Health Advisory

August 25, 2022
Please distribute to all providers in the facility
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Monkeypox Guidance for Vaccine, Testing and Treatment

Key Messages

As of August 24, 2022, there are 3066 probable and confirmed Monkeypox cases in California, in 37 counties. There is presently 1 confirmed case in Shasta County. The risk of monkeypox in the general population continues to be very low based on the information available.

Due to the scarce availability of vaccine in Shasta County the priority for vaccination remains at those identified as being in the highest risk groups. Vaccine eligibility will expand as vaccine supply increases.

Healthcare providers can order monkeypox virus testing as they normally would order other tests. People seeking testing for monkeypox must consult with their healthcare provider first; they cannot separately go to a lab.

Treatment for monkeypox is available in Shasta County. Tecovirimat can be requested from Shasta County Health and Human Services Agency Public Health Branch (SC HHSA PH) and we can support the logistical and clinical consultation regarding tecovirimat.

Background Information

The number of reported monkeypox virus cases has continued to increase across the United Sates including California. The strain circulating in the U.S. and globally has been a clade that causes milder illness.

Close, sustained skin-to-skin contact, including sexual contact, with a person with monkeypox appears to be the most significant risk factor associated with transmission among recent cases. Although this current outbreak many of the reported cases have been among gay, bisexual, or other men who have sex with men (MSM), it is important to remember that any person, irrespective of gender identity or sexual orientation, can acquire and spread monkeypox.

Monkeypox infections in the current outbreak may not be classical in appearance or progression. Therefore, the patient history is particularly important for identifying possible monkeypox cases

Actions Requested of Health Care Systems and Clinicians

1. **Isolate** patient suspected of monkeypox in single-person exam room or airborne precaution isolation room, if available, as soon as possible. Ensure patient remains masked, if tolerable, and cover any exposed skin lesions with gown or sheet. Health care personnel evaluating patient should wear gloves, gown, eye protection, and N95 or equivalent or higher-level respirator.
2. **Report** any suspect cases **immediately** by phone SC HHSA PH at (530) 225-5591.
3. **Collect** samples for testing as described below.
4. **Manage and treat** with supportive care and symptom control. Antiviral treatment and prophylaxis are available to request through SC HHSA PH. Many cases are mild enough that they can convalesce at home.

Vaccine

JYNNEOS is a live, non-replicating vaccine that is FDA licensed for prevention of smallpox and monkeypox in people ≥18 years, and for those under 18 in special circumstances. JYNNEOS can be considered for monkeypox vaccine in people who have had a high- or intermediate-risk exposure to monkeypox (see CDC guidance), as a method to prevent or reduce severity of disease. Monkeypox vaccine should be given, if possible, within 4 days of exposure to prevent disease but may still reduce severity of disease if given up to 14 days after exposure. It is administered as two subcutaneous or intradermal injections 4 weeks apart (see CDC – Intradermal Administration of JYNNEOS). CDPH recommends intradermal administration with exceptions for subcutaneous for individuals with a history of developing keloid scars, or persons who are younger than 18 years of age.

The federal supply of JYNNEOS remains limited, but more is expected in the coming weeks and months. The priority is to administer a first dose of vaccine to as many people who are at higher risk for monkeypox exposure as possible. As soon as federal vaccine supply expands, Shasta County Health and Human Services Agency Public Health (SC HHSA PH) will make second doses available to those who received their initial dose. The local availability of JYNNEOS is extremely scarce.

Eligibility will expand as vaccine supply increases. Due to the scarce availability of vaccine in Shasta County the priority remains at those identified as being in the highest risk groups.

Current Groups Eligible for JYNNEOS vaccine

1. Gay or bisexual men and transgender persons who:
    - Had multiple or anonymous sex partners in the last 14 days including engaging in survival and/or transactional sex.
        - Note: eligible persons who are immunocompromised, including those with advanced or uncontrolled HIV may be at high risk for severe disease and should be prioritized for vaccination. In addition, individuals meeting the prior eligibility criteria (i.e., had a diagnosis of gonorrhea and/or early syphilis within the past 12 months; or are on HIV pre-exposure prophylaxis (PrEP); OR attended or worked at a commercial sex venue or other venue where they had anonymous sex or sex with multiple partners within past 21 days) are still eligible for vaccination.

