Monkeypox virus* infection; pre- and post-exposure prophylaxis; treatment; and infection control in these populations.

## Recommendations and Information for Healthcare Providers on Monkeypox in People with HIV

In the current outbreak, available international [summary surveillance data](#) in the CDC-issued [clinical considerations for people with HIV](#) indicate 30-51% HIV prevalence among persons with monkeypox for whom HIV status was known. It is currently unknown whether HIV infection affects a person's risk of acquiring *Monkeypox virus* infection and developing disease after exposure.

Persons with advanced and uncontrolled HIV might be at higher risk for severe or prolonged monkeypox disease. Therefore, prophylaxis (e.g., vaccination), [medical treatment](#) and close [monitoring](#) are a priority for this population. Compared with other persons with monkeypox, [case reports](#) among persons with inadequately treated HIV who have CD4 counts  $\leq 350$  per mm<sup>3</sup> reported higher rates of secondary bacterial infection, more prolonged illness (and thereby also longer period of infectiousness), as well as a higher likelihood of a confluent or partially confluent rash, rather than discrete lesions. In

contrast, recent [reports](#) of patients with HIV infection and monkeypox who are on effective antiretroviral therapy (ART) have noted no deaths or evident excess hospitalizations to date. Providers should consider both viral suppression and CD4 count in weighing the risk of severe outcomes from monkeypox for any patient with HIV.

The rash of monkeypox can be confused with other rash illnesses that are considered in people with HIV, including herpes zoster (shingles), scabies, molluscum contagiosum, herpes, syphilis, chancroid, lymphogranuloma venereum, allergic skin rashes, and drug eruptions. Immunocompromised persons, including persons with advanced, untreated or inadequately suppressed HIV, may present with an atypical rash, including a disseminated rash that may make diagnosis more challenging.

[Prevention](#) of monkeypox and infection control practices in the [home](#) or [healthcare setting](#) are the same regardless of peoples' HIV status. [Post-exposure prophylaxis \(PEP\)](#) and antiviral [treatments](#), including [tecovirimat](#), are available for persons exposed to monkeypox or with *Monkeypox virus* infection. The safety and immunogenicity of JYNNEOS, a live, non-replicating viral vaccine, has been specifically established in people with HIV; however, immunogenicity among persons with HIV who have CD4 counts below 100 cells/mm<sup>3</sup> or who are not virologically suppressed remains unknown. ACAM2000, a replicating viral vaccine, should not be given to people with HIV (regardless of immune status). Antiviral treatments for monkeypox have [few](#) interactions with antiretroviral therapy. ART and opportunistic infection prophylaxis should be continued in all people with HIV who develop monkeypox.

### **Recommendations and Information for Healthcare Providers on Monkeypox in Children and Adolescents**

Limited [pediatric](#) data on infection with the Congo Basin clade of *Monkeypox virus* suggest increased risk of severe disease in children younger than 8 years of age. Rare complications of monkeypox include abscess, airway obstruction due to severe lymphadenopathy, cellulitis, corneal scarring, encephalitis, keratitis, pneumonia, and sepsis. The West African clade of *Monkeypox virus* involved in the current outbreak typically causes less severe disease than the Congo Basin clade.

*Monkeypox virus* can spread to children through contact with infectious body fluids (e.g., lesion exudates and respiratory secretions) of people or animals or through contact with fomites, as may occur in households and other close contact [settings](#). The number of monkeypox cases among children in the United States is currently low; however, CDC acknowledges that the expanding U.S. outbreak and the possible risk for transmission in households and other settings may result in additional pediatric cases. Pediatric providers should be familiar with prevention, recognition, and testing [considerations](#) for monkeypox in children and adolescents.

Families should be counseled about preventing the spread of *Monkeypox virus* between children, caregivers, and household members [in the home](#), including avoidance of contact with persons who have monkeypox, the body fluids of an infected person, and fomites (e.g., clothing, towels, bedding); wearing a well-fitting mask or respirator by the person with monkeypox and the contact (for children over 2 years of age) when interaction is unavoidable; and minimizing the number of caregivers for children with monkeypox. Particular attention should be made to keep children with monkeypox from scratching lesions or touching their eyes to prevent auto-inoculation and more severe illness. Caregivers should cover areas of broken skin with bandages to the extent possible and avoid direct skin-to-skin contact with the rash.

Children and adolescents who are close contacts of a person with monkeypox (e.g., household contact, other family member, caregiver, or friend) should be evaluated for illness and offered [post-exposure prophylaxis](#) with JYNNEOS or ACAM2000 (for children older than 12 months) or [treatment](#) when indicated. Monkeypox should be considered when children or adolescents present with [signs or symptoms](#) that could be consistent with the disease, especially if [epidemiologic criteria](#) are present. The rash of monkeypox can be confused with other rash illnesses that are commonly considered in children including varicella (chickenpox); hand, foot, and mouth disease; measles; scabies; molluscum contagiosum; herpes; allergic skin rashes and syphilis (including congenital syphilis); and drug eruptions.