2. Persons confirmed by SC HHSA PH to have high- or intermediate-risk contact with a confirmed monkeypox case (as defined by CDC and confirmed by SC HHSA PH) may be eligible for Poste Exposure Prophylaxis.
3. Persons who attended an event/venue where there was high risk of exposure to an individual(s) with confirmed monkeypox through skin-to-skin or sexual contact may be eligible for Poste Exposure Prophylaxis.
4. Persons experiencing homelessness (PEH) with high-risk behaviors.
5. High risk cohorts identified by clinical staff in the Shasta County Jail system.

Referring Eligible Patients for Monkeypox Vaccine

Shasta County Health and Human Services Agency Public Health (SC HHSA PH) currently has a limited number of the JYNNEOS vaccine. Providers with JYNNEOS vaccine from the Public Health Department should vaccinate their own patients meeting eligibility criteria #1 for monkeypox vaccine. Eligible persons who are immunocompromised, including those with advanced or uncontrolled HIV may be at high risk for severe disease and should be prioritized for vaccination.

Providers that do not have JYNNEOS vaccine should instruct persons meeting eligibility criteria #1 to call SC HHSA PH at 530-225-5591 to be put on the list for vaccination (see below for SC HHSA PH's vaccination strategy). Please actively encourage eligible patients that are immunocompromised, including those with advanced or uncontrolled HIV, to sign up for monkeypox vaccination. They will be prioritized for vaccine appointments.

Shasta County Health and Human Services Agency Public Health Vaccine Strategy

1) Contact SC HHSA PH at (530) 225-5591 to request a CD nurse to screen.
2) If the patient meets criteria for vaccination, a SC HHSA PH staffwill send them an invitation for the patient to schedule for an appointment through MyTurn.

For more information and updates on the MPX vaccine go to ShastaReady.org.

Laboratory Testing Guidance -Update

The Shasta County Public Health Laboratory is not conducting orthopox testing. Locally, Quest and Labcorp are providing monkeypox testing.

For more information regarding Quest services visit: Monkeypox | Quest Diagnostics. Quest's process employs PCR techniques to aid in the qualitative detection of non-variola orthopoxvirus and monkeypox virus DNA.

For more information regarding Labcorp services visit: Monkeypox (Orthopoxvirus), DNA, PCR Test | Labcorp. The test is qualitative and will indicate a result for the presence of DNA from non-variola orthopoxvirus species, of which monkeypox is one.

Personnel who collect specimens should use personal protective equipment (PPE) in accordance with recommendations for healthcare settings. Specimens should be collected in the manner outlined below.

QUEST directions for specimen collection:

- *Swab a pustule/lesion vigorously and place the swab into a viral culture media (VCM; or equivalent) tube.*
- *No additional confirmatory testing is required at the CDC; therefore, a duplicate swab from the same lesion is not needed. If clinically indicated, consider submitting additional swabs if multiple lesions with different stages are present. Multiple specimens collected from a single patient should be submitted separately; each should be accompanied by its own separate requisition and transported in its own sealed bag. Ship frozen (preferred) or refrigerated.*
- *Healthcare personnel should collect specimens using personal protective equipment (PPE) in accordance with recommendations for healthcare settings. Specimens will not be collected in our patient service centers.*

LABCORP directions for specimen collection:

- *Sample collection: Vigorously swab or brush the base of the lesion with a sterile dry polyester, rayon or Dacron swab. Insert the swab into the tube containing UTM or VTM. Carefully break the swab at the scoreline and tightly close the sample. Some UTM kits may contain two swabs; however, only one swab needs to be collected and submitted for testing. If multiple lesions with differing appearances are present, consider submitting an additional UTM/VTM collection, as described above, for each lesion.*
- *Here is a link to more detailed instructions for collecting specimens to be submitted to Labcorp:* 196405_DX_IFU_MonkeyPox-Collection_Final.pdf (labcorp.com)

Please note that, for both Labcorp and Quest, **healthcare providers can order monkeypox virus testing as they normally would order other tests. People seeking testing for monkeypox must consult with their healthcare provider first; they cannot separately go to a lab**. Please refer to the individual website for specimen collection and submission instructions.

Treatment

The current circulating strain of monkeypox has been to date limited to the West African clade, which tends to cause milder disease. Many patients have mild disease and recover without medical intervention. Patients with lesions or pain that interferes with the activities of daily living and patients at high risk for severe disease should be considered for treatment with tecovirimat (TPOXX). There is no shortage of tecovirimat.

Tecovirimat (also known as TPOXX or ST-246) is an FDA-approved antiviral medication for the treatment of human smallpox disease. The CDC holds an expanded access Investigational New Drug (EA-IND) protocol that allows for the use of stockpiled tecovirimat to treat monkeypox disease during an outbreak.

Data are 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.

Informed consent is required for all patients treated with tecovirimat and providers must follow the CDC EA-IND protocol. Tecovirimat is available in oral and intravenous formulations**.**

A limited supply of Tecovirimat in the oral formulation has now been positioned in Region III, healthcare providers may email DOC45@co.shasta.ca.us or call SC HHSA PH healthcare provider line. SC HHSA PH has developed guidance to support clinicians in obtaining and using tecovirimat (See attachment PDF).
See Guidance for the Treatment of Monkeypox-Tecovirimat. Healthcare providers should email DOC45@co.shasta.ca.us and also call the SC HHSA PH healthcare provider line for logistical and clinical consultation regarding tecovirimat.

Tecovirimat: New Treatment Provider Process

Steps Need – Shasta County Health and Human Services Public Health (SC HHSA PH) & Potential Provider

A. SC HHSA PH Communicable Disease/Emergency Preparedness Units sends the provider an informational package including:
   1) Tecovirimat-IND-Protocol-CDC-IRB.pdf
   2) Tecovirimat IND_Form FDA 1572.pdf
   3) Appendix A

B. SC HHSA PH will request a call between the SC HHSA PH Communicable Disease/Emergency Preparedness Units and CDPH Monkeypox Clinical Team.

C. Provider reviews information with their clinical facility and decides to become a tecovirimat provider.
   1) Provider can either rely on the CDC IRB (recommended by CDC) or can submit the protocol to their local IRB for review. This decision is at the discretion of the provider and their clinical institution.
      a. The CDC IRB is the central IRB that has reviewed and approved the tecovirimat EA-IND protocol.
      b. CDC has a written reliance agreement that facilities can sign to document their reliance on CDC IRB.
      c. Local IRB review does not necessarily have to occur before step D.
   2) Provider understands CDC minimum requirements for submission of the FDA_1572, Informed_Consent, Patient_Intake_Forms and reporting of serious adverse events (Appendix A).
   3) All patient visits (baseline, during and after completion of treatment) may be conducted via telemedicine.
   4) Providers are asked to inform SC HHSA PH of treatment starts so that treatment can be recorded in the case record (CalREDIE) and medication supply monitored.

D. Provider submits Tecovirimat IND_Form FDA 1572.pdf and CV to CDC within 3 days of treatment initiation. Only one provider per clinical facility should submit this form. If it is an urgent situation, see Immediate Need process, below.

E. SC HHSA PH approves the distribution of tecovirimat through their MHOAC.
   1) Tecovirimat is approved through the normal MHOAC process using a Resource Request and SitRep and emailing them to DOC45@co.shasta.ca.us .
   2) Providers and their facility are expected to track their inventory of tecovirimat including number of treatments started and amount of medication supply still available.

F. Treatment eligibility is reviewed in the protocol and is at the discretion of the provider unless the SC HHSA PH communicates other expectations.
   1) A positive lab result is not necessary to initiate treatment. 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.
   2) Guidance for Tecovirimat Use Under Expanded Access Investigational New Drug Protocol during 2022 U.S. Monkeypox Cases | Monkeypox | Poxvirus | CDC

G. Provider submits forms specified in Appendix A to CDC using one of the following methods:
   - Secure Share File for lesion photos and large file sizes (please zip multiple files and use filenames with patient identifier, hospital name, and date): https://centersfordiseasecontrol.sharefile.com/r-r3941801ebcbd4002b4dfe98e314ec697
   - Email: regaffairs@cdc.gov
   - Fax: 404-902-5921

H. Pediatric patients may be treated under CDC-sponsored tecovirimat EA-IND protocol.

For information on other therapies, see CDC Monkeypox Treatment Information.