Data are limited on the effectiveness of [PEP](#) for children who have been exposed to monkeypox or treatment for children with illness, and no vaccines or other products are currently licensed for monkeypox prevention or treatment in children or adolescents. However, PEP should not be withheld from children or adolescents who are otherwise eligible. Decisions about whether to offer PEP should take into account the patient's [degree of exposure](#) and the patient's individual risk of severe disease.

Prophylactic therapeutics that can be administered include vaccination, Vaccinia immune globulin, and antiviral medication. For almost all children and adolescents, vaccination is the preventive treatment that should be administered. Immune globulin or antivirals may also be considered for infants under 6 months of age, given their immature immune systems and possible decreased responses to vaccination.

[Tecovirimat](#) is currently being used as the first-line treatment for infection with *Monkeypox virus*, including [for children and adolescents](#) with severe disease or underlying medical conditions that may increase risk for severe disease and those with complications from monkeypox. Individual risks and benefits must be considered prior to initiating tecovirimat. Other treatments such as [Vaccinia immune globulin](#) [↗](#) may be considered in unusual circumstances.

In pediatric inpatient care settings, [infection control procedures](#) for children with monkeypox infection should also consider the child's age and caregiving needs; family and caregiver preferences; the extent, severity, and course of the child's illness; and risks for severe monkeypox disease in exposed caregivers (e.g., pregnancy or immunocompromising conditions).

### **Recommendations and Information for Healthcare Providers on Monkeypox in People who are Pregnant or Breastfeeding**

Data regarding *Monkeypox virus* infection during pregnancy are limited. It is unknown if pregnant people are more susceptible to acquiring *Monkeypox virus* infection or if illness is more severe during pregnancy. Other poxviruses cause more severe infection during pregnancy. *Monkeypox virus* can be transmitted to the fetus during pregnancy and to the newborn by close contact during and after birth. There are few case reports of spontaneous pregnancy loss and stillbirth, preterm delivery, and neonatal monkeypox infection; the frequency and circumstances for these outcomes are unknown. Whether *Monkeypox virus* is present in breast milk is unknown; however, it may be transmitted through close contact during breastfeeding.

[Prevention](#) measures for monkeypox infection are similar for pregnant and non-pregnant people. Pre- or post-exposure prophylaxis should be offered to people who are pregnant or breastfeeding. When pre- or post-exposure prophylaxis by [vaccination](#) is chosen, JYNNEOS, a live, non-replicating viral vaccine, can be used. ACAM2000, a replicating viral vaccine, should not be used in people who are pregnant or breastfeeding.

During pregnancy, the cause of fever may be difficult to differentiate from other infections, such as intraamniotic infection (chorioamnionitis), until the monkeypox rash appears. Pregnant patients with rashes initially considered characteristic of dermatoses of pregnancy (e.g., polymorphic eruption of pregnancy) or of more common infections (e.g., varicella zoster or sexually transmitted infections) should be carefully evaluated for a monkeypox [rash](#), and [submission](#) of specimens of lesions for monkeypox diagnosis should be considered, especially if the person has any [epidemiologic risk factors](#) for monkeypox infection.

While most adults with *Monkeypox virus* infection experience self-limiting infection and recover within 2–4 weeks, pregnant and breastfeeding people should be prioritized for medical treatment, if needed, due to the probable increased risk of severe disease during pregnancy, risk of transmission to the fetus during pregnancy or to the newborn by close contact during and after birth, and risk of severe infection in newborns. Treatment for *Monkeypox virus* infection should be offered to people who are pregnant or breastfeeding. The risks and benefits of [treatment options](#) should be discussed with the patient.

Recommendations for [infection prevention and control](#) of monkeypox in healthcare settings are the same for pregnant and non-pregnant patients. Newborns born to people with monkeypox should be placed in isolation, and healthcare personnel should follow infection prevention and control recommendations. Patients with monkeypox should be counseled about measures to prevent risk of transmission of *Monkeypox virus* to their newborn from [close contact and breastfeeding](#).

### **For More Information**

- [Clinical Considerations for Monkeypox in People Who are Pregnant or Breastfeeding | Monkeypox | Poxvirus | CDC](#)
- [Clinical Considerations for Monkeypox in Children and Adolescents | Monkeypox | Poxvirus | CDC](#)
- [Clinical Considerations for Treatment and Prophylaxis of Monkeypox virus Infection in People with HIV | Monkeypox | Poxvirus | CDC](#)
- Visit [CDC-INFO](#) or call CDC-INFO at 1-800-232-4636
- CDC 24/7 Emergency Operations Center (EOC) 770-488-7100

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