Next Steps:

- Any patient who is a suspect case should be counseled to implement appropriate transmission precautions, including isolation, while awaiting testing results. The California Department of Public Health has released Monkeypox Home Isolation Guidance for the General Public.
- CDPH requests that health care providers report cases of persons meeting the definition of a Suspect Case (Case Definitions for Use in the 2022 Monkeypox Response | Monkeypox | Poxvirus | CDC) to Shasta County HHSA Public Health at 530-225-5591.
- If a provider has a patient in urgent need of treatment, the provider may proceed with tecovirimat treatment ***once informed consent has been obtained.*** Contact SC HHSA PH to request Tecovirimat through DOC45@co.shasta.ca.us

Additional Information and Resources:

- CDC Testing Directory
- CDC Clinician FAQs
  - Monkeypox fact sheet for sexually active persons
  - CDPH Monkeypox Communications Toolkit
  - HAN Archive - 00468 | Health Alert Network (HAN) (cdc.gov)
  - 2022 United States Monkeypox Case | Monkeypox | Poxvirus | CDC
  - CDC Personal Protective Equipment Sequence
  - WHO Monkeypox Fact Sheet
  - BHOC Monkeypox Information for Gay, Bi, and Trans People Who May Be Exposed Through Sex and Intimate Contact

Appendix A. Minimal Required Information to Complete and Return to CDC

Required

1. **Informed Consent Form** [5 pages]**:** ***Obtain prior to treatment***.
2. **Patient Intake Form** [3 pages]**:** Baseline assessment.
3. **FDA Form 1572** [2 pages]**:** One signed 1572 per facility suffices for all tecovirimat treatments administered under the EA-IND at the same facility. Please return **within 3 calendar days** of the first tecovirimat treatment initiation at the facility along with a CV of the point-of-contact physician.
4. **Serious Adverse Events :** Report life-threatening or serious adverse events associated with TPOXX by completing a PDF MedWatch Form [3 pages] and returning it to CDC via email (regaffairs@cdc.gov) or uploading to ShareFile within 72 hours of awareness or sooner, if possible. The PDF MedWatch Form can also be downloaded from the FDA website. (Note: The MedWatch Form can only be viewed on the Adobe desktop app. Please save or download the form for viewing.)

Optional Photos and Samples

- **Clinical Outcome Form** [4 pages]**:** Progress information during and post treatment.
- **Photos of lesions:** If feasible, take lesion photos at baseline prior to TPOXX treatment, and post- treatment to follow lesion progression and healing during treatment.
- **Lesions samples for resistance testing:** If new lesions develop during and after tecovirimat treatment, sample at least one lesion to assess for the development of antiviral resistance mutations. See Optional Lesion Samples for Resistance Testing [1 page] for instructions on collection, storage, and submission of samples.
- **Pharmacokinetic samples for testing:** During tecovirimat treatment, plasma samples may be collected to monitor tecovirimat levels for adequate drug exposure in patients. See Optional Pharmacokinetic Samples for Testing [5 pages] for instructions on collection, storage, and submission of samples.

Optional Patient Diary and Instructions

- **Patient diary [2 pages]:** Ideally, give the diary to the patients during baseline assessment. Patient can use this form to record how they feel and any side effects to tecovirimat.
- **Instructions for mixing TPOXX capsules with food [2 pages]:** This patient instruction sheet explains how to open tecovirimat capsules and mix with breastmilk, infant formula, milk or food for infants and children.

Categories of Health Alert Network messages:

Health Alert	Requires immediate action or attention; highest level of importance
Health Advisory	May not require immediate action; provides important information for a specific incident or situation
Health Update	Unlikely to require immediate action; provides updated information regarding an incident or situation
HAN Info Service	Does not require immediate action; provides general public health information